Trial Progress – Over 17,000!

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 17 (N=50).
- **CTN 0056-Ot** – Testing and Linkage to HIV Care in China. Enrolled 401 (N=360).
- **CTN 0057-Ot** – SBIRT-PC (Screening, Brief Intervention, and Referral to Treatment in Primary Care). Enrolled 71 (N=200).
- **CTN 0059** – TAPS Tool (Tobacco, Alcohol, Prescription Medications, and Substance Use/Misuse Brief Screen/Assessment). Enrolled 97 (N=2000).

Total Enrolled All Studies: 17,036

Gender SIG Presentation at APA

The CTN Gender Special Interest Group presented a symposium at the American Psychological Association (APA) convention on August 10, 2014, titled “Gender Differences in SUD Treatment: Recent Findings from the Clinical Trials Network.” The panel presented data regarding gender differences in 4 recent CTN trials, and the slides are available in the dissemination library.

Elizabeth A. Wells, PhD, University of Washington: Gender Differences in Response to a 12 Step Engagement Intervention

Aimee N.C. Campbell, PhD, MSW, Columbia University in the City of New York: Gender Differences in Acceptability and Treatment Outcomes of a Web Based Psychosocial Intervention

Audrey Brooks, PhD, University of Arizona: Gender Differences in Treatment Access and Outcome Following an ED SBIRT Intervention

Therese K. Killeen, PhD, Medical University of South Carolina: Stimulant Reduction Intervention Using Dosed Exercise: Gender Differences / Treatment Acceptability

Discussant: Shelly F. Greenfield, MD, MPH, Harvard Medical School

Contact Carmen Rosa at crosa@nida.nih.gov for more information.

Above: CTN Gender SIG Speakers at APA from left to right: Greenfield, Brooks, Wells, Rosa, Campbell and Killeen
Executive Committee (EC)

The EC will hold a webinar on Thursday, September 4th at 1:00 PM Eastern Time entitled “What is the difference between adaptive designs, adaptive treatment strategies, and enrichment strategies?” The speaker will be Paul Wakim, PhD, Senior Statistician at NIDA.

"Adaptive designs" have been a hot topic in clinical trial designs for the last decade. This approach is increasingly recognized by the FDA. Designs testing "adaptive treatment strategies" make clinical sense because they are closer to mimicking clinical practice. And designs with "enrichment strategies" have been described in an FDA Guidance document to increase the likelihood of a positive result. This webinar will attempt to clarify the similarities and differences and the benefits and weaknesses of these three trial design strategies in non-technical terms.

To register for this webinar, visit https://cc.readytalk.com/r/vpofboqr1lql&eom. You will receive customized log-in information for the webinar with the confirmation.

Research Utilization Committee (RUC)

Following the departure from the CTN of Erin Winstanley, PhD of the Ohio Valley Node (see last month’s CTN Bulletin), the RUC chair position has passed to Christine Higgins, MA of the Mid-Atlantic Node. Congratulations Christine! Please contact Christine if you have questions or ideas for the RUC! chiggin2@jhmi.edu

On July 24, 2014, Fred Fridinger DrPH, CHES, the Chief of the Strategic and Proactive Communication Branch of the Center for Disease Control’s Division of Communication Services, presented a webinar to the CTN’s Research Utilization Committee. Dr. Fridinger is an expert in the use of quantitative and qualitative market research in the segmentation, selection, and profiling of target audiences to promote healthy behaviors. The one and a half hour webinar, entitled “How Social Marketing Informs Behavioral Health Interventions,” was highly informative, and of interest to anyone trying to reach a specific audience with information on a new or different health behavior that would benefit that segment of the population. Going beyond the more basic uses of social media, Dr. Fridinger offered principles and key approaches to develop a campaign to promote behavioral change, using various resources to reach a desired target audience. If you missed this webinar, here is the link – watch at your convenience! http://communique.adobeconnect.com/social_marketing_recording/event/registration.html

Node Coordinators Workgroup (NCW)

The new Chair of the Node Coordinators Workgroup is Jack Chally, MA, of the Mid-Atlantic Node. He is succeeding Dorothy Sandstrom, MS, of the Appalachian Tri-State Node, who previously served in this capacity. Thank you Dorothy!

News from the CTN Dissemination Library

Got publications? If you presented or published anywhere this summer about the CTN, we would love to hear about it! Send us an email with a brief description of where and what you presented and attach a copy of your slides or poster file. Help us keep our digital collection growing! info@ctndisseminationlibrary.org

In the meantime, here are a few recent additions:


This ancillary investigation of data from CTN 0021 (Spanish MET) found that family conflict plays a role in treatment outcomes for Latinos with substance use disorders.


This secondary analysis of data from CTN 0031 (STAGE-12) is the first study to evaluate oxidative stress and antioxidant defense systems in a clinical sample of stimulant-dependent patients.

This article discusses CTN 0030 (POATS) participants’ status 18 months following randomization. The report includes comparative data on the status of opioid use outcomes and treatment engagement.

Be sure not to miss the CTN Dissemination Library’s blog post about the recent CPDD workshop “Improving the Writing of Emerging Investigators in Addiction Science: Innovative Training, Evaluation Methods, and Resources.” This fantastic seminar was aimed at senior researchers who are mentoring new scientists to improve their writing quality and speed, and included talks from three current editors of addiction research journals. Check it out here: http://ctndisseminationlibrary.wordpress.com/2014/07/30/workshop-on-improving-the-writing-of-emerging-investigators-in-addiction-science/

The CTN Dissemination Library is hosted by the Pacific Northwest Node.

Study Updates and Information

CURB (CTN 0048)

Many thanks to the CTN 0048 (CURB) participating nodes who responded quickly and positively to the lead team’s request to retrieve additional screening information. The CURB study database was locked last summer, but given recent interest in baseline severity of cocaine use, the Lead Team asked sites to retrieve copies of the baseline screening form “Screening and Induction Checklist-Urine Results” that documents results of all screening Urine Drug Screens (UDS), to supplement the data (the last UDS collected during screening) entered into the CTN’s EDC system. Site staff had maintained this form for each participant consented in the CURB study, and forwarded copies to the Data and Statistics Center (DSC) where these results will be collated in a spreadsheet that the lead team will use in analyses. An estimate of the time needed to complete this task, as well as questions or concerns, should be directed to Christie Thomas MPH at 310-267-5319 or cthomas@friendsresearch.org. Again, a sincere thank you to the Greater New York, Texas, Ohio Valley, Pacific Northwest, Pacific Region, Western States, Southern Consortium, and Mid-Atlantic nodes for enthusiastically assisting in this effort.

CHOICES (CTN 0055)

The Western States Node would like to thank the CORE Center and UBC for all their hard work on the CTN 0055 (CHOICES) protocol. In the 8 weeks that the study has been opened for enrollment, a total of 15 participants have been randomized, a pace of recruitment that is 233% of the expected rate. Way to hit the road running team!

News from the CTN Nodes

Delaware Valley Node

The Delaware Valley Node and the Treatment Research Institute (TRI) have worked together since the start of the CTN and are pleased to announce that TRI will be joined by an exceptional leader, David R. Gastfriend, MD, who will assume the role of Chief Executive Officer effective September 1, 2014.

As David assumes the leadership of the organization, TRI’s founder and current CEO, A. Thomas McLellan, PhD, will assume the role of Chair of the Board of Directors.

Pacific Northwest Node

The Pacific Northwest Node bids a fond farewell to Elizabeth (Betsy) Wells, PhD, who recently retired after 30 years of service at the University of Washington’s School of Social Work and Alcohol & Drug Abuse Institute.

Betsy served as the Scientific Director for our node and also supervised our project directors, who referred to her affectionately as their “mother hen.”

She was our node National Steering Committee alternate in the early years of the CTN and was also extremely active in the dissemination of CTN research and results throughout her tenure in the Network. Betsy was an active member of the CTN Research Utilization Committee (RUC), and served as chair several years
ago. Additionally, she was a huge supporter of the CTN Dissemination Library from its inception forward, offering greatly appreciated encouragement and advice.

Betsy authored and co-authored numerous CTN publications and presentations, and was instrumental in organizing node dissemination trainings. She served on the CTN 0015 protocol team and was highly involved in our local implementation of that study. She also participated on the CTN 0018 and CTN 0019 teams, and was a scientific collaborator for CTN 0020 and the local node PI for CTN 0031.

We wish Betsy all the best in her retirement, and miss her tremendously already!

One of three new research awards to address multiple chronic medical conditions from the NIH HCS Research Collaboratory has been awarded to Douglas Zatzick, MD of the University of Washington for his project: “A Policy Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity” This trial focuses on patients who are being treated for acute physical injuries and who also have conditions such as post-traumatic stress disorder, alcohol and drug use problems, depression, and chronic pain, among others. The trial will be conducted in partnership with 20 Level I trauma centers across the United States. This project will be primarily overseen by the National Institute of Mental Health and secondarily by the National Institute on Alcohol Abuse and Alcoholism. More information on the NIH HCS Collaboratory can be found at https://www.nihcollaboratory.org/Pages/default.aspx

Southern Consortium Node

The Southern Consortium Node (SCN) and Lexington Richland Alcohol and Drug Abuse Council (LRADAC) co-hosted a Dissemination Workshop in Columbia, SC on August 14, 2014 at the Education Center at the LRADAC facilities.

The “Transformation Women’s Conference” workshop had 120 registrants, and targeted special population issues including prescription drug use in pregnant women and disordered eating in women’s recovery. Node presenters included Therese Killeen, PhD, APRN, and Constance Guille, MD, MSCR.

Western States Node

The Learning for Early Careers in Addiction and Diversity (LEAD) Program completed its first Summer Intensive Training at the University of California, San Francisco (UCSF) with great success! Our first cohort, consisting of Scholars Jemima Frimpong from Columbia University and LaTrice Montgomery from the University of Cincinnati, attended the month-long program geared at providing our Scholars with the necessary skills and guidance to help them succeed as future investigators in the field of Substance Use Disorders. Their development will continue through the coming three years of participation in the LEAD Program. Our scholars are mentored by Lisa Metsch, PhD from Columbia University and Principal Investigator of the Florida Node Alliance of the CTN and Theresa Winhusen, PhD from University of Cincinnati and Principal Investigator of the Ohio Valley Node of the CTN. Thank you Drs. Metsch and Winhusen for your participation and support.

We encourage the CTN Nodes to nominate candidates for the program’s second year. Queries can be sent to Node Coordinator Diane Coseo at Diane.Coseo@ucsf.edu

Clinical Coordinating Center

NEW! CTN GCP Certificates

The CTN GCP Certificate of Completion has been improved! Based on the needs of our users, the certificate now includes the list of topics covered in the training as well as the completion and expiration dates. These changes will increase transparency of the modules and information covered in the training and align the CCC’s certificate to that of other recognized GCP training providers in the industry. https://gcp.nihtraining.com/login.php

CTN Web Seminar Series

The CCC is pleased to announce that the CTN Web Seminar Series will host a presentation on Certificates of Confidentiality (CoC). On Wednesday, September 10, 2014 at 1:00 pm ET, Nadine Rogers, PhD (NIDA’s CoC Coordinator) will conduct a one-hour discussion to
define the purpose of CoCs, eligibility criteria, exceptions, and use within the CTN.

To register, copy and paste the following link into your web browser and follow the registration instructions: https://cc.readytalk.com/r/7vuz1sxreqiz&eom.

If you would like to participate in this webinar or future trainings and have not signed up, please contact CTN CCC Training Coordination at ctntraining@emmes.com to request registration assistance and to be added to our mailing list.

More Training Opportunities:

The CCC is planning webinars on the following topics in the coming months. Complete information on timing and logistics will follow:

- OHRP Prisoner Certification, presented by Julia Gorey, JD (October 2014)
- Family Involvement in Substance Use Disorders and Mental Health Research and Treatment, presented by Dennis Daley, PhD, and John Hamilton, LMFT/LADC (November 2014)
- Inclusion and Exclusion Criteria and Their Impact on Enrollment, presented by Robert Lindblad, MD (December 2014)

Data and Statistics Center

Earlier this summer, NIDA launched the NIDA Common Data Elements (CDE) website (http://cde.drugabuse.gov/). This website encourages investigators to use a core set of CDEs when developing case report forms. One set of standardized CDEs is principally intended for clinical research. Another small set of CDEs is intended for use by practitioners in EHRs in general medical settings, and categorized separately for ease of access. Many of these CDEs are derived from the Substance Abuse and Addiction (SAA) project and other components of the Phenotypes and Exposures (PhenX) Toolkit. This list is expected to grow as new data elements are developed and validated by external investigators and as the science evolves. It is hoped that common data elements housed in this website will be widely used across both EHRs and clinical research. These CDEs are intended to support useful comparative big data analyses/meta-analyses crossing the boundary between clinical research and care.

From our ATTC Colleagues

Evidence-Based Practices: New Resource and Opportunity

The ATTC Network and NIATx are offering a new web-based tool designed to link addiction treatment providers to each other and to researchers to find ways to better implement evidence based practices. The website, which launched earlier this month, will create an online learning community focused on promoting the adoption of evidence-based practices for substance abuse treatment. You may access the website at http://www.networkofpractice.org.

If you would like more information on the content or use of this resource, or are willing to be on the list of scientists that will be available to respond to questions about evidence-based practices and research, please email Kim Johnson at Kimberly.Johnson@chess.wisc.edu.

Upcoming Seminars and Workshops

The National Hispanic and Latino ATTC is hosting a conference titled “Integrating Research, Education, and Services to Reduce Behavioral Health Disparities in Hispanic and Latino Populations” on October 8-9th, 2014 at the University of Texas at Austin. Registration and call for posters are open! Please visit: http://www.hispaniclatinoattcconference.com/

ATTC Network’s Third Thursday iTrainings

Visit this website for upcoming opportunities every third Thursday!

Also don’t forget the following ATTC sources for news, articles of interest and training opportunities:

ATTC Messenger
ATTC/NIATx Service Improvement Blog
The Bridge (linking Science and Service)
HAROLD ROGERS PDMP NATIONAL MEETING 2014 –
Registration and Hotel Reservations
The PDMP Training and Technical Assistance Center (TTAC) at Brandeis University, in partnership with the Bureau of Justice Assistance, will be hosting the 2014 Harold Rogers Prescription Drug Monitoring Program National Meeting on September 22-24, 2014. The meeting will be held in Washington, DC at the Marriott Metro Center Hotel. Additional meeting information is available on the TTAC website.

News from NIDA

Funding Opportunities

RFA-DA-15-008
The National Institute on Drug Abuse (NIDA) has recently released a Request for Applications (RFA) http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-15-008.html. This Funding Opportunity Announcement (FOA) invites applications from clinical investigators to participate in the National Drug Abuse Treatment Clinical Trials Network (CTN).

RFA-DA-15-010


A NIH Guide Notice NOT-OD-14-120 was also released. This notice describes the solicitation and provides the necessary links and information. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-120.html)

The deadline for contract proposal submissions is Wednesday, November 5, 2014, at 4:30 p.m. ET and submissions must be on paper (not electronic, not through Grants.gov). Applicants are advised to follow the directions in the solicitation very carefully, and to address a topic listed in the solicitation.

Omnibus SBIR opportunities (http://grants.nih.gov/grants/guide/pa-files/PA-14-071.html) are still available, and STTR grant solicitations (http://grants.nih.gov/grants/guide/pa-files/PA-14-072.html) are open for the next receipt date of December 5, 2014. If you plan on an investigator-initiated submission, please use these announcement links.

NIDA Datashare
The CTN 0030 A-3 is the long term follow-up to the POATS study. The publication of the Month 18 data is announced in the CTN Dissemination Library’s article on page 2 of this Bulletin. The dataset is now available at http://datashare.nida.nih.gov/
New Webcast! NIH Workshop on the Enrollment and Retention of Participants in NIH-Funded Clinical Trials

On Friday, July 25, 2014, the National Institutes of Health (NIH) hosted a full day workshop to explore strategies to enhance enrollment, recruitment and retention of participants in clinical trials. Representatives from academia, patient advocates, ethicists, community concerned citizens, private foundations and industry came together to discuss promising strategies and new avenues to address:

- Current Challenges in Clinical Trial Participant Enrollment
- Cultural and Social Considerations in Clinical Trial Enrollment and Outreach
- Recruitment and Outreach Considerations for Underrepresented and Vulnerable Populations
- Roles for Public Foundations in Clinical Trial Enrollment and Retention
- Public Private Partnerships to Improve Patient and Public Awareness and Engagement
- Models to Identify and Support Clinical Trial Participants
- Strategies for Tracking and Monitoring Clinical Trial Participation and Post-Trial Communication


A Communication Resource for Researchers and Clinicians

Recently there was an article in Govexec.com that will be of interest to many in the CTN. This article focused on PubMed Commons (http://www.ncbi.nlm.nih.gov/pubmedcommons/), and the opportunity it provides for those of us engaged in research to communicate in a more timely and effective way than has been our historical approach. While much of the discussion focuses on research that is more from the basic science end of the spectrum, many comments refer to articles in clinical research. Written by the NIH Director Francis Collins, Ph.D., this brief article asks us to think of research as a “team sport” and to interact and comment on each other’s research, to help accelerate the pace of the discovery process. Dr. Collins’ article can be found at http://www.govexec.com/excellence/promising-practices/2014/08/imagine-if-thousands-medical-researchers-could-have-quick-conversation/90893/?oref=ng-channelriver

Labor Day Closures

NIDA CCC and DSC offices at EMMES will be closed on Monday, September 1 in observance of the Labor Day holiday. The DSC Help Desk staff will not be available that day but will respond to requests when they return on Tuesday, September 2.

NIDA’s CCTN office will also be closed September 1.

Department of Corrections

Dr. Grant Colfax is a member of the Western States Node, not the Pacific Node, as noted in the August issue of the CTN Bulletin.

Updates for this Bulletin should be sent to

Michele Straus at mstraus@nida.nih.gov

Connect with NIDA through: