Clinical Trials Network

CTN Bulletin
May 29, 2014
Volume 14 – 07 #307

Trial Progress – Over 16,000!

Trial enrollment numbers reflect study information as of May 28th, 2014.

Open Studies

- **CTN 0049** – **Project HOPE** (Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users). Enrolled 801 (N=800). Enrollment closed – in follow up period.
- **CTN 0050** – Long Term Follow-up to the CTN 0027 (**START**) Study. Enrolled 870 (Original N=1,267 Main Study).
- **CTN 0051** – **X-BOT** (Extended Release Naltrexone vs. Buprenorphine for Opioid Treatment) Enrolled 43 (N=400).
- **CTN 0053** – **ACCENT (**Achieving Cannabis Cessation: Evaluating N-Acetylcysteine). Enrolled 107 (N=300).
- **CTN 0054** – **ADAPT** (Accelerated Development of Additive Pharmacotherapy Treatment). Enrolled 26 (N=49).
- **CTN 0056-Ot** –Testing and Linkage to HIV Care in China. Enrolled 195 (N= 360)
- **CTN 0057-Ot** – **SBIRT-PC** (Screening, Brief Intervention, and Referral to Treatment in Primary Care). Enrolled 82 (N=200).

Total Enrolled All Studies: 16,762

New Studies Added to NIDA Data Share

The NIDA Data Share web site has been updated to include de-identified data sets and study related information for the following CTN trials:

- CTN 0044 Web-delivery of Evidence-Based Psychosocial Treatment for Substance Use Disorders: A total of 507 participants, recruited from 10 sites, were randomized.
- CTN 0052 BRAC (Buspirone for Relapse-Prevention in Adults with Cocaine Dependence): A total of 62 participants, recruited from 6 sites, were randomized.

For more information, visit the NIDA website at http://datashare.nida.nih.gov.

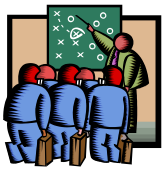
CTN is a program of the National Institute on Drug Abuse, part of the National Institutes of Health within the Department of Health and Human Services.

March CTN Steering Committee Presentations

Good news! The presentations from the March 2014 Steering Committee Meeting in Gaithersburg, Maryland, are posted on LiveLink for viewing by CTN members. You may access them at: https://livelink.nida.nih.gov/livelink/llisapi.dll?func=ll&objId=13134934&objAction=browse&viewType=1

If you do not see the presentation you are seeking, please contact the speaker directly.

Forgot your LiveLink Password? E-mail nidadsc2help@emmes.com for assistance.



Upcoming Webinar on Adaptive Designs

Save the date – Paul Wakim will present on Thursday, September 4th, 2014, 1:00 pm – 2:30 pm EDT, on "*What is the difference between adaptive designs, adaptive treatment strategies, and enrichment strategies?*"

Adaptive designs have been a hot topic in clinical trial designs for about 10 years, are very much appreciated by the pharmaceutical industry, and are getting increasingly recognized by the FDA as a valid approach. Designs testing "adaptive treatment strategies" make clinical sense because they are closer to mimicking clinical practice. Designs with "enrichment strategies" have been described in an FDA Guidance document to increase the likelihood of a positive result. There seems, however, to be some confusion about the differences between these three concepts. This webinar will attempt to clarify in non-technical terms their similarities and differences, their benefits and weaknesses.

Details on registering for this webinar will be sent out shortly. If you have any questions, please contact Paul Wakim at pwakim@nida.nih.gov.

Southern Consortium Node News

Kathleen T. Brady, M.D., Ph.D., Principal Investigator of the Southern Consortium Node, has been appointed Interim Associate Provost for Research and Chief Scientific Officer and Institutional Official at the Medical University of South Carolina effective June 10, 2014. Congratulations!

PCORI Discussion at Minority Interest Group Call

The CTN Minority Interest Group (MIG) will have its next conference call on Monday, June 2, at 3:00 p.m. EST. Two representatives of the PCORI (Patient-Centered Outcomes Research Institute) Addressing Health Disparities Program will attend and present at this meeting. Anyone interested in hearing about PCORI funding is welcome to attend. The call information is below. Please invite others that are interested. For additional information, please contact Carmen Rosa at crosa@nida.nih.gov.

