



# Clinical Trials Network

CTN Bulletin  
January 24, 2008  
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## 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 December 31, 2007.

## Open Studies (3)

- CTN 0027 – Randomized 571
- CTN 0028 – Randomized 218
- CTN 0030 – Randomized 359

**Total Randomized All Studies: 8,621**

## Executive Committee (EC)



The EC has recently approved practice guidelines on the release of trial data prior to data lock. A copy of the two-page document will be included in meeting folders at the CTN Steering Committee face-to-face meeting next month. For an advance copy of the guidelines or questions about them, please contact Paul Wakim (301-402-3057 or [pwakim@nida.nih.gov](mailto:pwakim@nida.nih.gov)).

## CTN 0029 - ADHD in Adult Smokers



The last participant completed the CTN 0029 study on January 22, 2008. The sites did a fantastic job of recruiting this difficult population and retaining them in the study over the 11 week treatment phase and 4 week follow-up period. Overall, a total of 255 participants were randomized (study target was 252), 216 (84.7%) completed the treatment phase, and 204 (80%) completed the one month follow-up visit. A total of 223/255 (90.3%) reached the target dose of OROS-MPH/placebo (72 mg) and, for participants reaching week 11, an average of 10.7/11 smoking cessation visits were attended. Sites are now hard at work cleaning the database. The lead team again thanks the entire study team for their hard work and looks forward to database lock, which is currently being targeted for late March.

## Research Utilization Committee (RUC)



A new RUC Chair has been chosen. Congratulations go to Steve Martino of the New England Node! Thank you to all the RUC members. We had 100% voter turnout!

*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.*

## Next Steering Committee Meeting



The NIDA CTN Steering Committee Meeting will be held Monday, February 25 thru Wednesday, February 27, 2008, at the Bethesda North Marriott Hotel & Conference Center in Bethesda, Maryland. You may call the hotel directly at (800) 859-8003 or (301) 822-9200, and ask for the NIDA CTN room block. To register for the Steering Committee meetings through the contractor web site, please visit the following link:  
[www.sei2003.com/NIDA/CTN/Meetings/](http://www.sei2003.com/NIDA/CTN/Meetings/)

## Design and Analysis (D&A) Workshop at SC Meeting



A workshop to discuss Simple Trials vs. Comprehensive Assessments has been scheduled on Monday, February 25<sup>th</sup> from 2:00 - 4:00 (*flyer attached to Bulletin*). The workshop will consider the tradeoffs between keeping CTN trials simple and adding assessments to allow for additional secondary hypotheses within that trial, as well as for future multi-study secondary analyses via common assessment instruments. The plan is to provide plenty of time for questions and discussion from the audience. Anyone from the CTN community who is interested in this topic is invited. The two speakers are:

- Mary A. Foulkes, Ph.D., Research Professor, Department of Epidemiology and Biostatistics, The George Washington University, and formerly with the NIH and FDA.
- Lawrence M. Friedman, M.D., renowned scientist and author on clinical trials, recently retired from the National Heart, Lung and Blood Institute.

## Minority Interest Group (MIG)



The MIG meets monthly to discuss issues regarding minority health and diversity in the CTN studies. Some of the activities that the group is discussing are: potential presentations in national meetings, possible publications (the group is currently working on a review paper), and future studies. This is an avenue to discuss new ethnic/minority studies (platform, secondary analysis or ancillary) that could be considered for funding. About twice a year CCTN receive notices from NIDA or NIH for supplemental funding, and this group gets notified. Last year we received funding for four projects. Currently, the MIG is seeking to increase member participation. If you are interested, please contact Carmen Rosa at [crossa@nida.nih.gov](mailto:crossa@nida.nih.gov).

## **Secondary Analysis of CTN Studies**



The accumulated data from CTN studies is a rich source of clinical information from which important secondary questions may be addressed. The CTN strongly encourages the design, conduct, and publication of secondary analyses.

CTN's Data and Statistics Center (DCRI) will support a total of 3 to 4 secondary analyses that involve multiple CTN studies. This support is comprehensive, with DCRI programmers and statisticians providing support from planning analyses through writing.

Receipt dates for proposals of secondary analyses of CTN studies parallel the NIH R01 receipt dates: February, June and October. For this cycle, the deadline is February 15, 2008. Proposals will be initially screened and prioritized by Ned Nunes (Long Island Node), Dan Blazer (DCRI), and Paul Wakim (NIDA CCTN), and then submitted to the CTN Executive Committee for final approval.

