

# Clinical Trials Network

## CTN Bulletin

March 14, 2012

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### Trial Progress –Nearing 15,000!



Trial enrollment numbers reflect study information as of March 14, 2012.

#### Open Studies

- CTN 0037 – Enrolled 256 (N=330)
- CTN 0044 – Enrolled 507 (N=500) (enrollment completed – in follow up phase)
- CTN 0046 – Enrolled 538 (N=528) (enrollment completed – in follow up phase)
- CTN 0047 – Enrolled 1,285 (N=1,285) (enrollment completed – in follow up phase)
- CTN 0048 – Enrolled 109 (N=300)
- CTN 0050 – Enrolled 362 (N=1,269)

**Total Enrolled All Studies: 14,688**

### Next CTN Steering Committee Meeting



The next NIDA CTN Steering Committee Meeting is scheduled to take place in Atlanta, Georgia, on April 17-18, 2012.

Registration information on the pre-ASAM Mini Blending Meeting, scheduled to take place at the Hilton Atlanta, in Atlanta, Georgia, on April 19, 2012, is also available. Hotel reservations are due by Friday, March 16, 2012, in order to qualify for the reduced rate. Please access on-line registration for the meetings at

<http://www.seiservices.com/NIDA/CTN/Meetings/>.

### Mid-Atlantic Node News: Congratulations to Dr.

#### Marc Fishman and Mountain Manor



Mountain Manor, a Mid-Atlantic Node Community Treatment Program, and its Medical Director and CTN Steering Committee member Marc Fishman MD,

have been named one of five national recipients of the 2012 SAMHSA Science to Service Awards for its youth office based opioid treatment. Since 2008, Mountain Manor has been treating 14 to 21 year olds with buprenorphine and extended release naltrexone (XR-NTX). This innovative model which integrates counseling and medication has proven feasible, successful, and sustainable in a community treatment setting. Mountain Manor was a site in CTN 0010 Buprenorphine for Youth and Young Adults, and Dr. Fishman has written one of the publications reporting data on XR-NTX for youth. Congratulations!

*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.*

### PhenX Is Here!



The PhenX (**Phenotypes and eXposures**) Toolkit is a catalogue of well-established, standard measures of phenotypes and exposures recommended for research studies with human subjects. The Toolkit is funded by the National Human

Genome Research Institute (NHGRI) through a cooperative agreement with RTI International, with additional support provided by the Office of Behavioral and Social Sciences Research (OBSSR) and the National Institute on Drug Abuse (NIDA).

NIDA is dedicated to advancing science by improving the yield and impact of its research portfolio. One way to accomplish this is to provide investigators with a common set of tools and resources. Toward this end, NIDA, in conjunction with the National Institute on Alcohol Abuse and Alcoholism, the National Cancer Institute, the National Human Genome Research Institute, the Office of Behavioral and Social Science Research, and the broader scientific community, has identified a series of Core and Specialty measures that will promote the collection of comparable data across studies. The measures from the Core and Specialty collections are available in the Substance Abuse and Addiction Collection of the PhenX Toolkit ([www.phenxtoolkit.org](http://www.phenxtoolkit.org)).

The 19 measures in the “Core: Tier 1” Collection are highly recommended, and take approximately 10 minutes to administer. The measures in Core: Tier 1 are deemed relevant and essential to all areas of addiction science. NIDA grantees/applicants conducting human-subject studies are strongly encouraged to incorporate the Core:Tier 1 measures.

The 8 measures in the “Core: Tier 2” Collection are also highly recommended, but require a greater time commitment. These measures are more burdensome and specialized than the Tier 1 measures. NIDA grantees/applicants conducting human-subject studies are strongly encouraged to incorporate them whenever possible and appropriate.

Through the use of these measures, NIDA-funded researchers will be able to share, compare, and integrate data across studies. Researchers are encouraged to incorporate the measures from the Core and Specialty collections in all human-subject studies. These are available in the Substance Abuse and Addiction Collection of the PhenX Toolkit ([www.phenxtoolkit.org](http://www.phenxtoolkit.org)).

### **Southern Consortium Node**



The Southern Consortium Node is pleased to welcome Dr. Effat Merghati Khoei, PhD, from Tehran, Iran, to their team as a NIDA INVEST CTN Research Fellow. Dr. Khoei is an

Assistant Professor at the Tehran University of Medical Sciences in the Public Health Department, Health Promotion Division. As the director of the family and sexual health division in the BASIR (Brain and Spinal Cord Injury Research) Center, she has established a clinical and research team to work with spinal cord injury patients. Since 2007, she has also been running a private sexual health clinic in Tehran. During her time as a research fellow, her primary focus will be to engage in research involving drug-using women, treatment and prevention programs with a focus on female drug users with high sexual risk behaviors, and HIV risk reduction. We are very excited to welcome Dr. Khoei!

### **Ohio Valley Node**



The Ohio Department of Alcohol and Drug Addiction Services (ODADAS) has just released a protocol on the use of suboxone. The ODADAS protocol on MAT (Medication Assisted Treatment) is

important because historically access to addiction medications in Ohio has been very low, and in fact an abstinence-based philosophy was part of the statute that governs ODADAS. Due to the devastating toll of the prescription drug epidemic in Ohio, in February 2011, Governor Kasich passed an executive order authorizing ODADAS to use FDA-approved medications to treat opioid dependence.

Drs. Somoza and Winstanley, of the Ohio Valley Node, served on the ODADAS MAT advisory committee and routinely cited the results of CTN-0030 (POATS – Prescription Opiate Addiction Treatment Study). The primary outcomes manuscript from CTN-0030 is cited in the Ohio MAT protocol, and the CTN study results were integral to ODADAS's recommendation that MAT be used for sustained periods (e.g., 18-24 months) rather than for limited durations (e.g., 2 weeks). In Ohio, the CTN has made a system-level impact to improve the adoption of medication assisted treatment for addictions.

### **Useful Sites for CTNers!**

- **Medication and lab supply orders** - [ctnsupport@emmes.com](mailto:ctnsupport@emmes.com)
- **Safety related issues/adverse event follow-up** - [ctnsafety@emmes.com](mailto:ctnsafety@emmes.com)
- **Training information, comments or requests** - [ctntraining@emmes.com](mailto:ctntraining@emmes.com)

### **Where to Get Information on the CTN**



The NIDA CTN website includes information on the CTN Nodes, CTPs, and studies. For more information go to:

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

### **Western States Node Updates**



The Western States Node is pleased to report that CODA, a Community Treatment Program in the Western States Node, has received a small grant to study the effects of massage on

chronic pain among methadone patients.

Katharina Wiest, PhD, Director of Research at CODA, participates in CTN trials and has built research capacity and staff. She is using the infrastructure to apply for non-CTN awards. Recently, she received a \$30,000 award from the Massage Therapy Foundation to assess the impact of massage on chronic pain among methadone patients. The March 2012 issue of *Massage Today* includes a description of the study and an interview with Katharina and the massage therapist:

<http://www.massagetoday.com/mpacms/mt/article.php?id=14546> .

The Western States Node, in collaboration with the Northwest Addiction Technology Transfer Center and the Methamphetamine Abuse Research Center, participated in Brain Fair on March 3, 2012. The Node's exhibit featured the research



conducted within the Clinical Trials Network, the Blending Products available through the ATTC network, and the latest on the neuroscience of addiction from the Methamphetamine Abuse Research Center. Oregon Health and Science University's Brain Institute sponsors the annual Brain Fair at OMSI (the Oregon Museum of Science and Industry) to showcase the University's neuroscience and brain related research. The 2012 Brain Fair (the largest Brain Fair in the country) celebrated the closing of the OMSI exhibit *Body Worlds and the Brain*. The Brain Fair included interactive exhibits, real human brains, crafts, demonstrations, prizes and OHSU scientists explaining their research. The Brain Fair is part of the 2012 Brain Awareness Season with public presentations on *The Brain and Society*. Scheduled speakers include Story Landis, PhD, (Director, National Institute for Neurological Disorders and Stroke – March 12), Alan Leshner, PhD, (Executive Director, American Association for the Advancement of Science – March 19) and Nora Volkow, MD, (Director, National Institute on Drug Abuse – April 26).



## New Funding Opportunities

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



- Notice Announcing Data Harmonization for Substance Abuse and Addiction via the PhenX Toolkit ([NOT-DA-12-008](#)) National Institute on Drug Abuse
- News from the National Institute of Mental Health – there are 2 new RFAs focusing on research of mental health and Health IT. These stem from a workshop to develop a research agenda that NIDA partnered with them on late in 2010. <http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-13-060.html> and <http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-13-061.html>
- The Agency for Health Care Research and Quality (AHRQ) has released a request for applications for Partnerships for Sustainable Research and Dissemination of Evidence-based Medicine (R24). AHRQ seeks Resource-Related Research Project (R24) applications that propose to build new and/or enhance existing capacity in research and dissemination infrastructure that will bridge the gap between clinical and health services research and everyday practice by building a knowledge base about how to improve the translation and dissemination of evidence-based health information, interventions, and clinical practices to populations not traditionally reached by such information or practice. AHRQ is especially interested in partnerships at the local and/or community level to facilitate the engagement of the target population. Complete announcement: <http://1.usa.gov/zmHckk>

## 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 cannot 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!

## Publications Committee (PC) Committee Reports



The CTN Publications Committee has been busy reviewing abstract submissions and publications. A couple of major meetings had their submission deadlines on Feb 15, so the first half of the month

had a high concentration of abstract submissions, as authors continued submitting things for PC review right up to the final hours before the deadline. Despite this occasional short time pressure, the PC review teams did a great job in completing reviews quickly and providing valuable comments to authors. PC reviews provided a valuable service in recommending changes for greater clarity and understanding.

### *Meetings for which the PC reviewed submissions included:*

*International AIDS Conference  
American Public Health Association  
NIH Dissemination Conference  
American Academy of Health Behavior*

### *Topics of reviewed abstracts included:*

*Barriers to condom use  
Condom use self-efficacy  
Treatment as prevention  
Drug users' HIV testing histories  
Efficacy of HIV risk-reduction counseling  
Barriers to substance treatment entry  
Factors contributing to clinical trial participation  
Impact of sexual abuse history*

### *Recent Acceptance for Publication:*

- **The Short Inventory of Problems-Revised (SIP-R): Psychometric properties within a large, diverse sample of substance use disorder treatment seekers.** *Kiluk, B.D., Dreifuss, J.A., Weiss, R.D., Morgenstern, J., & Carroll, K.M.* [Psychology of Addictive Behaviors](#)
- **Therapist effects in a NIDA CTN Intervention Trial with Pregnant Substance Abusing Women: Findings from a RCT with MET and TAU conditions.** Accepted for publication. *Erickson SJ, Tonigan JS, Winhusen T.* [Alcoholism Treatment Quarterly](#)
- **Tobacco dependence counseling in a randomized clinical trial.** Accepted for publication. *Ivana Croghan et al* [Contemporary Clinical Trials](#)

**Clinical Coordinating Center (CCC) at EMMES**



**GCP training**

Good Clinical Practice (GCP) renewal training certification is now available at <http://gcp.nihtraining.com>. This renewal capability supports recent CTN Policies and

Procedure Guide requirements for members to obtain Human Subjects Protection and GCP training with every new protocol or at least every three years. Questions regarding the GCP online training may be directed to [ctntraining@emmes.com](mailto:ctntraining@emmes.com).

**2012 Web Seminar Series – Getting Started with Social Media Webinar**

160 CTN members and guests joined the Leap Day session. The recorded session and handouts are available on the CTN Dissemination Library <http://ctndisseminationlibrary.org/ctntraining.htm>

**Upcoming webinars:**

<b>May 9</b>	<b>Managing Emotions in Recovery</b>
<b>June 13</b>	<b>Biological Measures and Specimen Handling</b>
<b>July 18</b>	<b>Co-occurring Disorders: Integrated Treatment of Addiction and Mood and Anxiety Disorders</b>
<b>August 15</b>	<b>Personality Disorders and Addiction</b>
<b>September 19</b>	<b>Build Your Team for Research Success</b>
<b>October 24</b>	<b>Managing Safety and Crisis Situations</b>

Don't forget to follow [CTN Training](#) on Facebook, and while you're there, be sure to check out the Facebook page for the [CTN Dissemination Library](#).

*Other CCC related questions and topics- Principal Investigator, Robert Lindblad, at 301-251-1161, [rlindblad@emmes.com](mailto:rlindblad@emmes.com), or Eve Jelstrom, Project Director, at 301-251-1161, [ejelstrom@emmes.com](mailto:ejelstrom@emmes.com).*

*NIDA Project Officer, Steve Sparenborg, at: [sparenborgs@nida.nih.gov](mailto:sparenborgs@nida.nih.gov), telephone (301) 496-4844.*

**EMMES Offices Closed**



The offices at the CCC and DSC 2 (EMMES) will be closed on Friday, April 6, 2012. The Help Desk staff will not be available that day but will respond to your requests upon their return on Monday, April 9.

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

