



Clinical Trials Network

CTN Bulletin
January 10, 2008
Volume 08 – 01

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 November 30, 2007.

Open Studies (3)

- CTN 0027 – Randomized 547
- CTN 0028 – Randomized 209
- CTN 0030 – Randomized 345

Total Randomized All Studies: 8,574

Executive Committee (EC)



On December 17, the EC discussed a proposal regarding feasibility studies and progress on ancillary/platform studies. The EC will ask the Research Development

Committee to review the proposal. The EC also discussed a proposal regarding the release of data prior to data lock. The EC agreed with the recommendation that baseline data could be released only once prior to data lock, after all baseline assessments were complete. Final guidelines have been circulated to the Steering Committee. Interested CTN members may forward questions or ideas for studies on exercise in addictions treatment to Drs. Rotrosen or Nunes by January 22.

Blending CD Set: The Science of Treatment



Since 2004, a total of 5 Blending Team products have been developed and are all available at:

<http://www.nida.nih.gov/blending/>.

This last summer, NIDA designed “*The Science of Treatment*” in an attempt to have all the completed

Blending products accessible in one easy-to-use package. A limited number of Blending CD Sets were produced and will be distributed to every attendee at the June 2-3, 2008, Blending Conference in Cincinnati. Also, NIDA is working with the National Office ATTC to reproduce and disseminate these Blending CD Sets by Spring of 2008. Contact NIDA’s Blending Project Officer, Denny Pintello dpintell@nida.nih.gov for additional information and Mary Beth Johnson (no@nattc.org) to submit your 2008 request for the Blending CD Set.

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.

The special government rate is \$201 plus tax per night. Reservations must be made by Thursday, January 31, in order to obtain the negotiated rate. 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/

The June CTN Steering Committee meeting will follow the NIDA Blending Conference June 4-6 in Cincinnati, Ohio. Mark your calendars for both!

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



You are invited to a workshop on “Simple Trials versus Comprehensive Assessments” scheduled for Monday, February 25, 2:00 PM - 4:00 PM, in conjunction with the CTN Steering Committee meetings in

Bethesda, Maryland. The purpose of the workshop is to discuss tradeoffs between keeping CTN trials simple and adding assessments to allow for additional secondary analyses and ancillary studies, or adding common assessment instruments for future cross-study analyses. Two distinguished speakers are scheduled for the workshop: Mary A. Foulkes, Ph.D., Research Professor, Department of Epidemiology and Biostatistics, The George Washington University, formerly with the NIH and FDA; and Lawrence M. Friedman, M.D., renowned scientist and author on clinical trials, recently retired from the National Heart, Lung and Blood Institute. The plan is to have plenty of time for questions from the audience and discussion.

The CCTN would like to continue this series of D&A workshops at SC meetings on topics generated from the CTN community, i.e. individuals from RRTCs, CTPs, DCRI, EMMES or CCTN. Interested individuals may suggest topics, volunteer to make a presentation, or even organize the workshop if they desire. The goal is to have one workshop at each SC meeting on a specific D&A issue of interest to the CTN community. If you have suggestions for future topics and/or speakers, please contact Paul Wakim (301-402-3057 or pwakim@nida.nih.gov).

CTN 0028 – ADHD in Adolescents Study



Recruitment is one of the more challenging aspects of any research protocol. It seems especially difficult among adolescents. One recruitment method that has been employed is known as “chain-referral” or “snowball” in which study participants may refer potentially eligible friends or acquaintances to the study. “Respondent-Driven Sampling” (RDS) is a type of “snowball” recruitment that offers additional incentives to study participants who refer friends/peers who are consented for baseline eligibility screening (Biernacki & Waldorf, 1981; Heckathorn, 1997). Any site using this recruitment method must obtain specific local IRB approval prior to implementation. Study participants will be provided with information to pass on to their peers and a means of identifying the referral source. Interested referred adolescents must contact the study site for additional information about pre-screening. If the referred adolescents complete the consent process, the referring participant will be given up to \$10.

The Lexington/Richland Alcohol and Drug Council (LRADAC), of the Southern Consortium, has used RDS within their agency to enhance recruitment. A study participant invites friends or acquaintances who may qualify for the study to contact study staff to determine eligibility. Participants who are interested in assisting with recruitment efforts are provided flyers to give to peers that may be eligible and interested in the study. If the distributed flyers result in the enrollment of a new study participant the person that assisted in the recruitment receives \$10 for each new participant.

LRADAC’s first experience with this RDS recruitment method resulted in having one participant show up for a weekly visit with seven of his friends. The staff were shocked but thrilled with the response and managed to screen all of those adolescents that day. The good news from that group: three of those seven subjects entered the study and one of them attended all 16 weekly visits. Since implementing the RDS method, half of the newly enrolled participants at this site have been referred by another study participant. One of the recruiters says “just add them to my tab” as he earns his \$10 per each new subject.

Kudos to LRADAC for implementing this innovative recruitment strategy!

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 0032 Update



The HIV Rapid Testing & Counseling (CTN 0032) protocol was approved by the DSMB and NIDA for project implementation. CTN 0032 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 community treatment programs throughout the United States. Since receiving DSMB approval, investigators and collaborators have begun site selection activities. The initial nominations and the required survey information were due back by January 4, 2008. Several nominations and surveys were returned; the site selection process is moving forward.

The Lead Team will be attending a database planning meeting at DCRI January 29-31. The purpose of the meeting is to: 1) review each data variable; 2) evaluate the possible responses, ranges or values; 3) assess the instructions; 4) look at the missing codes; 5) address the skip logic built into the data bases; and 6) appraise the entire system from the viewpoint of the participant and Research Assistant. At the end of the meeting, there will be a final sign off on the electronic databases.

SBIRT RFA Released



NIDA’s Division of Epidemiology, Services and Prevention Research has just released the following RFA: Screening, Brief Intervention and Referral to Treatment (SBIRT) for Drug Abuse in General Medical Settings (R01). The full text can be found at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-08-021.html>. Its purpose is to invite research applications to develop and test the effectiveness of models that integrate screening, brief intervention, and referral to specialized treatment for individuals with drug abuse entering into primary care and other general medical settings. The Letter of Intent Receipt Date is February 14, 2008 and the Application Submission/Receipt Date is March 14, 2008.

START Genetics Add-On Study Update



The Starting Treatment with Agonist Replacement Therapies (START) trial has two genetics auxiliary sub-studies. The Southern Consortium Node is delighted to report that all sites are fully endorsed for the genetics component and are actively recruiting for the START Genetics add-on study. As of December 31, the NIDA repository has received a total of 240 samples and MUSC has received 140 samples. Congratulations to all on their hard work!

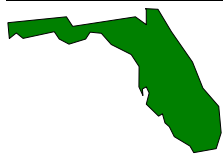
CA-AZ Node News



Varda Shoham, of the California-Arizona Node, is lead author on an article recently published in the Journal of Abnormal Psychology (Vol. 116, No. 4, 848-853), "Symptom-System Fit in Couples: Emotion Regulation When One or Both Partners Smoke." Other authors include Michael

Rohrbaugh, also of the CA-AZ Node, Emily Butler, and Sarah Trost. Having a spouse or partner who smokes has been identified as a major risk factor for continued smoking and for failure to quit. Research on links between smoking and regulation of emotions in close relationships has been surprisingly slim. This study examined the role smoking plays in single- versus dual-smoker couples, focusing on variations in emotional experience. In a laboratory experiment, 25 couples in which one or both partners continued to smoke despite one of them having heart or lung disease discussed a health-related disagreement before and during a period of smoking. Immediately after the discussion, the partners used independent joysticks to recall their moment-to-moment emotional experience during the interaction while watching themselves on video. Participants in dual-smoker couples reported increased positive emotion contingent upon lighting up, whereas those in single-smoker couples reported the opposite. The results highlight the role of smoking in close relationships, particularly in regulating emotional closeness when both partners smoke. Although more research is needed, attention to this fit between symptom and system could potentially be useful in helping smokers achieve stable cessation of smoking.

Good news from the Florida Node!



The Center for Drug Free Living (CFDFL), a community treatment program in the Florida Node, has been awarded a \$100,000 Blue Foundation grant. The funds will

be used to establish and provide infrastructure support for a regional hepatitis care consortium (HepCaN), building on fragmented and stretched existing resources. The aims of the grant are to survey existing services, resources, sources of referral, and sources of funding; quantify existing need for hepatitis prevention and treatment services in the uninsured and underinsured population; develop any possible mechanisms to better utilize existing resources; and partner with consortium members to write grants to obtain resources for services. The overall goal of CFDFL is to attract grant dollars and philanthropic donations to open a full service Hepatitis Center of Excellence. Congratulations!

CTN Dissemination Library -- A Year in Review



Year 2007 was a great year for the CTN Dissemination Library. Here are a few of the numbers to prove it!

2007 Web Site Statistics

Page Loads: 24,935 (up from 15,064 in 2006!)

First Time Visitors: 6,956 (3,719 in 2006)

Returning Visitors: 1,688 (740 in 2006)

Most popular pages: Homepage, Basic Search screen, What's New, Protocols page

How most found us: Google, CTN Data Share, Yahoo

Commonly-used search engine keywords leading to us: CTN Dissemination Library, NIDA contingency management, suboxone taper, NIDA CTN, POATS

26% of users came directly to the site

34% came via a referring link on another web site (CTN Data Share, e.g.)

38% came via search engine (e.g. Google)

2007 Additions to the Catalog

Articles (Peer-Reviewed): 35

Magazine Articles: 4

Manuals: 1

Posters: 16

Presentations: 24

Reports: 3

Miscellaneous (Bibliographies, Brochures, etc.): 8

Total Items Added: 91

Please help to make 2008 another great year! Submit your CTN-related articles, posters, presentations, manuals, and other documents to the CTN Dissemination Library at info@ctndisseminationlibrary.org. The library is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: <http://ctndisseminationlibrary.org>.

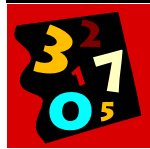
CTN 0030 POATS



The Prescription Opiate Addiction Treatment Study (POATS) was reviewed by the DSMB on November 29, 2007.

Overall, the DSMB was pleased with the study progress and recommended study continuation. Sites are working hard to recruit participants. At this time, 360 participants have been randomized into Phase 1 of the trial with an overall recruitment rate of 95%. The study has passed the halfway mark for the overall target recruitment of 648 participants. Special congratulations to McLean Hospital (Northern New England Node), Chestnut Ridge Hospital (Appalachian Tri-State Node), and East Indiana Treatment Center (Ohio Valley Node) for surpassing or approaching their original target of 54 participants. Super job!

CTN Data Share Web Site



Eleven data sets from the first two groups of CTN studies are available on the CTN Data Share Web Site at:

<http://www.ctndatashare.org>. Data are available for download in both SAS and

ASCII formats. Each dataset is posted with corresponding study documentation, including the final study protocol, annotated CRF and data dictionary. Look next for data from CTN 0003, which should be posted in January 2008. The results of the recent survey sent out to users of the web site suggest that data in a flat file format would be preferable for many users. Based on those comments, DCRI will be making all the data sets available in a flat file format as well as the current CDISC format. A time line for the new file format has not been finalized. It is hoped that this additional change will make the data as widely available as possible to many levels of users. So far, nearly 80 requestors from five countries have downloaded 150 data sets.

Appalachian Tri-State (ATS) Node



Dissemination activities: ATS Node continues to provide many EBT training programs and programs on consultation to the community. Motivational Interviewing, Integrated Treatment of SUD and Psychiatric Illness, and Group Treatment of Addiction were provided

during the past two months with several MI projects including ongoing consultation. Dr. Maxine Stitzer (LI for the Motivational Incentives studies CTN 0006/7) will visit the ATS Node in late January to consult with several CTPs on pilot projects in which they are using Motivational Incentives.

In a new initiative, Dennis Daley, PI of the ATS Node, played Santa Claus this year for several of his treatment programs, including the Perinatal Addiction Center (PAC). He **disseminated** gifts to all the children of the patients at PAC. **Primary outcome:** there were many happy kids and moms ($p < .0001$). **Secondary outcome:** a happy PI who had a great day ($p < .005$). **Adverse event:** a few kids cried and resisted interacting with Santa. **Serious adverse events:** the food provided after the PAC party ran out before Santa got his share of chicken; Santa got very hot and itchy under that X%X% beard! Way to go!

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

First INVEST/CTN Fellows Are Named



NIDA has selected the first three researchers to be named INVEST/CTN Drug Abuse Research Fellows. The Fellows will spend 1 year working with a mentor who is affiliated with one of the 16

NIDA Clinical Trials Network Regional Research and Training Centers.

Former NIDA Hubert H. Humphrey Fellow Dr. Amit Chakrabarti, India, will work with Dr. Roger Weiss, McLean Hospital (Northern New England Node). Dr. Chakrabarti will focus on clinical research experience in the treatment of prescription opioid dependence, participating in the Prescription Opioid Analgesic Treatment Study (POATS), a randomized, controlled, open-labeled clinical trial of buprenorphine/naloxone, and the effect of ethnicity on treatment outcome. Drs. Chakrabarti and Weiss intend to develop a collaborative research project based on the POATS project for implementation in the ethnically diverse Sikkim state in India. He will start on September 1, 2008.

Dr. Gvantsa Piralishvili, Georgia, will work with Dr. George E. Woody, University of Pennsylvania (Delaware Valley Node). As a physician and treatment researcher at the addiction/HIV prevention centers Union Alternative Georgia and New Way Center for Psychosocial Information and Counseling, Dr. Piralishvili will focus on assessing outcomes of methadone maintenance treatment programs. He and Dr. Woody intend to prepare a grant application to investigate methadone maintenance and HIV risks in Georgia. Dr. Piralishvili will observe CTN studies to learn about integrating research with practice, human subjects protection, good clinical practice, identifying adverse events, quality assurance, web-based systems, and various research instruments. This fellowship builds on the relationship established between Dr. Woody and former NIDA Hubert H. Humphrey Fellow Dr. David Otiashvili, Union Alternative Georgia. He will start April 1, 2008.

Dr. Chen Hanhui, China, will work with Dr. Walter Ling, University of California, Los Angeles (Pacific Node). A psychiatrist at the Shanghai Mental Health Center (SMHC), Dr. Hanhui will study how ethnicity and cultural differences affect the outcomes of contingency management programs designed to address drug use and HIV risk behaviors. Dr. Hanhui intends to learn more about the UCLA model of comprehensive, integrated drug abuse treatment services as China moves to expand both pharmacological and behavioral treatments for opioid dependence. His start date has not been determined yet.

Publications Committee (PC)



On December 18, the PC approved three articles for journal submission. These were submitted by Magruder et al.; Fitzgerald, McCarty et al.; and Craig. The Committee reported that the primary outcome report for TELE (CTN 0011) and an article on cross-clinic variation and cost-effectiveness in the MIEDAR studies were published in the *American Journal on Addictions*. The PC will be considering additional items for posting in the *CTN Bulletin*—stay tuned!

Eighth Annual Summer Institute on Randomized Clinical Trials Involving Behavioral Interventions



Members of the CTN community may be interested in the following opportunity: The NIH Office of Behavioral and Social Sciences Research (OBSSR) has organized a summer training on randomized

clinical trials. The classes will be held July 13 - 25, 2008, at the Airlie Conference Center, Virginia. The objective is to provide a thorough grounding in the conduct of randomized clinical trials to researchers and health professionals interested in developing competence in the planning, design, and execution of clinical trials involving behavioral or social interventions.

Costs: The NIH Office of Behavioral and Social Sciences will pay for travel to and from the Summer Institute site, room and board, and course materials. There are no additional fees. Family members may accompany participants at their own expense.

The curriculum will:

- Describe the principles underlying the conduct of unbiased clinical trials.
- Contrast biomedical vs. behavioral interventions in the context of RCTs.
- Evaluate and interpret critically the literature on RCTs for behavioral interventions.
- Contrast and evaluate alternative research designs in terms of their appropriateness.
- Contrast and evaluate methods for monitoring, coordinating, and conducting RCTs.
- Select appropriate outcome measures, enrollment strategies, and randomization techniques.
- Design a specific research proposal in collaboration with a multidisciplinary team.

STUDENTS: Priority will be given to individuals who already have their Ph.D. or M.D. (equivalent degrees accepted) and two years of subsequent research

experience. Applicants should not yet have achieved a tenured position at their institution. Beyond these eligibility criteria OBSSR is seeking researchers who have demonstrated research experience and who will benefit from this summer institute on randomized controlled clinical trials.

Preference will be given to individuals who are not employees of NIH. While OBSSR will consider and may even accept applicants who do not meet these criteria, those who do will have higher priority.

Due to the limited number of spaces in the course, applicants must be citizens or non-citizen nationals of the United States, or must have been lawfully admitted to the United States for permanent residence (i.e., possess a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Women, minorities, and individuals with disabilities are encouraged to apply.

Location: The course will be held at the beautiful Airlie Conference Center in the foothills of the Blue Ridge Mountains in Northern Virginia, "...providing a serene atmosphere for work and thought in a community of scholars..." Airlie is approximately 60 minutes driving time from Washington, D.C. and surrounding airports: <http://www.airlie.com>

General Information and Applications Available at: http://obssr.od.nih.gov/Content/Training_and_Career_Development/Annual_RCT_Course/RCT_2008/2008_RCT.htm

Applications are due January 31, 2008 and must be submitted electronically. The application instructions and forms are posted at: <http://www.blsweb.net/app2attend/>

Frequently Asked Questions: http://obssr.od.nih.gov/Content/Training_and_Career_Development/Annual_RCT_Course/RCT03_QA.htm

Contacts: Do you have questions about the course? Please address them to:

Ronald P. Abeles, Ph.D.
Special Assistant to the Director
Office of Behavioral and Social Sciences Research
National Institutes of Health
Bldg. 31C, Rm. B1C19, MSC 2027
Bethesda, MD 20892-2027
Telephone: 301.496.7859
Email: abeles@nih.gov

Health Services Research (HSR) SIG



The Health Services Research SIG (Special Interest Group) meets on the second Tuesday of each month at 2:30 pm EST. At the last conference call the group discussed opportunities for HSR ancillary studies to Protocol 0032. The study team is soliciting ideas for consideration. The group also discussed two current ancillary studies: (1) CTN 0031C: Organizational and Practitioner Influences on Implementation of STAGE-12 (ancillary to CTN 0031); and (2) CTN 0030A: Collection of Economic Data for the Prescription Opioid Addiction Treatment Study (ancillary to CTN 0030). If you have questions about the SIG, please contact Jim Sorenson (Chair) or Carmen Rosa (CCTN at crosa@nida.nih.gov).

Data and Statistics Center (DSC) at DCRI



The EDC Helpdesk is the hub that supports answering questions and providing resolution to many different types of issues. 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.

Project Leader Contacts - All sites should continue to contact the Help Desk for technical issues. However, for operational issues, you may find it easier to contact your Project Lead directly. Project Lead contact information is listed below:

CTN 0014 - Peggy Arias	919-668-8545
arias001@mc.duke.edu	
CTN 0027 - Bart Evans	919-668-8981
bart.evans@duke.edu	
CTN 0028 - Melanie McAlpine	919-668-8343
melanie.mcalpine@duke.edu	
CTN 0029 - Melanie McAlpine	
CTN 0030 - Thomas Barfield	919-668-7031
thomas.barfield@duke.edu	
CTN 0031 - Thomas Barfield	
CTN 0032 - Craig McLendon	919-668-8140
craig.mclendon@duke.edu	

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

Clinical Coordinating Center (CCC) at EMMES



Welcome New Team Members!

The CCC is pleased to announce the welcome addition of 3 new staff members to our project. **Jack Chally** joined the project as Protocol Specialist. He is working on CTN 0027 and CTN 0032 and has been a wonderful addition to these teams. **Yvonne Rodriguez** joined the project as a Protocol Monitor. She is working on CTN 0030 and has been visiting a number of sites. You will be seeing a lot more of her. Finally, **Andrea Dedier** joined the project as Protocol Monitor. She will be working with the CTN 0027 team in the near future and will be a great asset to our monitoring team.

Training:

The CCC recently completed a Training Needs Analysis and is working on identifying training topics and possible events for 2008. Any training ideas or topics that the network would like to propose are always welcome. Please send any ideas you have to Liz Buttrey at ebuttrey@emmes.com.

Who to contact:

Michele Straus – *Other CCC related questions and topics* – 301-251-1161, mstraus@emmes.com

NIDA Project Officer, Ron Dobbins, at:
rdobbins@nida.nih.gov, telephone (301)451-9575

New Staff Member

The CCTN is pleased to welcome Dr. Steve Sparenborg to our team. Dr. Sparenborg has extensive experience working in preclinical and clinical neuroscience/ pharmacology areas in the U.S. Army, FDA, NIH, and private industry. Steve can be reached at: sparenborgs@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

Federal Offices Closed



The CCTN office and NIDA will be closed on Monday, January 21, 2008, for the Martin Luther King Jr. holiday observance.

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