Clinical Trials Network

CTN Bulletin
May 2, 2013
Volume 13 - 07

Trial Progress – Over 15,000!

Trial enrollment numbers reflect study information as of May 1, 2013.

Open Studies

- **CTN 0047** – **SMART-ED** (Screening, Motivational Assessment, Referral, and Treatment in Emergency Departments) Enrolled 1,285 (N=1,285). Enrollment completed – in follow up phase.
- **CTN 0048** – **CURB** (Cocaine Use Reduction with Buprenorphine). Enrolled 302 (N=300). Enrollment completed – in follow up phase.
- **CTN 0049** – **Project HOPE** (Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users). Enrolled 447 (N=800).
- **CTN 0050** – Long Term Follow-up to the CTN 0027 (START) Study. Enrolled 804 (N=1,267).
- **CTN 0052** – **BRAC (**Buspirone for Relapse-Prevention in Adults with Cocaine Dependence). Enrolled 62 (N=60). Enrollment completed – in follow up phase.

Total Enrolled All Studies: 15,868

Delaware Valley Node Update

Dr. George Woody, Delaware Valley Node PI, presented a poster at the 2013 Global Health and Innovation Conference entitled "Sustained Release Naltrexone Implant vs. Oral Naltrexone or Placebo for Preventing Relapse to Opioid Dependence." The conference was held at Yale University, New Haven, Connecticut, from April 13-14, 2013.

The Global Health and Innovation Conference is the world's leading global health and social entrepreneurship conference, whose goal is to exchange ideas and best practices across disciplines in order to improve public health and international development. Unite for Sight welcomed over 2,000 participants from all 50 states and 50 countries. For more information about this meeting, please go to: http://www.uniteforsight.org/conference/

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 Update

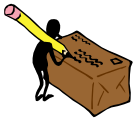
Kathleen M. Carroll, Ph.D. (Co-PI) was recently appointed as the Albert E. Kent Professor of Psychiatry at the Yale School of Medicine.

Dr. Carroll is also the principal investigator of the School of Medicine's Psychotherapy Development Research Center—the only National Institute on Drug Abuse (NIDA) center devoted to behavioral therapies research. Her research focuses on studying behavioral, pharmacological, and combined treatments for addiction, with an emphasis on improving the quality of such therapies through rigorous research on their clinical efficacy. To read more about this appointment go to http://www.medicineatyale.org/ (March 13, 2013, Vol. 9, No. 1). Congratulations Dr. Carroll!

Dr. Carroll was also featured in an article in *Psychiatric News* (April 5, 2013, Vol. 48, No. 7, pages 15-18) summarizing a recent briefing to congressional staff on Capitol Hill on March 12, 2013. The briefing was organized by the Friends of the National Institute on Drug Abuse. The APA was a co-sponsor. Dr. Carroll provided testimony at the briefing urging Congress to continue to support NIH research efforts in substance abuse treatment to help military personnel and their families. To read more go to: http://psychnews.psychiatryonline.org/newsArticle.aspx?articleid=1676234.

New Funding Opportunities

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



- Notice of NIDA's Participation in PA-13-194 Mechanisms of Alcohol and Nicotine Co-Addiction (R01) (NOT-DA-13-024)
- Notice of NIDA's Participation in PA-13-193 Mechanisms of Alcohol and Nicotine Co-Addiction (R21) (NOT-DA-13-025)
- Medications Development Centers of Excellence Cooperative Program (U54) (RFA-DA-14-004)
- Eradication of HIV-1 from CNS Reservoirs: Implications for Therapeutics (R01) (RFA-MH-14-170) (R21) (RFA-MH-14-171)

Report from the Florida Node Alliance (FNA)

Researchers from the Florida Node Alliance (FNA) led by Executive Director, Dr. Viviana Horigian, were recognized by the National Institute of Psychiatry in Mexico for successfully completing the first phase of a groundbreaking collaboration involving the transfer of technology for clinical trials implementation. Dr. María Elena Medina-Mora, General Director of the National Institute of Psychiatry "Ramón de la Fuente" presented the award during a ceremony celebrating the completion of the first randomized study conducted as part of a nationwide clinical trials network of substance abuse and mental health researchers and community treatment providers.

This first Mexican study was an adaptation of the CTN 0021 study, "Motivational Enhancement Treatment to Improve Treatment Engagement and Outcome for Spanish-Speaking Individuals Seeking Treatment for Substance Abuse (METS)". The FNA team developed and pioneered a model of technology transference using NIDA-CTN's experience from over 12 years of changing clinical practice in the United States for the treatment of substance abuse. Together with Dr. Horigian, the Project Director, Rosa Verdeja, M.Ed., and the Director of Quality Assurance, Elizabeth Alonso, Ph.D., delivered training, coaching, and mentoring in all aspects of real world clinical trials implementation and specific protocol development to a core team at the National Institute of Psychiatry "Clinical Trials Unit". The Mexican Clinical Trials Unit in turn led the first clinical trial, trained the Community Treatment Programs and monitored the study progress through its successful completion on April 1st.

The Mexican pilot study *"Intervención de Incremento Motivacional"* (or *IIM* for its Spanish initials) allowed the development and testing of the newly formed network. Dr. Rodrigo Marin-Navarrete, Coordinator of the "Clinical Trials Unit" and PI of the study, presented preliminary data during the International Forum at the CTN Steering Committee Meeting in March. This study reached its randomization target of 120 participants one month ahead of schedule and obtained a remarkable 95% retention rate at the second follow-up, three months after treatment completion. A celebrated outcome of this project was the fact that three Mexican institutions working in the prevention and treatment of drug abuse came together in a coordinated effort for the first time through the implementation of this project. In addition to the IIM study, Dr. Marcela Tiburcio and Dr. Asunción Lara of the National Institute of Psychiatry are currently leading the development of an online intervention for the treatment of substance abuse and depression as part of the collaboration project with the FNA.

The ceremony held in Mexico, D.F. on April 16, 2013, was attended by government dignitaries including the Director of International Narcotics & Law Enforcement Affairs of the U.S. Department of State, and the Director of the National Institutes of Health in Mexico amongst other distinguished members from the Mexican government, academic institutions, mental health research institutions and participating community treatment programs.

Dr. Viviana Horigian**, (left) Executive Director of Florida Node Alliance ;** Dr. María Elena Medina-Mora**, (right) General Director of the National Institute of Psychiatry Ramón de la Fuente, México**

The collaboration between the FNA and the National Institute of Psychiatry in Mexico was sponsored by a two year grant in 2011 from the U.S. Department of State's Merida Initiative for drug demand reduction. Based on the success demonstrated in the past two years, the U.S. Department of State awarded an extension of the grant through the end of 2013 for publications and dissemination.

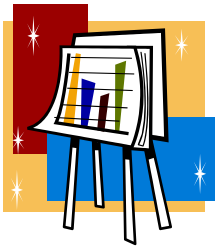
The FNA team thanks NIDA CTN for contributing to the unparalleled success of this bilateral project and specifically to Chris Farentinos and Thelma Vega for training MET supervisors, and therapists Manuel Paris and Luis Anez for training the independent raters, and Kathleen Carroll and her team for their support and for lending the design and materials of the METS study.

Help FDA Help Patients: The Patient Network Web Site

With its new Patient Network Web site, PatientNetwork.FDA.gov, the Food and Drug Administration (FDA) Office of Health and Constituent Affairs welcomes the unique perspective of patients, family members, caregivers, and patient advocates directly affected by serious disease to the Agency's decision-making processes.

FDA's Patient Network Web site supports people who are looking for reliable information about medical products and their approvals, clinical trials and other treatment options. The site contains information on the drug and device approval process, clinical trials, investigational drugs, burgeoning treatment options, off-label drugs, and new FDA approvals—and it's all written in plain language. For more information on FDA's Patient Network, email: PatientNetwork@fda.hhs.gov or visit the web site at: PatientNetwork.FDA.gov

Pacific Node News - CATES



The Pacific Node is co-sponsoring a California Addiction Training and Education Series (CATES) entitled "The Changing Behavioral Health Care Landscape: Integration, Innovation, and Financing Models for Success" in California. The regional trainings are part of a series of research-to-practice trainings that have taken place throughout California since 2004. The free trainings are being held on May 17th in Rialto, CA; June 28th in San Leandro, CA; and July 12th in Hanford, CA.

The target audience for CATES includes substance use and mental health disorders treatment providers, directors, researchers, family therapists, and anyone interested in the latest information on the health care landscape, specifically integration, innovation and financial models. Pre-registration is required. For more information, please visit the web site at: www.psattc.org. CE credit will be available for a small fee.

Changes to the CTN Policies and Procedures

1. *Common Assessment Measures:* Last year NIDA issued a policy on data harmonization using the PhenX toolkit. CTN requires collection of PhenX Core Tier 1 items at baseline. The policy document refers users to the Investigator Toolbox for details.

   The Toolbox file includes:

   a. CTN's Plan to implement PhenX
   b. Tier 1 Measures: Substance Abuse and Addiction
   c. Mapping TLFB to PhenX
   d. TEAM taskforce recommendations

2. *Study Budget*: Submission of study budgets is required at concept, Protocol Review Board (PRB) and site selection stages.
   a. Provide an estimated study budget with the concept sent to the Research Development Committee (RDC). The RDC will not consider concepts without accompanying budgets.
   b. An updated budget is required for PRB review.
   c. A detailed site budget is required from each proposed site to be considered for site selection.

3. *Publications*:
   a. Information from the Trial Progress Report or Data Status Report should not be used in presentations or publications. Only analyses from data sets should be published.
   b. Manuscripts based on secondary data should not be submitted before the main outcome paper is submitted for publication.

Reminders:

1. *NIH policies*: CTN studies must comply with all NIH policies, found on http://grants.nih.gov/grants/policy/nihgps_2012/index.htm. The CTN Policies and Procedures only highlights some of these NIH policies when conducting human subject research, e.g. research misconduct and FCOI policies.

2. *Lead Team (LT):* NIDA CCTN and personnel from the coordinating centers are part of the study LT.

3. *PRB/DSMB*: Investigators should not contact members of the Protocol Review Board or Data and Safety Monitoring Board.

4. *Documents needed for PRB review*:
   a. Study Budget
   b. Study Timeline
   c. Leadership Plan
   d. Site Selection Plan
   e. Recruitment and Retention Plan

5. *Publications*: Lead Investigators must submit publication plans when 50% of the sample is recruited, and updates at least 6 months after database lock and every 6 months thereafter.

Regarding the above, please contact: Carmen Rosa at crosa@nida.nih.gov .

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

Connect with NIDA through: