Trial Progress – Still Climbing!

Trial enrollment numbers reflect study information as of the October 29, 2014 Trial Progress Report

Open Studies

- **CTN 0050** – Long Term Follow-up to the CTN 0027 (START) Study. Enrolled 872 (Original N=1,267 START Study participants).
- **CTN 0055** – CHOICES (Comparing Treatments for HIV-Positive Opioid Users in an Integrated Care Effectiveness Study). Enrolled 31 (N=50).
- **CTN 0056-Ot** – Testing and Linkage to HIV Care in China. Enrolled 462 (N=360).
- **CTN 0075-Ot** – SBIRT-PC (Screening, Brief Intervention, and Referral to Treatment in Primary Care). Enrolled 72 (N=120).
- **CTN 0059** – TAPS Tool (Tobacco, Alcohol, Prescription Medications, and Substance Use/Misuse Brief Screen/Assessment). Enrolled 653 (N=2000).

Total Enrolled All Studies: 17,791

News from the CTN Nodes

**Western States Node**

APPLICANTS NEEDED FROM CTN NODES!

The recently funded “Learning for Early Careers in Addiction and Diversity (LEAD) Program” has initiated training for the first cohort of scholars and completed our first Summer Intensive Training at the University of California, San Francisco (UCSF).

The Western States Node in the Department of Psychiatry at UCSF is currently seeking applicants for the next cohort of this program.

The three-year LEAD Program uses the NIDA Clinical Trials Network as a platform for training and mentorship of early career academic scientists in the addictions and focuses on increasing the numbers of racial/ethnic minorities conducting substance use disorder clinical trials research. During their training, these researchers will complete an annual 4-week summer intensive program in San Francisco and also working closely with a mentorship team at their home institutions. Applications are currently being accepted through December 15, 2014 for the Summer 2015 training in residence. For questions about this program please contact James Sorensen, PhD at james.sorensen@ucsf.edu. To request an application packet, please contact Diane Coseo at 415-206-3051 or diane.coseo@ucsf.edu (Node Coordinator).

The NIDA CTN Steering Committee Meeting

April 14-16, 2015

Gaithersburg Marriott Washingtonian Center

Logistical information will be available by November 17, 2014

Registration will open on January 12, 2015

*We hope you can join us!*

To ensure receipt of future CTN-related communications and alerts, please add the domain “@leedmci.com” to your Safe Senders list.

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.
New England Consortium Node

2014 Cape Cod Symposium on Addictive Disorders

Members from the New England Consortium Node presented a workshop at the 2014 Cape Cod Symposium on Addictive Disorders in Hyannis, Massachusetts on September 13, 2014. The seminar was entitled The National Drug Abuse Clinical Trials Network (CTN) in New England: Advancing Treatment Through a Partnership Between Researchers and Community Treatment Programs. Presenters from the Node included Roger Weiss, MD, Patrice Muchowski, ScD, John Hamilton, LADC, LMFT, and Genie Bailey, MD. The presenters described the CTN and offered results from the Prescription Opioid Addiction Treatment Study (POATS, CTN-0030). Key to the discussion was the impact of the CTN on the adoption of empirically supported treatments in community settings. Dr. Muchowski described how the Patient Feedback study (CTN-0016) influenced clinical practice and how future research participation is evaluated. Mr. Hamilton discussed how CTN participation helped distinguish the agency and improved client outcomes and staff morale. Dr. Bailey described how participating in CTN studies was the catalyst for establishing a separate research department within the agency, leading to continued participation in CTN studies, independent NIDA-funded grants, and industry-sponsored clinical trials.

NE ATTC/NEC Node Conference – Using Evidence-Based Practices in Community Settings: The NIDA/SAMHSA Blending Initiative

In partnership with the New England Addiction Technology Transfer Center, the New England Consortium Node hosted a one-day conference on September 18, 2014 in Marlborough, Massachusetts. Roger Weiss, MD, R. Kathryn McHugh, PhD, and John Hamilton, LADC, LMFT were among the presenters from the New England Consortium Node. Dr. Weiss presented on treatments for prescription opioid dependence, and Mr. Hamilton presented on the role of the provider organization in developing Blending products.

Mid-Atlantic Node

On September 22, 2014, the Mid-Atlantic Node, in collaboration with Johns Hopkins Medicine and with support from the JHU Center for AIDS Research, presented a one day symposium: A Look at Tobacco and Cannabis. The featured guest speaker was Carlo DiClemente, PhD, the Director of MDQUIT, Maryland’s Tobacco Resource Center. Dr. DiClemente highlighted the importance of addressing tobacco cessation where the use and impact is disproportionately high among substance use and mental health populations. A cadre of experts in the field discussed the pharmacology, medical, and psychiatric impact of cannabis use. The presenters included Ryan Vandrey, PhD, who is doing extensive research on the drug at Johns Hopkins University, Ann Bruner MD and Marc Fishman, MD, psychiatrists at Mountain Manor Treatment Center in Baltimore, MD, and Elizabeth Disney, PhD, the Associate Director of a Baltimore-based methadone maintenance treatment center.

The audience of 150 included substance use disorder clinicians, researchers, nurses, and other health care providers. Copies of the presentations will be available through the CTN Dissemination Library.

Texas Node

The Texas Node hosted its annual Texas Addiction Research to Practice Conference on October 8, 2014 in collaboration with Nexus Recovery Center in Dallas, Texas. Nexus provided the venue and continuing education credits free of charge to attendees while the Node provided the speaker. Gabriella Grant, MA, a Seeking Safety trainer and the director of the California Center of Excellence for Trauma Informed Care, provided a full day focused on Seeking Safety using didactics, videos, experiential training, and a good dose of humor.

Seeking Safety is a present-focused, manualized treatment targeting individuals experiencing symptoms of posttraumatic stress disorder (PTSD) or who have a history of trauma and/or individuals with substance use disorders with the goal of helping them attain safety and increase their coping skills. Seeking Safety, begun in 1992 by Lisa M. Najavits, PhD under grant funding from the National Institute on Drug Abuse, was designed for flexible use with 25 topics that can be presented in any order in group or individual format for women and men in a variety of settings (outpatient, inpatient, or residential).

Information presented at the conference included a review of research and clinical issues in treating trauma and substance abuse, the Seeking Safety format and topics, assessment and treatment resources, as well as hands-on practice sessions for the attendees. DVDs and handouts were available to attendees. The conference was attended by 94 Texas Node affiliates as well as front-line clinicians from a variety of community treatment centers across the Dallas metroplex.
Delaware Valley Node

A paper by Gvantsa Pirashvili, MD, PhD, a former CTN/INVEST fellow from Tbilisi, Republic of Georgia, has recently been accepted for publication by JSAT. The paper reports findings from a secondary analysis of data from a trial, conducted in Georgia, in which buprenorphine-injecting opioid addicted individuals were randomized to daily buprenorphine/naloxone (Suboxone®) or daily methadone. The primary outcome paper for the trial (DAD; Otiashvili et al., 2013), on which Dr. Pirashvili was a co-author, reported excellent retention in the trial overall and marked reductions in opioid use in both treatment conditions. The new analysis to be published in JSAT examines the prevalence of non-opioid drug use among participants in each treatment group.

Southern Consortium Node

The Southern Consortium has been awarded an administrative supplement to fund a response to NIH’s Office of Research on Women’s Health PA-14-027 (Administrative Supplements for Research on Sex/Gender Differences). Led by Jeffrey Korte, PhD, this study (CTN 0063-S) will assess gender differences in the interrelationships between sexual abuse, risky sexual behavior, and anxiety/depression in treatment efficacy and drug use over time among individuals with substance use disorders through the analysis of opiate and stimulant users across 3 different treatment modalities from 7 CTN trials.

Kathy Magruder, PhD, MPH, Professor in the Department of Psychiatry and Director of the Office of Research Integrity at the Medical University of South Carolina, has been awarded the H. Alfred Tyroler Distinguished Alumni Award. This award is sponsored by the University of North Carolina at Chapel Hill, Epidemiology Chapter of the Gillings School of Global Public Health Alumni Association.

Just published!

Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure (COPE) is a cognitive-behavioral psychotherapy program designed for patients who have posttraumatic stress disorder (PTSD) and a co-occurring alcohol or drug use disorder. COPE represents an integration of two evidence-based treatments: Prolonged Exposure (PE) therapy for PTSD and Relapse Prevention for substance use disorders. The book’s authors are Therese Killeen, MSN, PhD and Kathleen Brady, MD, PhD from the Southern Consortium, and Kathy Carroll, PhD from the New England Consortium.

COPE is an integrated treatment, meaning that both the PTSD and substance use disorder are addressed concurrently in therapy by the same clinician, and patients can experience substantial reductions in both PTSD symptoms and substance use severity. Patients use the COPE Patient Workbook while their clinician uses the Therapist Guide to deliver treatment. The program is comprised of 12 individual, 60 to 90 minute therapy sessions, and includes several components. Some examples are: how PTSD symptoms and substance use interact with one another and information about the most common reactions to trauma. Specific techniques are also addressed such as those to help manage cravings and thoughts about using alcohol or drugs and coping skills to help the patient prevent relapse to substances. In vivo (real life) and imaginal exposures to target the patient's PTSD symptoms are included.

More information about the book can be found at multiple online vendors or your local bookstore.

Clinical Coordinating Center

NIDA CTN Training Update

On October 1, 2014, Julia Gorey, JD, Public Health Analyst in the Division of Policy and Assurances, Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS), presented at the CTN Web Seminar Series on the process for Prisoner Certification and requirements for research based on current regulations and protections (45 CFR part 46). The CCC registered 90 participants for the training, which included an interactive discussion with the presenter on aspects of compliance relevant to CTN studies. Please review the webinar and materials on the CTN Dissemination Library’s website at:

NOTE: The webinar scheduled for November 19th on Family Involvement in Substance Use Disorders and Mental Health Research and Treatment has been cancelled. An update will be provided as soon as the webinar is rescheduled. The current plan is to provide it during the 2015 schedule.

Please mark your calendars! The next webinar will be held December 17th at 1:00 pm ET. Robert Lindblad, MD of the NIDA Clinical Coordinating Center and Data & Statistics Center will discuss The Impact of Inclusion and Exclusion Criteria on Enrollment. An invitation will be circulated from CTNtraining@emmes.com with the details for registration.

If you would like to participate in this webinar or future training and have not signed up, please contact NIDA CTN Training Coordination at CTNtraining@emmes.com to be added to the mailing list.

From the National Institute on Drug Abuse

NIDA Director speaks on the adolescent brain at the American Academy of Pediatrics National Conference

Nora Volkow, MD was the plenary speaker at the AAP conference in October. Here are some quotes from her address as noted in the AAP News for October 14, 2014:

“Now we know that repeated use of drugs can lead to impaired function in areas of the brain that are needed for executive function and these changes are unfortunately long lasting.

“We also know that addiction is a developmental disease in that it often starts early during adolescence—sometimes in childhood—and there are multiple factors that make adolescents particularly vulnerable to drugs of abuse.

“Drug addiction can be treated, but we need to recognize our interventions should follow a chronic model of treatment.

“Additionally, pediatricians cannot afford to ignore the patterns of substance abuse in their patients because it will adversely affect their outcomes, whether it is directly from the medical outcomes, but perhaps as importantly, from the teenagers’ behaviors. The transition from adolescence to adulthood is a period where the risk from adverse behaviors increases.”

New Blending Initiative Products!

The NIDA-SAMHSA Blending Initiative has new training and educational offerings!

Development of an infographic to reflect the findings of CTN-0046 S-CAST and other NIDA research was led by Barbara Sullivan of the Central Rockies ATTC with input from the CTN research team. This very useful document is available by contacting Joanna Weston at Synergy Enterprises, Inc. (jweston@sei.com).

Blending Initiative Motivational Interviewing CME/CE and Patient Simulation

A new continuing medical education/continuing education course (CME/CE), Talking to Patients About Health Risk Behaviors, adds to a growing body of tools available through the National Institute on Drug Abuse (NIDA) to help healthcare professionals care for patients at risk for substance use disorders. The online module provides a real-time patient simulation where physicians can practice motivational interviewing, a science-based technique designed to enhance patient/clinician interaction about problem health behaviors. The course—a joint program between NIDA, Medscape Education and SIMmersion—was developed by experts from the fields of internal medicine, family medicine, and emergency medicine. It was created with the support of NIDA’s Blending Initiative, a program that helps translate the latest research findings into useful clinical tools. The launch of the new CME/CE was announced earlier this month at the American College of Emergency Physicians Scientific Assembly in Chicago. The new course is available at http://www.drugabuse.gov/blending-initiative/cme-ce-simulation.

Mind The Gap!

A seminar series is offered through the NIH Office of Disease Prevention that periodically touches on various topics in prevention that may be of interest to the CTN. This upcoming Wednesday, November 5, at 1:00 PM ET the seminar will address: The National Prevention Strategy: Prioritizing Prevention to Improve the Nation’s Health. These seminars are presented live at NIH and are available for web-based viewing both live and in archive form. More information on this series (and an

The archived videocast of *Pathways to Prevention: The Role of Opioids in the Treatment of Chronic Pain* is also available. This workshop was held September 29-30, 2014 at NIH, and addressed the state of chronic pain and pain treatment in the US. Experts from a variety of disciplines spoke on the prevalence of chronic pain and examined the use of opioids in this diverse population. The materials available for this workshop include the archived videocast of the meeting, and the report developed by the panel. [https://prevention.nih.gov/programs-events/pathways-to-prevention/recent-workshop/opioids-chronic-pain](https://prevention.nih.gov/programs-events/pathways-to-prevention/recent-workshop/opioids-chronic-pain).

**NIDA Research Tools**

**NIDA’s New Data Collection System**

NIDA recently announced the development of a new, enhanced data collection system through a partnership with CESAR (Center for Substance Abuse Research) at the University of Maryland. The National Drug Early Warning System (NDEWS) will be the first national public health surveillance system with the ability to identify emerging drugs and their metabolites, including a focus on synthetics. NDEWS will establish a system of harmonized community indicators for tracking emerging drug trends nationally, using both traditional data collection strategies as well as social media and web scans. NDEWS will serve as the national coordinating center to generate this critically needed information. See the press release here: [http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg](http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg).

NIDA launched its **Common Data Elements (CDE)** website on June 12, 2014 ([cde.drugabuse.gov](http://cde.drugabuse.gov)). This website is available to all investigators and developers, to encourage them to use a core set of CDEs when developing case report forms. Use of this resource will help establish a standardized collection of CDEs compatible with Electronic Health Record Systems (EHRS) data elements and will support the meaningful exchange and integration of data between EHRS and research data systems to answer future research questions on substance use disorder (SUD) treatment. Many of these CDEs originated in the Substance Abuse and Addiction (SAA) project and other components of the Phenotypes and Exposures (PhenX) Toolkit. Different sets of CDEs are available and have been crafted to meet specific data needs such as clinical research and EHRS. EHR vendors are strongly encouraged to select SUD-relevant data elements for their systems from this list, with the goal of developing a core set of common standards nationwide. This current CDE list is expected to grow as new data elements are developed and validated by investigators and as the science evolves; it is thus hoped that the CDEs housed in this website will be universally useful for both EHRS and clinical research.

**NIDA’s National DRUG FACTS WEEK 2015 to begin January 26th**


Last year, more than 1,000 events were held around the country. To see if your community held events last year, check out the 2014 map at [http://teens.drugabuse.gov/national-drug-facts-week/view-events-and-highlights/map/2014](http://teens.drugabuse.gov/national-drug-facts-week/view-events-and-highlights/map/2014). Scroll down to see listings for each state.

Planning on holding an event, or need more information? Once an event is registered on the NIDA NDFW site, NIDA will send free materials to the event holders.

Funding Announcements that may be of interest to CTN investigators:

RFA-DA-15-008

Notice of Participation of the National Institute on Drug Abuse in PA-14-334 "Advancing Interventions to Improve Medication Adherence (R01)" (NOT-DA-14-052)

RFA-DA-15-010


Notice of Availability of Funds for Competitive Revision Applications for Research to Determine if Reduction in Illicit Drug Use is Associated with Improvement in Clinical Outcome(s) (NOT-DA-14-049)

Notice of Clarification of Instructions for the Description of the Program Advisory Committee in RFA-AA-15-001 "Specialized Alcohol Research Centers (P50)" (NOT-AA-14-013)
National Institute on Alcohol Abuse and Alcoholism

November Schedules

Veterans Day, November 11, 2014
NIDA offices will be closed on November 11, 2014 in acknowledgement of Veterans Day. The CTN CCC and DSC offices will be open.

Thanksgiving, November 27, 2014
NIDA offices will be closed on November 27, 2014. The CTN CCC and DSC offices will be closed on November 27, and 28, 2014.

Updates for this Bulletin should be sent to:
Michele Straus at mstraus@nida.nih.gov

Connect with NIDA through: