Trial Progress – Over 13,000!

Trial enrollment numbers reflect study information as of August 10th.

Open Studies

- CTN 0037 – Randomized 172 (N=330)
- CTN 0044 – Randomized 482 (N=500)
- CTN 0046 – Randomized 422 (N=528)
- CTN 0047 – Randomized 805 (N=1,285)

Total Randomized All Studies: 13,499

ARRA Project AWARE Completes Follow-Up!

The Project AWARE: HIV Rapid Testing & Counseling in STD Clinics in the U.S. team is happy to report that all of their 9 sites have completed the 6-month Follow-Up stage of the project; a preliminary total of 4,302 participants out of 5,012 total randomized, and are currently preparing for data lock! Their dedicated, hard-working teams achieved an overall retention rate of 85.8% as of Friday, July 15, 2011! Congratulations and thanks are in order to the incredible site PIs, study coordinators and their site teams, as well as their corresponding University affiliates for their efforts:

- Allegheny County Health Dept (University of Pittsburgh Western Psychiatric Institute & Clinic)
- Duval County Health Dept (University of Miami)
- L.A. Gay & Lesbian Center (University of California, San Francisco)
- Miami-Dade County Health Dept (University of Miami)
- Multnomah County Health Dept (Oregon Health & Science University)
- Public Health—Seattle & King County (University of California, San Francisco)
- Richland County Health Dept (Medical University of South Carolina)
- San Francisco Department of Public Health (University of California, San Francisco)
- Whitman-Walker Clinic (Columbia University & Research Foundation for Mental Hygiene)

CTN GO Grant Study (AWARE) – Randomized 5,012

CTN 0044-A2 Ancillary Study: Acceptability of a Web-delivered Intervention among American Indian / Alaska Native Individuals in Outpatient Substance Abuse Treatment

This ancillary study has completed enrollment. This study was carried out at two sites (N=40; 20 per site). The Lead Team estimates that the participant follow-up interviews will be completed by the 2nd or 3rd week of September and qualitative data collection (staff focus groups) by the end of September or very beginning of October.

STRIDE (CTN 0037) Hits Halfway Point!

The STRIDE (Stimulant Reduction Intervention using Dosed Exercise) study recently randomized 50% of their total goal of 330 participants. The Lead Team is very pleased to have achieved this milestone. The STRIDE Lead Team would like to recognize the outstanding efforts of the many people who contribute to this study on a daily basis. This includes all of their Wave 1 sites, who have now been implementing the study for over a year: Arapahoe House in Thornton, Colorado (Florida Node Alliance), Gateway Community Services in Jacksonville, Florida (Florida Node Alliance), Gibson Recovery Center in Cape Girardeau, Missouri (Ohio Valley Node), and Nexus Recovery Center in Dallas, Texas (Texas Node). This also includes all of their Wave 2 sites who have been implementing the trial for several months now: Memorial Hermann PaRC in Houston, Texas (Texas Node), Morris Village in Columbia, South Carolina (Southern Consortium Node), Presbyterian Medical Center in Philadelphia, Pennsylvania (Delaware Valley Node), Ralph H Johnson VA Medical Center in Charleston, South Carolina (Southern Consortium Node), and St. Luke’s Hospital in New York, New York (Greater New York Node). The Lead Team also wants to recognize the node staff supporting these sites, and the CCC (EMMES), DSC 2 (EMMES), and CCTN team members for their ongoing support in the conduct of the trial. We appreciate the efforts of our team!

CTN 0049-Project HOPE - Update

The CTN 0049 Project HOPE (Hospital Visit as Opportunity for Prevention and Engagement for HIV Infected Drug Users) site selection process is underway. The Lead Team appreciates the efforts of nodes and sites that completed and returned site selection surveys. Telephone interviews will commence in the next few weeks followed by site visits.

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.
Southwest (SW) Node Updates

The SW Node congratulates Meredith Davis, she has moved away to begin her Ph.D. program. Meredith has been a valued member of the CTN, and the SW Node, since 2004. She has worked on several different projects with the SW Node. We thank her for all her hard work and efforts, especially on protocol CTN 0033b. Best wishes, Meredith. We will miss you!

Thanks go to the 499 students who helped put together the 0033b Tool Kit that was created to reach out to those who may not know where to go to find the right resources and information regarding methamphetamine and other drug use.

SMART-ED (CTN 0047) continues to go well. Study recruitment is at 103% of the expected recruitment overall at all 6 sites. The total randomized participants is 805 to date. Keep up the good work 0047 team!

The SW Node welcomes Dr. Rogerio da Paz, who is here as part of his Hubert H. Humphrey fellowship. Dr. da Paz wants to gain as much knowledge as possible about Motivational Interviewing (MI), so that he can disseminate and implement MI techniques in his home country of Brazil. Welcome aboard, Dr. da Paz!

Congratulations to Dr. Barbara McCrady, Center on Alcoholism, Substance Abuse, and Addictions Director from the SW Node, who has been recently nominated as President Elect of the Research Society on Alcoholism!

News from the Florida Node Alliance

The Florida Node Alliance (FNA) hosted the Node’s bi-annual Steering Committee meeting on June 2-3, 2011. Thirty members of the FNA Steering Committee met in South Florida to discuss the Node’s research agenda for the coming year. This bi-annual meeting brought together FNA members located in Colorado, Florida, New York, North Carolina and Puerto Rico to review progress in all areas of the Node, and discuss policies and research interests.

FNA co-PIs, Drs. José Szapocznik and Lisa Metsch, together with Node Project Director, Dr. Viviana Horigian, facilitated the meeting which included attendees from the Node’s original drug treatment centers and special guests from the University of Miami’s Pediatrics unit. The meeting agenda included: a) NIDA and CTN updates by Dr. Horigian; b) updates on current CTN protocols in which FNA sites are participating (AWARE, STRIDE, WEB, S-CAST, and SMART-ED; c) discussion of lead Node activities with Project HOPE; e) discussion of the new HIV rapid testing blending product born out of CTN 0032; d) discussion of Node dissemination activities; e) updates about protocol concepts moving forward with the CTN Research Development Committee; f) presentations from two Node scientists about novel adolescent treatment ideas ranging from innovative pharmacotherapies to technologically-based interventions which we expect will represent the FNA’s future research agenda; and g) the unveiling of the Node’s much awaited website.

Please visit their new virtual home – the Florida Node Alliance website beckons! http://biomed.miami.edu/fnactn

Congratulations goes to Gateway Community Services, Inc. – for being a Gold Star Site in July for CTN 0046. Gateway consistently met all four recruitment and retention goals each week. This is the 7th consecutive month Gateway is recognized for their consistent study performance. Go team!

Florida Node Alliance teams spread the news!

Dr. Viviana Horigian, FNA Project Director, was once again invited to present at the June 2011 Interdisciplinary Research Training Institute on Hispanic Drug Abuse with the National Hispanic Science Network Summer Institute in Houston, Texas. Dr. Horigian delivered a 3 hour special presentation on “Treatment Intervention Science and Clinical Trials on Drug Abuse.”

Drs. Lisa Metsch and Dan Feaster were invited to deliver a feature presentation at the 73rd annual meeting of the College on Problems of Drug Dependence held this June in Hollywood, Florida. The presentation titled “Missed Opportunities for Hepatitis C Virus Screening among Injection Drug Users in Drug Treatment” was well attended by CPDD members.

Dr. Lisa Metsch has been invited to present at two upcoming conferences:

a. August 2011 - “Adoption of HIV Counseling and Testing Following Completion of Randomized Clinical Trial.” Oral presentation to be delivered at the 2011 National HIV Prevention Conference, August 14 - 17, 2011, in Atlanta, Georgia.

b. September 2011 - “Implementing Rapid HIV testing with or without risk-reduction counseling in drug treatment centers: results of a randomized trial.” Oral presentation to be delivered at the 13th Annual Meeting of the International Society of Addiction Medicine, in Oslo, Norway.
Registration is open for the CTN Fall Steering Committee Meeting to be held September 26-28, 2011, in Bethesda, Maryland. Please visit [http://www.seiservices.com/NIDA/CTN/meetings/index.asp](http://www.seiservices.com/NIDA/CTN/meetings/index.asp).

There will be a Design and Analysis Workshop on Monday, September 26, from 3 to 5 p.m. before the SC meeting. The workshop is titled *Determining Stimulant Drug Use by Combining Results from Timeline Follow-Back and Urine Drug Screening*. All are welcome!

**Poster Session at September SC Meeting**

A poster session will be held at the Steering Committee Meeting in September. Please notify Ron Dobbins at rdobins@nida.nih.gov by close of business on August 26th if you’re interested in submitting a poster.

**Publication on Outcome Measures**

Clinical trials test the safety and efficacy of behavioral and pharmacological interventions in drug-dependent individuals. However, there is no consensus about the most appropriate outcome(s) to consider in determining treatment efficacy or on the most appropriate methods for assessing selected outcome(s). This paper summarizes the discussion and recommendations of a panel of treatment and research experts, recently convened by the U.S. National Institute on Drug Abuse (NIDA) to select appropriate primary outcomes for drug dependence treatment clinical trials, including the National Drug Abuse Treatment Clinical Trials Network (CTN), and examine the feasibility of selecting a common outcome to be included in all or most trials.

Journal: *Addiction*, title: “Primary Outcome Indices in Illicit Drug Dependence Treatment Research: Systematic Approach to Selection and Measurement of Drug Use Endpoints in Clinical Trials.” Here is a link to the online version in the CTN Dissemination Library [http://ctndisseminationlibrary.org/display/683.htm](http://ctndisseminationlibrary.org/display/683.htm). See the last page of the article for a list of participants at the December 2009 Science Meeting.

**Data Available from the University of Chicago**

The University of Chicago is pleased to announce the availability of data from the Making Connections Survey. This ten-year data collection effort has produced nearly 28,000 interviews with residents in ten disadvantaged urban communities at up to three points in time. The survey data are now available to approved researchers through NORC’s Data Enclave, a secure environment that allows access to sensitive data from any computer. The Foundation encourages interested researchers, faculty, and advanced graduate students to apply for access to the longitudinal and cross-sectional datasets. They are especially interested in collaborating with faculty and researchers who reside in or near the ten sites. Please note that applicants must be affiliated with an institution that is overseen by an institutional review board (IRB).

For more information, please visit [http://bit.ly/rsO8ok](http://bit.ly/rsO8ok)

**Snowflake**


**New Funding Opportunities**

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

- **2012 NIDA Translational Avant-Garde Award for Medication Development for the Treatment of Substance Use Disorders (DP1)** ([RFA-DA-12-010](http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-12-010.html)).

- **FY12 NIDA Avant-Garde Award Program for HIV/AIDS Research (DP1)** ([RFA-DA-12-011](http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-12-011.html)).


Clinical Coordinating Center (CCC) at EMMES
Over 171 CTN members and guests registered for the Relapse Prevention Webinar held on July 20, 2011.

Good News! The CCC has arranged to supplement the Relapse Prevention Webinar by providing the following books to each site actively working on a CTN protocol:

- **Relapse Prevention Counseling (a 140 page book targeted to professionals)**
- **Relapse Prevention Workbook (a 32 page guide targeted to the clients)**

The books will be shipped to the sites in late August. The CCC is providing the book and guide as a gesture of our appreciation for your help in making knowledge sharing possible via the NIDA CTN Web Seminar Series.

2011 WEB SEMINAR SERIES – Be a part of it!
- **Drs. Dennis Daley and Antoine Douaihy will present a webinar discussing Integrated Treatment of Co-Occurring Disorders on September 14th at 10am PT/1pm ET.**
- **October 12** Informed Consent
- **December 7** A New Look at Manual of Procedure (MOP) Development

Help make the most of the CTN’s unique partnership between community treatment providers and academic research leaders by welcoming non-CTN members to join our webinars and share our knowledge. Those interested in registering may contact ctntraining@emmes.com or Liz Buttrey at ebuttrey@emmes.com

All webinars are available online on the CTN Dissemination Library at the following site: http://ctndisseminationlibrary.org/ctntraining.htm

The CCC is constantly reviewing efforts to be greener. As part of this effort the webinar certificates of attendance and webinars on disc will be provided only upon request to the CCC Training Office ctntraining@emmes.com.

CTN Website: http://www.drugabuse.gov/CTN/index.php

CTN Dissemination Library: http://ctndisseminationlibrary.org

Policies and Procedures - Updates

CCTN staff members are updating the Policies and Procedures document. Please note the following:

- The documents will be posted on the DSC 2 website, e-TPR (electronic - Trial Progress Report), equipped with a search engine
- There will be 3 separate files:
  a) **Policies and Procedures** (will include information regarding the governing policies and key procedures to conduct of clinical trials in the CTN)
  b) **Investigator Toolbox** (will include the details of the procedures for submission and conduct of the clinical trials, from concept submission to publications)
  c) **By-laws** (rules for governing the CTN, committees, elections, membership, etc.)
- There are new policies, effective immediately, regarding publication plans, submission and review of protocol violations, submission of ancillary study proposals, definition of Lead Investigator Teams, financial disclosures for studies under IND, etc.
- The updates will be posted on the website by Sep 15 2011.

For questions regarding these documents please contact Carmen Rosa at crosa@nida.nih.gov.

DSC 2 – EMMES Data and Statistics Center

*What is Integrity?*
Integrity is a program used by the DSC 2 to identify data discrepancies and anomalies that may require modifications to assure clean data for analyses. Integrity analyzes patient data within a form and across multiple forms to identify inconsistencies based on protocol specifications. On a monthly basis, the study data manager (DM) uses Integrity to identify data anomalies and to issue queries. These queries can be viewed by selecting the "Integrity Data Queries" link on the Main Menu of AdvantageEDC (EMMES’ electronic data capture system for CTN trials).

There are two ways to resolve Integrity Data Queries. The first is to verify that the data that resulted in the query are correct as reported. In this case, the query generated lists an anomaly where the data reported is either correct, or cannot be changed. To resolve this type of query, select the “Check if Verified as Correct” checkbox on the Integrity Data Queries report. The study DM will review this submission and determine if an exception can be granted. (cont’d page 5)
The second method of query resolution is to correct the data that resulted in the query. If the data referred to by the query is incorrect as submitted, access the referenced form(s) and update the form(s) with the correct data. You should NOT check the “Check if Verified as Correct” checkbox when resolving these types of queries. When the Integrity program is run again by the study DM, the query will automatically resolve.

Additional information about resolving queries can be found in each protocol's AdvantageEDC User's Guide/CRF Handbook. In addition, questions about Integrity data queries may also be directed to your study DM.

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:**
[Callen@emmes.com](mailto:Callen@emmes.com)

**DSC 2 PI, Paul Van Veldhuisen, at:**
[pvanveldhuisen@emmes.com](mailto:pvanveldhuisen@emmes.com)

### 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)

### Who’s Looking at the CTN Data Sets?
Over 1,000 data downloads have been recorded since the first CTN trial data were made available in the summer of 2006. Twenty-four data sets are now available from the CTN trials. No approval is needed to download the data – just provide your name, country, e-mail address, etc.

Enhancements will be coming to the data share website next month. This will include a listing of Case Report Forms (CRFs) from all the listed trials, descriptions of each CRF, and a search engine to identify assessments across the studies. More information will be forthcoming once the improvements are finalized.

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A preliminary review of the requestors for CTN trial data on the data share web site shows an interesting mix of countries and people:

### List of Countries - 18

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To access the website – go to [http://www.ctndatashare.org/](http://www.ctndatashare.org/).

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