



# Clinical Trials Network

## CTN Bulletin

June 6, 2013

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### Trial Progress – Over 15,000!



*Trial enrollment numbers reflect study information as of June 5, 2013.*

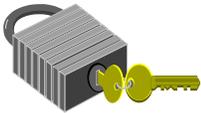
#### Open Studies

- **CTN 0049 – Project HOPE** (Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users). Enrolled 496 (N=800).
- **CTN 0050 – Long Term Follow-up to the CTN 0027 (START) Study.** Enrolled 816 (N=1,267).
- **CTN 0052 – BRAC** (Bupirone for Relapse-Prevention in Adults with Cocaine Dependence). Enrolled 62 (N=60). Enrollment completed – in follow up phase.

**Total Enrolled All Studies: 15,929**

### CTN 0037 Locked Database!

The Stimulant Reduction Intervention using Dosed Exercise (STRIDE) study database was locked on May 31, 2013. STRIDE began enrollment in July 2010, recruiting 302 participants across 9 participating residential treatment programs. Patient recruitment was completed in June 2012, and data collection was completed in February 2013. The Lead Team will begin working on the final study report. As a reminder, the STRIDE team has several planned manuscripts and welcomes participation. Please contact Tracy Greer or Kolette Ring for details. Congratulations to the entire study team!



### Mid-Atlantic Node News



Maxine Stitzer (Node PI) and George Bigelow were honored by the Association for Behavior Analysis International with receipt of their Award for Scientific

Translation. The award was bestowed at the annual meeting of the society in Minneapolis, Minnesota. The award acknowledges the pioneering contribution of this pair of investigators to the development of effective behavioral-based contingency management interventions for use in substance abuse treatment. Congratulations to Maxine and George!

*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.*

### Upcoming Events and Milestones

June 2013	<ul style="list-style-type: none"> <li>• <b>CTN-0048</b> Database lock</li> <li>• <b>CTN-0052</b> Last Participant Last Visit (target 6/21/2013)</li> <li>• <b>CTN-0056OT</b> PRB review (scheduled 6/26/2013)</li> <li>• <b>CTN-0057OT</b> Data collection begins</li> </ul>
July 2013	<ul style="list-style-type: none"> <li>• <b>CTN-0049</b> Data Freeze for September DSMB Meeting</li> <li>• <b>CTN-0052</b> Database Freeze (target 7/22/2013)</li> <li>• <b>CTN-0051</b> Data Management Meeting</li> </ul>
August 2013	<ul style="list-style-type: none"> <li>• <b>CTN-0054</b> Data Management Meeting</li> <li>• <b>CTN-0053</b> Data Management Meeting (scheduled 8/21-22/2013)</li> <li>• <b>CTN-0052</b> DSMB Meeting (scheduled 8/27/2013)</li> </ul>

#### *What is a Data Management Meeting?*

Prior to initiating programming of databases for new trials, a face-to-face meeting with the Lead Investigator, NIDA, and other key personnel is required. This 2-day meeting is held at EMMES, the data and statistics center for the CTN. This meeting serves as a 'walk through' for each new trial to see how the data and statistical processes and the project flows in the real world. A second purpose is to problem-solve potential issues, proactively, before the database is moved into production. The attendees review the CRFs (Case Report Forms) and other EDC systems to:

- Examine each variable – is it worded correctly?
- Examine the response choices
- Assess possible ranges and values
- Review instructions to the research staff and patient
- Consider missing codes
- Decide what to query, what to pre-populate
- Agree on skip logic
- Identify critical variables
- Look at the sequence of questions and answers, position of buttons on the screen, etc.
- Focus on reducing patient burden and the site burden by reducing the number of CRFs and questions where possible

At the end of this meeting, there is a sign-off for the entire CRF/EDC package. For any questions, contact Carol Cushing, Project Officer for the data and statistics contracts, at [ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov).

### **New Funding Opportunities**

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



- FY14 NIDA Avant-Garde Award Program for HIV/AIDS Research (DP1) ([RFA-DA-14-008](#))
- Notice of Change in Application Due Date for RFA-OD-13-009 "Short Courses on Innovative Methodologies in the Behavioral and Social Sciences (R25)" The Change of Date for the Short Courses RFA has been published at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-073.html> See also [NOT-OD-13-070](#) on change in personnel cost limits.
- Prize Competitions/Challenges in Area of Drug Abuse and Addiction ([NOT-DA-13-029](#))
- Seek, Test, Treat, and Retain Data Harmonization Coordinating Center (U01) ([RFA-DA-14-007](#))
- Reissue PHS 2013-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44]) ([PA-13-234](#))
- Reissue PHS 2013-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42]) ([PA-13-235](#))
- Native American Research Centers for Health (NARCH) (S06) ([PAR-13-239](#))

### **SAMHSA Training Offered**



*Free course for counselors interested in primary care careers*

A free five-hour online course for addiction treatment professionals who are interested in career opportunities in primary care has been developed by the SAMHSA-HRSA Center for Integrated Health Solutions (CIHS) in collaboration with the Addiction Technology Transfer Center (ATTC) Network and the Morehouse School of Medicine National Center for Primary Care. It is expected that the Affordable Care Act will bring many new patients into primary care, and that many of those patients will have substance use needs. Note that unlike many other offerings from CIHS, this course is for addiction only, not "behavioral" health.

To sign up, go to <https://www.thedatabank.com/dpg/423/donate.asp?formid=meetb&c=939837> .

### **Western States Node Updates**



#### ***Co-sponsors Neuroscience Webinar for Clinicians***

On April 18, 2013, the Western States Node presented the webinar, "Neuroscience of Impulsivity & Addictive Disorders," in collaboration with the Central Rockies, Northwest, and Pacific Southwest Addiction Technology Transfer Centers. Suzanne Mitchell, Ph.D., of the Methamphetamine Abuse Research Center at Oregon Health and Science University, discussed measures of impulsivity and how performance on these measures can predict changes in addictive behaviors. She also discussed factors that impact impulsivity, from genetics to adversity and stress, and substance withdrawal symptoms. This free webinar was attended by 254 participants from 17 states across the CTN, including Alaska and Hawaii. The Western States Node thanks Dr. Mitchell and expresses appreciation to our ATTC partners for presenting a webinar that highlighted ways basic science research and clinical research can inform each other, and ultimately lead to even more effective treatments for addictions.

The Node plans to continue a webinar series that discusses exciting developments in the neuroscience of addictions with clinicians, and examines ways in which these findings can inform treatment. The April webinar is available on the CTN Dissemination Library at: <http://ctndisseminationlibrary.org/display/984.htm>

#### ***Addiction Health Services Research Conference-Registration is now open!***

Oregon Health & Science University is pleased to host the 2013 Addiction Health Services Research Conference (AHSR 2013) in Portland, Oregon, the Rose City. The conference will be held October 23 - 25, 2013. The theme is Translating Research into Policy and Practice. We invite health services and implementation science investigators to join with clinical practitioners and policy makers in our exploration of more effective translation strategies.

The AHSR 2013 website ([www.AHSR2013.com](http://www.AHSR2013.com)) is now up and running. Please click the more information button to visit the site and register.

#### ***Western States Logo***



We are happy to introduce the Western States Node Clinical Trials Network LOGO! This logo represents the strong collaboration between investigators and community based service providers that play such a critical role in conducting studies and disseminating results. Look for it on websites, publications and dissemination materials.

### Appalachian Tri-State (ATS) Node News



The special edition of the *Social Work in Public Health Journal* focusing on addiction entitled *The Role of Social Work in the Prevention and Treatment of Substance Use Disorders* has been

published electronically, and will be in print in a few weeks (Volume #28, Numbers 3-4). This journal was organized and edited by Betsy Wells (Pacific NW Node), Tom Kelly and Dennis Daley (ATS Node PI), and Valire Carr Copland (University of Pittsburgh School of Social Work). Valire facilitated this opportunity with Dr. Marvin Feit (Journal Editor) to prepare this special edition.

This was a unique opportunity to publish a double edition of the journal on a broad range of topics related to etiology, assessment, treatment, and prevention of substance use disorders. This journal reaches a wide range of social workers and others who do not specialize in addiction. The ATS Node was able to promote the work of the CTN and NIDA with all of the papers co-authored by many involved in the CTN, as well as work by NIAAA. Over 30 individuals involved in many of the Nodes and the CCTN (including Drs. Nora Volkow, Betty Tai, Mary Ellen Michel and others) contributed to 14 of the 21 papers accepted in this journal. Also, a colleague from NIAAA, Dr. Howard Moss, contributed a paper.

A very special thanks to Betsy Wells (*now an honorary member of the ATS Node*), Tom, and Valire for their excellent collaboration in organizing a comprehensive double-edition of this journal, recruiting authors, editing papers, and many other things they were asked to do. Another very special thanks goes to Janis McDonald (ATS Node) who organized all of the editorial work, and went beyond the call of duty with reformatting and even helping with some of the papers' bibliographies. Janis was the one who communicated to all of the co-authors and made sure we kept on track with our timeframes. Thanks for the gentle nudges Janis!!!

### SAMHSA News



SAMHSA (Substance Abuse and Mental Health Services Administration) announced a new opportunity for individuals and organizations to help prevent high-risk drinking among college students. SAMHSA is seeking solutions to this problem through cost-effective, portable, technology-based products that effectively reach a diverse population of college students and their parents, as well as faculty and staff, and that can be adapted to meet the local needs of these institutions throughout the United States. Technology-based products may include web applications, mobile apps, short message services (SMS), and podcasts. To see the posting, please visit <http://collegestudentdrinking.challenge.gov/>.

### Recap of the Society for Clinical Trials (SCT) Annual Meeting, May 19-22, 2013

CTNers contributed to the SCT conference in Boston, Massachusetts, by presenting, chairing and organizing several workshops and invited sessions. These included:



- On May 19, Carmen Rosa (CCTN) organized and presented a workshop: *OMG, Facebook and Research can be BFFs, LOL! Using New Media Tools in the Design and Conduct of Clinical Trials*. This 4 hour workshop included presentations and demonstrations from Erin Winstanley (OV Node) and Gloria Miele (GNY Node) on using the internet and social media, as well as cell phones, for clinical trials recruitment, retention, data collection, dissemination and overall communications. The session also included Lynn Simpson (Harvard CTSA) with a demonstration of an EDC currently designed to conduct secure data collection.
- On May 19, Paul Wakim (CCTN) presented in the workshop titled *Practical Statistical Reasoning in Clinical Trials for Non-Statisticians*. In this 4 hour class, Paul presented the basic statistical concepts involved in the clinical trial cycle, from trial design, analysis plan, final analysis and publication.
- On May 20, Paul Wakim (CCTN) and Paul Van Veldhuisen (EMMES) presented in a panel titled *Public Use Datasets*. They discussed the NIH requirements and the CTN Data Share example.
- On May 20, Carmen Rosa (CCTN) chaired and presented a panel on *Community Based Clinical Trials: Innovative Regulatory Procedures to Enhance Translation*. This panel included Royce Sampson and Kimberly Pressley (SC Consortium Node) to discuss issues and recommendations in conducting rigorous clinical trials in community settings, based on the CTN experience.
- On May 21, Robert Lindblad (EMMES) chaired and presented 3 panels: a) *Two Years after the Implementation of New Safety Reporting Regulations – What has Worked?* b) *Can Qualitative Research Methods Revolutionize the Design and Conduct of RCTs?* and c) *Cell Therapy Clinical Trials: What is Unique About the Conduct of Clinical Trials Using Cell and Gene Therapies?*
- On May 22, Richard Saitz (Boston Medical Center) delivered the closing plenary: *Challenges for Health Behavior Trials From Design to Practice: the Example of Unhealthy Alcohol Use*. His lecture provided insights of using evidence based interventions, SBIRT, for alcohol and other substance use disorders.

### **New England Consortium Node at the American Psychiatric Association (APA) Meeting**



Members of the New England Consortium Node delivered presentations at the 116<sup>th</sup> Annual Meeting of the APA held in San Francisco, California, May 18-22, 2013.

**Shelly Greenfield, MD, MPH** delivered a presidential symposium entitled, “Treatment of Women with Addiction throughout the Lifespan.” **Roger D. Weiss, MD** delivered a scientific and clinical report from the NIDA-CTN-0030 POATS study entitled, “Patient Characteristics that Predict Buprenorphine-Naloxone Treatment Outcome for Prescription Opioid Dependence: Results from a Multi-Site Study.” **Margaret Griffin, PhD** delivered a scientific and clinical report from the NIDA-CTN-0030 POATS study entitled, “Characteristics and Treatment Outcomes in Prescription Opioid-Dependent Patients with and without Co-Occurring Psychiatric Disorder.”

### **DSC 2/3 – EMMES Data Center**



The Data and Statistics Center (DSC 2/3) at the EMMES Corporation recently presented two abstracts at the Society for Clinical Trials Annual Meeting in Boston,

Massachusetts. Dr. Paul VanVeldhuisen presented as part of an invited Session on Public Use Datasets on Monday, May 20. The session discussed the NIH requirements and expectations for sharing data and creating public use datasets. He presented the NIDA CTN Data Share as a case study for data sharing, noting details on how data from NIDA CTN trials are prepared and posted on the data share website for public use.

Drs. Neal Oden and Gaurav Sharma presented a poster entitled “Algorithms for Inference following Bernoulli Random Walks with Desirable Absorbing Boundaries” on Monday, May 20. The novel methodological work in this poster deals with estimation of the parameter of a random Bernoulli walk with a simple boundary. Drs. Oden and Sharma show how to calculate uniformly minimum variance unbiased estimators (UMVUE’s), p-values, expected run lengths, and confidence intervals for Bernoulli walks with finite closed attainable simple boundaries, like that in CTN-0054 (ADAPT-MD).



*(Pictured left to right: Gaurav Sharma, Neal Oden and Paul Wakim)*

If you have any questions for the DSC 2, please feel free to contact them at [nidadsc2@emmes.com](mailto:nidadsc2@emmes.com) or telephone (301) 251-1161.

### **NIDA – EMF Training Awards**



The NIDA Blending Initiative has partnered with the Emergency Medicine Foundation (EMF) for a career development training award in drug abuse and addiction. It includes one year of training and mentorship for a first year graduate, resident, junior faculty member or fellow. For questions, please contact Cynthia Singh at: [csingh@acep.org](mailto:csingh@acep.org). You may apply online at: <http://www.emffoundation.org/EMFGrants>

### **NIDA Special Populations Research Development Seminar Series Workshop**



There will be a NIDA Special Populations Research Development Seminar Series Workshop (Part I) on September 19-20, 2013, in Bethesda, Maryland, for new investigators (from underrepresented, diverse groups) interested in applying for and receiving funded research support from NIDA. The Seminar Series is designed to provide information and experiences to participants that will improve their understanding of the competitive research funding process and encourage them to seek research grants. During this workshop, new investigators will have opportunities to hear about research priorities from NIDA and other Institutes, learn about the NIH grant application and review process, and discuss and get feedback from Institute program officials and NIDA/NIH funded investigators on their research concepts/plans.

To be eligible, candidates must have completed a Ph.D./M.D. or equivalent degree, provide a detailed curriculum vitae and submit a 3-5 page single-spaced concept paper, which is due an estimated 3 weeks before the workshop. The concept paper should include: (1) a statement of the problem(s); (2) research questions to be addressed in the proposal; (3) proposed research design describing the subject population, analysis and other critical elements; and (4) a brief budget detailing personnel and other costs associated with the conduct of the project.

NIDA will cover expenses associated with participation: round-trip airfare, lodging, per diem and ground transportation (all not to exceed Federal government rates).

Candidates should send an e-mail to Flair Lindsey ([flindsey@nida.nih.gov](mailto:flindsey@nida.nih.gov)) confirming their interest, along with a statement of research interests and a curriculum vitae by **June 18, 2013**. Notifications of acceptance will be sent on **June 25, 2013**.

**Ohio Valley Node News**



Join us in congratulating Dr. Winhusen (Ohio Valley Node PI) on her promotion to the Director of the Division of Addictions, University of Cincinnati's Department of Psychiatry. Congratulations Theresa!

**New Horizons – Leaving CCTN**

Mary Ellen Michel, PhD, Deputy Director of the CCTN, is leaving the CCTN/NIDA and joining the National Center for Medical Rehabilitation Research (NCMRR) program at the National Institute of Child Health and Human Development (NICHD) in mid June. At NICHD, she will manage clinical programs on head injury, stroke and rehabilitation. Although her departure is a big loss for the CCTN and NIDA, she will be a valuable addition to NICHD.



Mary Ellen will be missed but we are excited for her as she embarks upon the next step in her career.

Petra Jacobs, M.D., Assistant Director of the CCTN, has agreed to serve as Acting Deputy Director upon Mary Ellen's departure.

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

**Connect with NIDA through:**

