Clinical Trials Network

Trial Progress – Nearing 15,000!
Trial enrollment numbers reflect study information as of May 22, 2012.

Open Studies
- CTN 0037 – Enrolled 291 (N=300)
- 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 166 (N=300)
- CTN 0050 – Enrolled 483 (N=1,269)

Total Enrolled All Studies: 14,891

Obesity Research
A number of NIH institutes have been involved with a new public health initiative on obesity. The Weight of the Nation documentary series and public awareness campaign by the cable network HBO features NIH research showing how obesity affects the country's health and how interventions can turn the tide against obesity and its complications. The network, in consultation with NIH and other major health organizations, developed four documentaries focused on obesity.

The films feature several NIH-funded clinical studies that have formed the basis of scientific evidence on the causes and consequences of being overweight or obese. This is one of HBO’s periodic public health campaigns where they partner with government and health organizations, create a series of documentary films, partner with community groups, develop a robust web site and a book. NIDA Director, Dr. Nora Volkow, is interviewed in one of the films because of her own obesity research. The same pleasure centers of the brain that respond to drugs of abuse also respond to food. More info is available on the HBO site: http://theweightofthenation.hbo.com/

Here’s the link to the NIH release: http://www.nih.gov/news/health/apr2012/niddk-30.htm

STRIDE Approaches Target Enrollment!
CTN 0037 – The STRIDE (Stimulant Reduction Intervention using Dosed Exercise) study is fast approaching its new target enrollment of 300 randomized participants! Based on an interim analysis requested by the DSMB, the existing data show less variance than expected and therefore a sample size of 300 has been determined as sufficient to evaluate the aims of the study. Our sites are working very hard to enroll eligible participants into the study, and the Lead Team would like to recognize their continued efforts.

The expected timeline for remaining activities is:
- Date Last Participant Randomized 7/1/2012
- Date Trial Completed (last follow-up) 3/25/2013
- Date of Database Lock 5/26/2013
- Date of Submission of Primary Outcome Paper 11/28/2013
- Date of Acceptance of Primary Outcome Paper 1/29/2014
- Date to Data Share 12/5/2014

STRIDE Publications to Date:

Primary outcome selection paper

STRIKE 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.
Publications Committee (PC)

Activity Level. The PC continues to be busy. There are several manuscripts and meeting presentations currently under review. The meeting presentations include both posters and slide/talk presentations.

CPDD Meeting. Several items for the upcoming June CPDD meeting have come in for review. The workload and time-pressure as the meeting date approaches are always difficult for the review teams. Everyone is encouraged to urge meeting presenters in your Nodes to submit items for review as soon as possible.

Premature Presentation/Publication. The issue of premature data presentation has come up recently. With several submissions to the PC we’ve had to decline to approve materials and ask the authors/presenters to wait until their projects are further along before it is appropriate to go public with study reports. Everyone is encouraged to remind study groups or writing groups in your Nodes that CTN policies prohibit premature presentations or publications. In general, that means the study data need to be locked before outcome data can be reported. Recruitment and baseline data can only be reported after all study enrollment is completed. These are difficult decisions. We all want to promote the presentation and diffusion of knowledge from CTN studies. But policies limiting the rush to go public with preliminary data serve to protect the integrity of both the CTN and the scientific enterprise as a whole.

CTN Policies. All CTN publications and presentations are subject to applicable policies. Version 4.0 of the CTN Policies was published September 2011 and can be found at the TPR (Trial Progress Report) website under the CTN Documents tab: http://www.ctndsc2.com

News from the New England Consortium Node

Stanley Street Treatment & Resources, Inc. (SSTAR) of Fall River, Massachusetts celebrated the 35th Anniversary of the agency on May 4, 2012, with a day-long conference entitled, “Meaningful RECOVERY.” Speakers and guests included individuals from Russia and Germany who provided examples of innovative programs that have made recovery meaningful in employment for women in Pern, Russia, and for a special group of methadone-treated patients who climbed the Alps. Other sessions included presentations on research-supported treatments promoting recovery.

Patrice Muchowski, ScD and colleagues from AdCare Hospital had an article, “The Value of Patient Feedback: What Our Patients Tell Us When We Listen” published in the Spring 2012 issue [Vol. 16 (No. 3)] of Paradigm magazine describing the role of patient feedback as a tool for ongoing clinical and quality improvement, based in part on the experiences of AdCare in the NIDA CTN-0016 Patient Feedback protocol.

Roger Weiss, MD, Kathleen Carroll, PhD, Nancy Petry, PhD, Shelly F. Greenfield, MD, MPH, and Hilary Connery, MD, PhD from the New England Consortium Node were all presenters at the McLean Hospital/Harvard Medical School “Addictions in 2012 Conference” held on May 18-19, 2012, in Boston, Massachusetts. Presentations covered advances in motivational interviewing, contingency management, cognitive behavioral treatment (CBT) for addictions, use of medications for treating opioid dependence, gender-specific treatment for women, and the assessment and treatment of patients with co-occurring substance abuse and bipolar disorder. A number of the presentations highlighted results from CTN studies. Denise Hien, PhD, from the Greater New York Node, was also a presenter at the conference, discussing empirically supported treatment models for PTSD and Substance Abuse. William Miller, PhD (formerly of the CTN Southwest Node) was the keynote speaker at the conference.

CTN 0055 Approved!

The newest CTN protocol, CTN 0055 Comparing Treatments for HIV-Positive Opioid Users in an Integrated Care Effectiveness Study (CHOICES), has been approved for development. The Lead Investigator is Todd Korthuis, Oregon Health and Science University of the Western States Node. Raul Mandler is the CCTN liaison at NIDA. Congratulations team!

Caldar Summer Institute Award and Poster Session Opportunities

The UCLA Center for Advancing Longitudinal Drug Abuse Research (Caldar) is now accepting poster abstracts and applications for Travel Awards for the Summer Institute on Longitudinal Research: Promoting Substance Abuse Recovery within the Changing Health Services System. The CALDAR Summer Institute will take place on August 13-15, 2012, in Marina del Ray, California.

For more information, please visit the CALDAR website: http://www.caldar.org.
Delaware Valley Node
Dr. George Woody, PI of the Delaware Valley Node, gave a presentation entitled "Opioid Treatment for Adolescents" at a conference in Kiev, Ukraine. Dr. Marc Fishman was a co-author of the presentation as it included data from Mountain Manor Community Treatment Program that involved residential treatment as well as buprenorphine-naloxone (Suboxone) and extended-release injectable naltrexone (Vivitrol), and CTN 0010. The meeting took place on May 21-23 and was jointly sponsored by the State Drug Control Service, Ukraine; the UN Office on Drugs and Crime World Federation on Treatment of Opioid Dependence Council of Europe's Pompidou Group; and the National Academy of Legal Sciences in Ukraine. Participants were from the Russian Federation, most of the former Soviet States, the US, UK and Europe and conversations were lively and interesting.

Call for Abstracts from Grantees
Grantees are encouraged to submit abstracts for the 2012 Summit on the Science of Eliminating Health Disparities. This HHS-wide event will be convened October 31-November 2, 2012, at the National Harbor, Maryland near Washington DC. The Summit is organized around the core principle of integrating science, policy, and practice in building a healthier global society, and offers a forum to advance scholarship and translate new knowledge into action.

The abstract submission deadline is June 15, 2012 at 5:00 p.m. ET. Abstracts will be accepted in three categories:
- Posters
- Oral presentations
- Integrated panel presentations

Applicants may submit abstracts to more than one category, but each submission must be based on a separate research paper. Additional information about the Summit and the Call for Abstracts is available at: http://www.nimhd.nih.gov/summit_site/index.html.

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

- NIDA is broadening the scope for PAR 10-099, Collaborative Clinical Trials in Drug Abuse (Collaborative R01), to include non-pharmacological trials (NOT-DA-12-014)
- Identifying Health Outcomes Associated with Changes in Use of Illicit Drugs (R01) (RFA-DA-13-007)
- SAMHSA Is Accepting Applications for a Minority Fellowship Program Grant for up to $825,000 The grant aims to reduce health disparities and improve health care outcomes among diverse populations by increasing the number of culturally competent mental health counselors.
- SAMHSA Is Accepting Applications for up to $35 Million in Primary and Behavioral Health Care Integration Grants The purpose of this program is providing for the provision of coordinated and integrated services by co-locating primary and specialty care medical services.
- HRSA Is Accepting Applications for Mental and Behavioral Health Education and Training Grants The Health Resources and Services Administration (HRSA) program aims to increase the number of social workers and psychologists who pursue clinical work with high-need and high-demand populations.

NIH Selects Centers of Excellence in Pain Education
The NIH Pain Consortium has selected 11 health professional schools as designated Centers of Excellence in Pain Education. These schools will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools. The awardees include: University of Washington (Seattle), University of Pennsylvania Perelman School of Medicine, Southern Illinois University, University of Rochester, University of New Mexico, the Harvard School of Dental Medicine, University of Alabama (Birmingham), the Thomas Jefferson University School of Medicine, University of California (San Francisco), University of Maryland (Baltimore), and the University of Pittsburgh. For more information, please visit the Pain Consortium website at http://painconsortium.nih.gov/index.html.
At the American Psychiatric Association Meetings in Philadelphia in early May, Petra Jacobs (CCTN Medical Officer) organized a session on Assessment of Substance Use Disorder Patient Outcomes Based on Longitudinal Registry / EMR Data. Dr. Don Stablein from the DSC 2 presented a talk on Overview and Methods for Large Registry Databases. While covering a wide area, Dr. Stablein reviewed design and purpose issues noting the substantial value of such studies in describing the disease process and identifying risk factors, treatment prevalence and temporal trends. The presentation focused on bias-associated difficulties in assessing treatment effects including a review of classes of bias sources. With increasing sample sizes from large databases, random variation can be minimized which exacerbates the relative importance of the bias problem. More recent approaches including propensity scoring and sensitivity analyses for examining potential bias were discussed. Special problems of confidentiality in SUD studies were noted.

Live Link and TPR Requests
All requests for access to Livelink and the TPR (Trial Progress Report) website must be sent to the NIDA DSC 2 Help Desk (nidadsc2help@emmes.com). Authorized persons within their Node have been selected by Node Coordinators for approval of Livelink and TPR website requests. If requests are not sent from an authorized person, the NIDA DSC 2 Help Desk will follow up and confirm authorization.

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

DSC 2 Project Director, Colleen Allen, at: Cullen@emmes.com

DSC 2 PI, Paul Van Veldhuisen, at: pvanveldhuisen@emmes.com

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

EMMES Offices Closed
The offices at the CCC and DSC 2 (EMMES) will be closed on Monday, May 28, 2012, for the Memorial Day holiday observance. The Help Desk staff will not be available that day but will respond to your requests upon their return on Tuesday, May 29th.

Clinical Coordinating Center (CCC) at EMMES

TRAINING Update
For all CTN training requests, please send a detailed e-mail request to ctntraining@emmes.com or contact a CCC Administrative and Training Coordination staff member as follows:

- Tracee Williams, NIDA CCC Administrative Coordinator, twilliams@emmes.com 301-251-1161 ext. 133;
- CarolAnne Saunders, NIDA CCC Administrative Coordinator, csaunders@emmes.com 301-251-1161 ext. 243.

Webinar Reminder: The NIDA CCC will host a webinar for “Biological Measures and Specimen Handling” on Wednesday, June 13th from 1:00 – 2:00 pm (ET), which will highlight strategies and precautions to manage risks associated with potentially infectious materials and waste. View the CCC’s 2012 Web Seminar Series Catalog (p. 8) posted on the CTN Dissemination Library’s web site at http://ctndisseminationlibrary.org/ctntraining.htm.

An e-mail invitation with registration and webinar access information has been circulated to all those included in the CTN mailing list. If you have not been added to the mailing list and would like to participate in this or future training sessions, please send an e-mail request to ctntraining@emmes.com.

Other CCC related questions and topics- Principal Investigator, Robert Lindblad, at 301-251-1161, rlindblad@emmes.com, or Eve Jelstrom, Project Director, at 301-251-1161, ejelstrom@emmes.com

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

CTN at the Society for Clinical Trials (SCT) Meeting
At the SCT meeting in Miami, Florida, May 20-23, three NIDA CCTN staff (Paul Wakim, Carmen Rosa, and Michele Straus) gave presentations relevant to the CTN. These included:

- Dealing with treatment compliance in clinical trials on inherently low-compliant populations: what to do at the design, monitoring, and analysis stages
- Practical statistical reasoning in clinical trials for non-statisticians

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