Meeting Number: 993 974 443
Meeting Password: pcorictn

Go to:
https://fedgov.webex.com/fedgov/j.php?MTID=me00602e512b290755595664bc7debe25

Call-in toll-free number (US/Canada): 1-877-668-4490

Delaware Valley Node News

The Delaware Valley Node teamed up with Christiana Care Health System, the Delaware Academy of Medicine, and the Delaware Nurses Association to hold the "2nd Annual Addiction Medicine Symposium: Breaking Down the Barriers." It was held in the John H. Ammon Medical Education Center at Christiana Hospital and included presentations on:

- Addiction as a brain disorder as something more than lack of willpower or moral deficiency;
- Managing pain;
- The VA homeless program;
- Identification and management of patients with dual diagnoses;
- Approaches for getting hospitalized patients with substance use disorders into treatment; and
- A closing panel led by the First Lady of Delaware.

The meeting was well attended with all 180 available registration slots having been filled two weeks prior to the meeting.

On another note, Dr. Metzger just returned from a trip to Jakarta where he reviewed findings from a NIDA funded study of behavioral and HIV risk counseling for methadone patients. During his visit he worked closely with Dr. Adhi Wibowo Nurhidayat, a former NIDA and ISAM fellow, and had dinner with Dr. Vivi Lubis, a recent NIDA/CTN fellow, along with her three children and husband who is also a physician. Vivi has just started a 4-year psychiatric residency program in Jakarta with the goal of developing a career in addiction medicine and expressed very positive feelings about her yearlong fellowship with the CTN.

CPDD Workshop

The 76th Annual Meeting of the College on Problems of Drug Dependence (CPDD) is being held June 14-19, 2014, in San Juan, Puerto Rico. CPDD attendees are invited to participate in a workshop on Tuesday, June 17, 7-9 pm, *"Addiction Treatment Research vs. Usual Care: What Are the Foreseeable Risks?"* The workshop, organized by Dr. Andy Saxon from the Western States Node, will discuss the ethical/regulatory issues of using treatment-as-usual interventions in research. Topics to be discussed include:

- **Introduction** – Carmen Rosa, M.S., NIDA CCTN
- **A Cautionary Tale: Do Not Include Risks of Usual Care in Study Consent Forms** – Andrew Saxon, M.D., University of Washington
- **Does Research Treatment Always Pose Increased Risk over Usual Care, and Does It Matter?** – David A. Gorelick, M.D., Ph.D., University of Maryland School of Medicine
- **Treatment as Usual in Vulnerable Populations: Case Study of Two Clinical Trials in HIV-Infected Individuals** – Todd Korthuis, M.D., Oregon Health Sciences
- **Discussant** – Collin O'Neil, Ph.D., New York University

News from the Florida Node Alliance

Congratulations to Dr. Carlos del Rio, CTN 0049 Co-Lead Investigator, for being the 2014 Thomas Jefferson Award recipient, Emory University's highest award for distinguished service to the University. Dr. del Rio is the Hubert Professor and Chair of the Hubert Department of Global Health and Professor of Epidemiology at Rollins School of Public Health, as well as a professor of medicine at Emory School of Medicine and chief of the infectious disease service at Emory University Hospital. He is also the director for clinical sciences and international research of the Emory Center for AIDS Research (CFAR) and directs the Emory AIDS International Training and Research Program.

Dr. del Rio has spent his career as a clinician and researcher working to prevent, treat, and improve patient outcomes for infectious diseases locally and globally. He has focused his work on HIV/AIDS prevention and early diagnosis, access to care and compliance with anti-retrovirals in hard-to-reach populations, including substance abusers. Please join us in congratulating Dr. del Rio for this well-deserved accolade!

Special Issue of JSSWR

The Journal of the Society for Social Work and Research (*JSSWR*) announces a special issue dedicated to studies of social work interventions. This special issue might be of interest to CTN members. This issue will broadly define social work interventions to include intentional action strategies designed to promote positive outcomes (or prevent adverse outcomes) among individuals, groups, organizations, or communities served by the social work profession. The deadline for submission is November 1. The call for papers is also available at this link:

http://www.press.uchicago.edu/ucp/journals/journal/jsswr.html

ATTC Tidbits

The Addiction Technology Transfer Center Network (ATTC) funded by the Substance Abuse and Mental Health Services Administration serves to raise awareness of evidence-based and promising treatment and recovery practices and builds skills to prepare the workforce to deliver addiction treatments. Here are some current resources:

ATTC/NIATx Service Improvement Blog:
http://attcniatx.blogspot.com/

The Bridge
http://www.attcnetwork.org/explore/priorityareas/techtrans/thebridge/currentissue.asp,
Spring 2014