If you are interested in leading such a project, please send a one-page proposal to Paul Wakim ([pwakim@nida.nih.gov](mailto:pwakim@nida.nih.gov)) and include the following:

- Your name as primary investigator
- Collaborators and co-authors to be included on the final paper (DCRI staff will be part of this authorship)
- Name of Node PI sponsoring the project
- Research question(s)/hypothesis(es) and its (their) importance
- CTN trials to be included
- Brief description of analytic method(s)
- Rough timeline

We remind you that data from completed CTN studies are also available to the public on the CTN Public Data Share website ([www.ctndatashare.org](http://www.ctndatashare.org)) approximately 18 months after completion of the study or after publication of the primary manuscript, whichever occurs first. Currently, the CTN Public Data Share website contains data from the following CTN studies: CTN 0001, 02, 04-09, 11, 12 & 16. Within the next six months, the website will also include data from CTN 0003, 13 & 17-21.

Please contact Paul Wakim (301-402-3057 or [pwakim@nida.nih.gov](mailto:pwakim@nida.nih.gov)) for questions on secondary analyses, and JJ Pan (301-443-8888 or [jpan@nida.nih.gov](mailto:jpan@nida.nih.gov)) for questions on the CTN Public Data Share.

## **Are You Reading This?**



In order to gauge how many people read the Bulletin, I am asking readers to send me an e-mail.

Just click on [ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov) and hit

Enter and Send. No message needed. Thanks!

## **CTN Members Help Shape CSAT TIP**



A meeting of a second working group / consensus panel was convened by the Center for Substance Abuse Treatment (CSAT) in Bethesda on December 10 -

11. This is the next phase in the development of a Treatment Improvement Protocol (TIP) focusing on relapse prevention and recovery promotion and support, initiated in treatment settings and continued into the community. The first meeting, held in October, focused on information needed for counselors and supervisors to provide relapse preventive interventions and to facilitate the transition of clients to community support services to help maintain and sustain their recovery process. This second meeting focused on practical issues and potential barriers that would be involved at the programmatic and management levels in implementing an integrated model of relapse prevention and recovery promotion in treatment programs. Some issues included: funding, staffing, training, and linkages with community agencies and recovery support services.

Dennis Donovan, PI of the Pacific Northwest Node, was the Chair for both consensus panel meetings. Tiffany Linkovich Kyle, from the Center for Drug Free Living in the Florida Node, was a participant in the first consensus panel meeting, which included researchers, members of treatment programs, and representatives from community-based recovery support centers. Candace Hodgkins, Senior Vice President of Clinical Services Administration for Gateway Community Services in Jacksonville of the Florida Node, and John Hamilton, CEO for the Regional Network of Program in Bridgeport, Connecticut, of the New England Node, served as participants in the second consensus meeting. The TIP is currently being edited and will be sent out for field review in June. Given the involvement to date of CTN members in the development of this TIP, it is highly likely that additional members of the CTN will be asked to provide reviews of the TIP from their perspective as community-based treatment providers.

## **Topics for CTN Articles in NIDA Notes**

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

### **APA Early Career Travel Awards**



The American Psychological Association (APA) is holding its annual convention in Boston, Massachusetts, from August 14 – 17, 2008. As in previous years, NIDA (in collaboration with NIAAA) and APA Divisions 50 (Addictions) and 28 (Psychopharmacology and Substance Abuse) are planning a Poster Session/Social Hour focusing on Early Career Investigators. The 2008 session will take place on August 14 from 4 – 6 pm.

NIDA is soliciting abstracts from Early Career Investigators who would be interested in presenting a poster at this session. If selected, the investigator may be eligible for a travel stipend of up to \$750.00. If you know of anyone that may be eligible and interested in this, please have them send an abstract of a proposed poster no later than noon on Wednesday, January 30, to Dr. Harold Perl at [hperl@nida.nih.gov](mailto:hperl@nida.nih.gov).

As an added incentive, Dr. Teri Levitin (Director of NIDA's Office of Extramural Affairs) and Dr. Perl will be teaching their popular half-day course on grantsmanship ("*Inside the Black Box at NIH (NIDA & NIAAA): Grant Writing Tips They Didn't Teach You in Graduate School*"). This free course is open to all, regardless of career status.

### **Grants Tidbit Corner – New Grants**



The following grant opportunities may be of interest to researchers in the CTN:

Community Participation in Research (R01) (PA-08-074) National Institute on Drug Abuse (NIDA) <http://grants.nih.gov/grants/guide/pa-files/PA-08-074.html>

Community Participation Research Targeting the Medically Underserved (R01) (PAR-08-075) NIDA <http://grants.nih.gov/grants/guide/pa-files/PAR-08-075.html>

Community Participation Research Targeting the Medically Underserved (R21) (PAR-08-076) NIDA <http://grants.nih.gov/grants/guide/pa-files/PAR-08-076.html>

NIDA's Division of Epidemiology, Services NOT-DA-08-001 "Notice of Intent to Publish a Request for Applications for the Use of Real-Time fMRI for Control of Brain Activity in Substance Abuse." Due date is March 14, 2008. <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-08-020.html>

### **CTN 0032 Update**



The HIV Rapid Testing & Counseling (CTN 0032) protocol seeks to evaluate the most effective testing strategy to ensure that persons in drug treatment programs get HIV tested, receive their HIV test results and reduce their HIV risk behaviors. The Lead Investigator is Lisa Metsch, Ph.D., of the FL Node and the Co-Lead Investigator is Grant Colfax, M.D., of the CA/AZ Node. The project will be implemented in 12 CTPs throughout the United States. Since receiving DSMB approval of the protocol, investigators and collaborators have begun conducting site selection activities with the first call for CTP nominations being distributed to Node PIs and Coordinators on December 13, 2007. Survey A for the second phase of site selection, involving collection of information concerning client demographics and site infrastructure, was initiated with nominated and potentially eligible sites on January 16, 2008. Responses to Phase 2 Survey A were due to back to the CTN investigative team (via [ctn32hiv@gmail.com](mailto:ctn32hiv@gmail.com)) on January 23, 2008.



Congratulations to Lisa Metsch on the birth of her baby girl, Gabriella Ilana Metsch! Mom and baby are both doing very well.

### **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 data base of network members' expertise and research interests.

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

### Texas News



Dr. Susana E Méndez (Texas Node CTP – Homeward Bound, Inc.) just returned from a trip to Buenos Aires, Argentina. She was an invited speaker at the 10<sup>th</sup> International Conference for Chemical Dependence and

Mental Health Rehabilitation, from October 29 to November 3, 2007, where members of Mexico, Uruguay, Brazil, Ecuador, Chile, Argentina, and Spain participated. The focus was substance abuse and dependence, mental health and HIV treatment. Her topics were “Chemical Dependence, Mental Health and HIV Treatment with Eastern and Western Medicine” based on her experience with Homeward Bound, Inc. and the Clinical Trials Network. The conference was attended by 300 psychiatrists, social workers and psychologists who are involved in addiction treatment; the focus was on cocaine and alcohol addiction treatment in South America.

As the result of her presentation, she was also invited to speak at three university hospitals in Buenos Aires: Hospital Interzonal de Agudos y Crónicos Especializado Neuropsiquiátrico Dr. Alejandro Korn - Melchor Romero, Hospital de Agudos Juan. A. Fernández, and (H.O.G.A.M.) - Unit N°22 of the Penitentiary System, *Lisandro Olmos*, La Plata.

Cocaine and alcohol are problems in South America; especially in Argentina, Mexico, Uruguay, and Chile where 20% of the population are using cocaine. The national health system in South America is different among all these countries; some of them have “socialized” medicine, which allow patients to have access to care almost immediately; and other countries have started to utilize a “managed care” system which seems to be a key factor in the lack of access to care, especially for people with HIV problems. In the maximum security HOGAM-Unit 22, the state pays for the cost of medication for those in need of retroviral medication, new generation antipsychotic or counseling for addictions. Research in all these South American countries is crucial. The utilization of U.S. data will help them to have an impact on public health and the duplication of treatment that we have may also open doors to a better care system. They are seeking help in developing courses that will teach care providers to replicate what we have in the U.S.

### NIDA Blending Conference

The next NIDA Blending Conference will be held June 2-3, 2008, in Cincinnati, Ohio. The website for information is: [www.NIDABlendingConference.info](http://www.NIDABlendingConference.info)

### Data and Statistics Center (DSC) at DCRI



Please let the DSC know if you have any new staff members that need InForm Training or refresher training. The DSC plans to set up a training session in the near future. Please e-mail or call the EDC Site Support Help Desk at: [edchelp@mc.duke.edu](mailto:edchelp@mc.duke.edu) or 1-888-372-7743.

### Clearing Discrepancies (Queries) in Paper CRF Trials Query Types:

There are two query types, Automatic and Manual. Both are resolved by completing a Data Clarification Form (DCF). Automatic queries are generated by the DSC system based on pre-programmed data validation checks. Manual queries can be generated by the DSC or by the sites when an error is detected. All DCF forms, regardless of type, must be complete and legible and must also be signed and dated by the site staff member completing the form in order to be processed by the DSC.

Automatic DCFs have an assigned discrepancy number, subject #, name of affected form, and specific field information.

Manual DCFs must have this information provided in order to accurately identify the participant, the form, and data value to be changed. For CTN 0014, all DCF forms, regardless of type or origination, should be accompanied by a copy of the corrected CRF when faxed into the DSC.

### Common reasons for CRF to Database Discrepancies:

- The source data (paper CRF) at the site does not match the database values at the DSC. *Often this is a result of a missing manual DCF, or a DCF that was not completed correctly.*
- No signature or date is present on DCF. *All DCFs must have a signature and date at the bottom before they can be processed by the DSC.*
  - Transcription errors in copying automatically generated DCF's onto a blank DCF form. *Enter the corrected value directly onto the automated DCF form. It is not necessary to recopy the information onto a new form.*
  - DCF corrections are illegible. *Write corrections clearly and avoid abbreviations wherever possible.*
  - Additional changes made to the CRF that are not included on the DCF form. *The DSC can not process corrections directly from the CRF. If the initial correction results in additional corrections to the CRF, complete a manual DCF for the additional fields and send it to the DSC.* (continued page 5)

- DCFs are sent to the DSC multiple times or in multiple forms. *Avoid sending DCFs multiple times, or in multiple forms (e.g. system generated DCF is returned followed by a site generated manual DCF for the same error).* Allow the DCF to clear the system. If you have a question about whether a DCF has been received, contact the lead CDS for the trial before resending the form(s).
- CRFs with corrections are sent to the DSC, without an accompanying DCF form. *These CRFs are typically discarded as duplicates and the corrections are not made to the database, resulting in source to database audit discrepancies.*

**Additional Tips:**

- Review data status reports soon after you receive them. Open discrepancies are listed on the Participant Report(s) and should be resolved in a timely manner. If you notice discrepancies on the data status reports that should be closed, please contact the DSC before resending the same information. Resending the same erroneous form will not resolve the discrepancy.
- Remember that manual DCFs (DCF's generated by the sites or copied onto blank forms at the site) *do not have discrepancy numbers assigned to them* and as such, they are generally more time consuming to investigate and correct.
- Occasionally it is necessary for the DSC to reissue a discrepancy (query) to the site. *Re-issued queries contain a new (unique) discrepancy number.* It is therefore possible for the same data error to have two different discrepancy numbers. In this case, return *both* DCF forms to the DSC.

**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](mailto:CTNSupport@sei2003.com) For questions, please call Cheryl Brinkley at (240) 485-1998.

**Motivational Incentives in Texas**

The Texas Node has been disseminating contingency management (CM) training to the Node's CTPs. Headed by Traci Rosvall and Craig Field, Ph.D., the target behavior chosen to impact was outpatient group attendance. In one of their first efforts, selected patients attending the 16-week methamphetamine treatment program (MTP) of Mental Health Mental Retardation of Tarrant County (MHMRTC) earned the opportunity to draw tickets from a prize bowl for attendance at all of their treatment groups. This project was funded with the support of SAMHSA. Attendance was analyzed for 3 months prior and 3 months after CM implementation. Results were robust, particularly in the therapy groups with the lowest baseline attendance rates. In most cases, attendance continued to increase with each successive month that the incentives were used. They are presently assessing the efficacy of CM for improving outpatient attendance in 5 other Node CTPs. *See the chart below.*

*Updates for this Bulletin should be sent to Carol Cushing at: [ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov)*