June ATTC Messenger
http://www.attcnetwork.org/find/news/attcnews/epubs/eof/index.asp

June 2: ATTC Website Redesign Launch

Webinars coming up:

- Thursday, June 5, 2:00pm EDT: Problem Gambling, Special Populations
  Register**:**
  https://www2.gotomeeting.com/register/307178354

- Thursday, June 19, 2:00pm EDT: Third-Thursday iTraining: "Working in Multidisciplinary Teams to Promote Healthcare Integration"
  Register:
  https://www2.gotomeeting.com/register/881008666

SAMHSA Public Listening Session

The Substance Abuse and Mental Health Services Administration (SAMHSA) announced this week that they will hold a public listening session on Wednesday, June 11, 2014, to solicit information concerning the **Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2.** The scheduled listening session provides an opportunity for SAMHSA to seek public input on potential changes to the regulations including changes to the research provision.
https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records

SAMHSA is considering expanding the authority for releasing data to qualified researchers and research organizations and is asking listening session participants to consider the following questions:

- Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?
- Would this change address concerns related to research?
- Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?
- Are there additional use cases that should be considered in the research context?

Members of the public are invited to attend or view the proceedings, with space available on a first-come, first-served basis. Written comments may also be submitted.

For additional details please see:
https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records

To register: http://42cfrpart2-listeningsession.eventbrite.com

CTN Dissemination Library

The CTN Library is web-based, and includes a catalog with descriptive records for each item in the Library. The web site is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: http://ctndisseminationlibrary.org.

NIH Peer Review Challenge

The National Institutes of Health Center for Scientific Review (CSR) is issuing two challenges for ideas to detect potential bias in peer review and ideas to strengthen reviewer training to enhance impartiality and fairness in the review of grant applications.

A First Prize in the amount of $10,000 and a Second Prize in the amount of $5,000 is offered in each category below.

Challenge #1
New Methods to Detect Bias in Peer Review
Submit your idea on how to detect bias among reviewers due to gender, race/ethnicity, institutional affiliation, area of science, and/or amount of research experience of applicants. Additional details can be found at FRN Doc.2014-10196.

Challenge #2
Strategies to Strengthen Fairness and Impartiality in Peer Review
Submit your idea on how to strengthen reviewer training methods to enhance fairness and impartiality in peer review. First and Second prizes will be offered for the best overall ideas. Additional details can be found at FRN Doc.2014-10203.

Instructions:

1. Review the Complete Rules for Each Challenge.
2. Fill out the Appropriate Coversheet (Challenge 1) (Challenge 2).
3. Submit Your Ideas and Coversheet at CSRDiversityPeerRev@mail.nih.gov **by 11:59 PM (EST) on June 30, 2014.**

New Funding Opportunities

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

- Clinical Evaluation of Adjuncts to Opioid Therapies for the Treatment of Chronic Pain (R01) (PAR-14-225)
- Long-Term Retention in Care for U.S. Substance Using Populations (R34) (PA-14-222)
- Long-Term Retention in Care for U.S. Substance Using Populations (R21) (PA-14-223)
- Long-Term Retention in Care for U.S. Substance Using Populations (R01) (PA-14-224)

Mid-Atlantic Node News

The Mid-Atlantic Node welcomes its new co-node coordinator – Heather Fitzsimons! Heather comes to the CTN with over 15 years of experience in the study and treatment of substance use disorders. She has been a team member on several NIH-funded studies investigating behavioral interventions for the treatment of substance use disorders at Johns Hopkins University as well as a multi-center trial examining familial transmission of substance use and behavioral disorders at the University of Colorado.

In addition, she served as an assessment consultant to the University of Maryland for the Maternal Opioid-Treatment: Human Experimental Research project, an international, multi-site trial evaluating methadone and buprenorphine use during pregnancy.

As the co-node coordinator at the Mid-Atlantic, Heather will provide regulatory oversight and assist Community Treatment Providers with implementation of CTN protocols. Heather earned her Master's of Public Health from Johns Hopkins University as well as a post Master's Certificate in Public Mental Health Research. She is a Certified Clinical Research Professional and member of the Society of Clinical Research Associates. To contact Heather you can email: hfitzsim@jhmi.edu.

Web Portal for Women's Health Resources

The HHS Coordinating Committee on Women's Health and the Intimate Partner Violence Research Symposium Committee released its report of the Symposium held on December 9, 2013, at NIH. NIDA was represented as a co-chair of the meeting. The report highlights research gaps identified and recommendations for future research.

The National Library of Medicine and the Office of Research on Women's Health, both part of the NIH, have created a Web Portal (**Women's Health Resources - Women's Health Topics**) to serve as a central electronic resource for this research symposium. Most of the HHS agencies participating in this effort have provided content, as well as other federal agencies such as the Department of Justice, the Department of Labor, and the U.S. Department of Veterans Affairs. The summary report may be accessed on the above link at: http://whr.nlm.nih.gov/Report_IPV_Symposium.pdf.

For inquiries about the meeting and related follow-up activities, please contact Dr. Samia Noursi, Co-Chair of the Symposium, snoursi@mail.nih.gov.

NIDA Changes

The National Institute on Drug Abuse (NIDA) has named Wilson Compton, M.D., M.P.E., a nationally known expert on the causes and prevention of drug abuse, as the Deputy Director of the Institute. Since 2002, Dr. Compton has served as the Director of NIDA's Division of Epidemiology, Services, and Prevention Research. Dr. Compton has been a member of the DSM-5 Task Force and the Substance Use Disorders Workgroup for the past five years. In addition, he has been leading an effort jointly sponsored by NIDA and the FDA's Center for Tobacco Products to field a large scale longitudinal population study of over 50,000 persons to assess the impact of new tobacco regulations.

NIDA is pleased to announce that Joni Rutter, Ph.D., has accepted the role of Division Director for the Division of Basic Neuroscience and Behavioral Research (DBNBR). The division's primary goal is to support basic biomedical and behavioral research to address the public health problem of drug addiction, including the neurobiological and behavioral mechanisms of drugs of abuse and their consequences. Dr. Rutter's career spans 15 years of basic and clinical research in human genetics and the study of genetic and environmental risk factors in the fields of cancer and addiction. Dr. Rutter has also built, supported, and maintained the NIDA Genetics Consortium, a group of more than 20 investigators who study addiction genetics.

Congratulations to both!

DSC – EMMES Data Center

The Data and Statistics Center (DSC) at the EMMES Corporation has created a web based portal for tracking and managing all CTN studies. The CTN Trial Progress Reports (TPR) site has been an effective management tool to monitor the progress of all on-going trials, from date of first randomization through final closeout and publication.

The TPR is on the NIDA DSC website (http://ctndsc2.com), with reports updated regularly (daily to monthly, depending on the report). On a monthly basis, the TPR is archived. TPRs from completed studies are also provided on the website.

If you are CTN staff member and wish to have access to the TPR site to obtain detailed information on all aspects of on-going clinical trials, please send an e-mail to nidadsc2help@emmes.com or call the DSC Help Desk at (888) 337-7071.

NIH Grants Funding FAQs

The NIH Grants Funding - Reporting Race and Ethnicity Data FAQ website includes the following guidance which may be relevant to CTN trials:

***Question*:** What is the purpose of the NIH policy on the inclusion of women and racial/ethnic groups as participants in research?

Answer: The overarching goal of this policy is to ensure the appropriate inclusion of women and minorities in all clinical research supported by the NIH. NIH supported clinical research should address/include the population(s) at risk for the disease or condition under study and ensure that the distribution of study participants by sex/gender, race and ethnicity reflects the population needed to accomplish the scientific goals of the study. Full details on the policy are available here.

Question: Are there additional inclusion policy requirements for NIH-defined Phase III clinical trials?

Answer: For an NIH-defined Phase III clinical trial (defined here), in addition to addressing inclusion as for any NIH-defined clinical research study, investigators must also address requirements for valid analysis in their competing application and address progress in their non-competing (progress report) application. Additional details on applying NIH inclusion policy to NIH-defined Phase III clinical trials can be found here.

Question: Does the NIH inclusion policy apply to foreign studies supported by the NIH?

Answer: Yes, inclusion does apply to foreign studies. Working with foreign participants can present a unique challenge to reporting racial and ethnic information to the NIH. However, investigators are expected to collect this information (as well as information on the sex/gender of participants). It is not expected that investigators would use the U.S. categories for race and ethnicity in data collection instruments designed for use in other countries. Investigators are encouraged to design culturally appropriate data collection instruments that allow a participant to self-identify with their racial and ethnic affiliation. However, these data collection items must be designed in a way that will allow investigators to aggregate self-reported data into the OMB-defined categories for NIH.

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

Connect with NIDA through: