



Clinical Trials Network

CTN Bulletin

July 10, 2009

Volume 09 – 12

Trial Progress – Over 11,000!



Trial enrollment is taken from the official Trial Progress Report prepared by the Data and Statistics Center (DCRI) each month. These enrollment numbers reflect information in the database through **June 30, 2009**.

Open Studies (5)

- CTN 0027 – Randomized 1115
- CTN 0027A (Genetics) – Randomized 679
- CTN 0031 – Randomized 337
- CTN 0031A – Randomized 174
- CTN 0032 – Randomized 1,281

Total Randomized All Studies: 11,161

CTN 0037 STRIDE



The CTN 0037 STRIDE (Stimulant Reduction Intervention using Dosed Exercise) team has received approval to proceed with version 1.0 of the protocol.

The team is currently focusing on the site selection process, case report form development, and the development of study procedures. The team is led by Dr. Madhukar Trivedi, Co-PI of the Texas Node. We are greatly appreciative to all who have helped in the development of this study and look forward to preparing for study implementation! Further information will be forthcoming regarding the selected sites and training plans.

CTN 0030 POATS



The Prescription Opiate Addiction Treatment Study (POATS) team members are very happy to announce that the visit window for the last remaining participant in the trial has closed! They successfully enrolled 653 participants into Phase 1 and 360 participants into Phase 2. This was a great accomplishment that could not have been achieved without the hard work and dedication from all of those involved in the study, including the staff from the NIDA CCTN, EMMES, and DCRI. The Lead Team looks forward to collaborating with staff at the participating sites on publications after data lock.

Many, many people contributed to the success of this trial. Below is a list of the current research staff from the participating CTN 0030 sites. Congratulations to all of them for a job well-done!

ADAPT (Oregon/Hawaii Node)

Linda Clary, Dawn Fox, John G. Gardin, Davina Jones, Lynn Kunkel, Amy Strong, Joanne Weidemann

Behavioral Health Services of Pickens County (Southern Consortium Node)

Elizabeth Chapman, Susan Sonne, Josie Spittler, Clare Tyson

Bellevue Hospital (New York Node)

Daniela Bustamante, Marc Gourevitch, Shirley Irons, Connie Klein, Bridget McClure, Patricia Novo

Chestnut Ridge Hospital (Appalachian Tri-State Node)

Mimmie Byrne, Elisa Cupelli, Kimberly Honaker, Dorothy Sandstrom

East Indiana Treatment Center (Ohio Valley Node)

Ron Coleman, Mary Ann Detmer, Emily Dorer, Kati Krome, Frankie Kropp, Sharon Pickrel, Eugene Somoza, Jeff Theobald

UCLA Integrated Substance Abuse Programs (Pacific Node)

David Chim, Cindy Fernandez, Al Hasson, Walter Ling, Sandy MacNicoll, Claire Manneh, Mark Oyama, Michele Smith

Long Island Jewish Medical and St. Luke's Roosevelt Hospital (Long Island Node)

Michelle Cordner, Megan Ghiroli, Joanne Gomez, Neikeisha Grenade, Deborah Haller, Eva Kourniotis, Jennifer Lima, Catherine LoDuca, Olga Vorobyoff

McLean Hospital (Northern New England Node)

Hilary Smith Connery, Nadia Mohamedi, Susan Putnins

Providence Behavioral Health Services (Pacific Northwest Node)

Bill Dickinson, Mary Hatch-Maillette, Lindsay Jenkins, Stephen Lubatti, Ryan McMeans, Andrew Saxon

Notice from OHRP



Beginning on **July 14, 2009**, institutions and organizations needing to register a new IRB, or update or renew an existing IRB registration, must do so electronically via the OHRP (Office for Human Research Protections) website at <http://ohrp.cit.nih.gov/efile/> unless the institution or organization lacks the ability to register its IRBs electronically. Please note this new requirement.

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.

News from the California/Arizona Node



The CA-AZ Node, in collaboration with the Native American Health Center (NAHC) in Oakland, CA, recently organized a workshop on

the conduct of community-based participatory research in Native American communities. Dr. Candace Fleming, a clinical psychologist at the University of Colorado Denver School of Medicine and member of the Kickapoo-Oneida-Cherokee tribes, facilitated the workshop, which was held on May 15, 2009 with 22 participants in attendance. Themes that emerged from the workshop included:

- 1) The limited resources available to address the health care needs of urban American Indian communities;
- 2) An assessment of which evidence-based practices might be suitable for adoption by Native American communities and which Native American cultural practices could be tested for efficacy (e.g., Gathering of Native Americans or Talking Circles);
- 3) The role of Indian/Native spirituality in positive change;
- 4) The possibility of developing a grant application in which a practice is adapted for Indian/Native populations (e.g., trauma-focused CBT);
- 5) Past abuses and exploitation of Native Americans in research and how this might fit into the dialogue in forming a future research collaboration; and
- 6) The inappropriateness of developing manual-guided interventions of Native American cultural and spiritual practices.

A more detailed summary is being prepared, and will be available to interested partners in the national CTN.

Country Singer in our Midst!



The news from the Southwest is that Bill Miller, previous PI of the Southwest Node, is a songwriter and singer. Bill wrote a country-western tune called "Six Pack" and sang it at the close of the annual meeting of the MI Network of

Trainers in Spain. Bill says, "It all started with a country-western song title that popped into my head. That seemed so good I just had to write a song around it. [You just shouldn't waste a good song title. One of my favorites is Billy Ray Cyrus: 'I'm so miserable without you, it's almost like you're here.'] Six-Pack" came together in a couple of hours."

Dennis Donovan quipped that this makes Bill an "abs-minded professor." Here is the clip of Bill singing his song: <http://www.youtube.com/watch?v=obw2ifjCw7A>

CTN INVEST Fellowships for 2009



The National Institute on Drug Abuse is recruiting fellows for the 2009 INVEST/CTN research fellowship program. Clinical trial researchers from all non-U.S. countries including

"developing" and "developed" nations are encouraged to apply for this opportunity to work with a research mentor at one of the sixteen CTN Regional Research and Training Centers. INVEST/CTN fellowships encourage postdoctoral fellows to conduct drug abuse and addiction research and promote collaboration with their U.S. mentors, creating an international network of scientists dedicated to exchanging information and collaborating on drug abuse research at a national, regional, and global level. Qualified fellowship candidates must meet the following standards:

- An earned doctoral degree in medicine, public health, biomedical, behavioral, or social sciences.
- A minimum of 2 years of postdoctoral research experience, including a demonstrated ability to engage in independent research.
- Written assurance from an institution in the home country that there is a position for the applicant after completing the fellowship.
- Proficiency in written and spoken English.
- Citizenship or permanent residency in a country other than the United States.
- Status of living and working outside the United States at the time the application is submitted.
- Eligibility for the J-1 visa to enter the United States.

INVEST/CTN mentors are required to have:

- A current NIDA grant that will be active throughout the fellowship period.
- Affiliation with one of the Regional Research and Training Centers in the sixteen CTN Nodes. See <http://www.drugabuse.gov/CTN/> for more details.

Current CTN Node PIs can participate or encourage interested colleagues in their respective Nodes to mentor INVEST/CTN fellows. During the fellowship year, fellows and mentors are encouraged to jointly develop and seek funding for a collaborative research project to be completed in the Fellow's home country.

Applications for the fellowship are due September 1st, 2009. For additional information, please contact Petra Jacobs, M.D. (pjacobs@nida.nih.gov) or visit the website at http://international.drugabuse.gov/research/fellowships_InvestCTN.html

First CTN Regional Dissemination Workshop



The Oregon/Hawaii and Pacific Northwest Nodes of the Clinical Trials Network collaborated with the Northwest Frontier Addiction Technology Transfer Center and the National Institute on Drug Abuse's Center for the Clinical Trials Network to host the first CTN Regional Dissemination Workshop June 3 and 4 in Portland, Oregon. The Regional Dissemination Workshop highlighted treatment products tested and found effective in the clinical trials conducted by the Clinical Trials Network. The workshop series promotes and encourages adoption and implementation of the CTN products.

The first day focused on providing introductions for specific therapeutic techniques and approaches and was oriented toward practitioners. Day Two was directed at administrators and supervisors and addressed the implementation of the evidence-based practices described on Day One. There were 135 registered participants for Day One and 110 for Day Two. The workshops featured speakers from the CTN and ATTC Networks. Betty Tai (Director of the Center for the Clinical Trials Network) delivered the plenary presentation. Special thanks to Lynn Kunkel (Oregon/Hawaii Node) and Mary Anne Bryan (Northwest Frontier Addiction Technology Transfer Center) for coordinating the conference planning and implementation.

Pacific Northwest News



The SouthEast Alaska Regional Health Consortium (SEARHC) Tobacco Control and Behavioral Health Prevention programs are introducing a campaign aimed at limiting youth access to tobacco and alcohol, *Capital City Weekly* reports. According to the *Capital City Weekly*, research shows that 65 percent of youth obtain tobacco products from a friend or family member, while 80 percent of youth report that they consumed their last alcoholic beverage at a friend or family member's home. To address the issue, the five-month campaign will feature fliers posted in health clinics, businesses, schools, libraries and other community gathering spots. The fliers will include headlines saying either "Dei A Wé," which is Tlingit for "enough" or "Háwsduwaan," which is Haida for "that's enough, stop doing that." They also will feature five separate messages about who supplies youth with tobacco and alcohol, with one flier informing the public of criminal penalties for supplying a youth with alcohol or tobacco. Program officials anticipate that the campaign will encourage adults and youth to engage in conversations regarding the dangers associated with underage tobacco and alcohol use (*Capital City Weekly*, 6/3/09).

Oregon/Hawaii Node Welcomes Harold Perl



Harold Perl (CCTN) attended the Regional Dissemination Workshop in Portland and visited three Community Treatment Programs participating in CTN clinical trials. On June 4, Richard Drandoff led a tour of ChangePoint's Portland clinic and introduced his clinical and research staff. ChangePoint recently met recruitment goals for STAGE-12 and is completing follow-up data collection.

Friday morning, June 5, began with a morning visit to CODA. Katharina Wiest (Research Director) and Jeanine Bassett (Clinical Director) met Harold and led a tour of the busy facility – a visit to the outpatient and mental health services, observations of the methadone and buprenorphine medication stations, and meetings with research staff conducting the START and HIV Rapid Testing studies. The new research suite was a highlight of the tour.

The two hour drive to Eugene and a visit to Willamette Family was the next stop. It was lunch time and mothers were busy feeding children and getting ready for afternoon groups. The research staff for STAGE-12 guided the tour. Lucy Zammarelli and Davina Jones served a macrobiotic lunch in the "little brown house," a recent addition to the Willamette Family campus. Micki Knuckles, the new Executive Director for Willamette Family, joined the group for lunch. The visit continued with stops at Buckley Detox (site for the CTN 0017 trial) and the new central intake and outpatient clinic in downtown Eugene. The visit concluded with a tour of the University of Oregon and all the Duck landmarks. Thanks to all for these informing site visits!

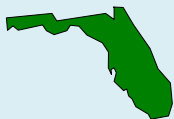
Save the Date – October Evidence-Based Conference



The Appalachian Tri-State Node, in collaboration with NIDA and other agencies, is holding a conference on "Evidence-Based Treatments for Addiction" from October 28-29 in Pittsburgh, Pennsylvania. Six clinical workshops will be offered on: 1) Twelve-Step Facilitation Therapy; 2) Integrated Treatment of Co-Occurring Disorders; 3) Relapse Prevention and Recovery Management; 4) Helping Families and Children; 5) Use of Motivational Incentives; and 6) Treatment Planning. These workshops will range in length from 3-8 hours each.

Speakers will include national and local representatives who have developed evidence-based treatments (EBTs), participated in clinical trials, or implemented EBTs in their treatment agencies. Registration and hotel information will be available shortly.

Florida Node News



Dr. José Szapocznik, Florida Node PI, met with Health and Human Services Secretary Kathleen Sebelius on May 26th to discuss drug abuse prevention and treatment; and with ONDCP Director Gil Kerlikowske and a group of drug prevention scientists to discuss drug prevention.

The Brief Strategic Family Therapy™ Training Institute, a division of the University of Miami Center for Family Studies, recently awarded its first-ever international certificate of competence in BSFT™ to Anne-Sofie Larsson, a family therapist at Maria Youth (Ungdom) Center in Stockholm, Sweden. Maria Youth is a Swedish governmental organization that provides treatment to adolescents and their families. Senior BSFT™ Institute trainer Monica Zarate has been supervising a team of six therapists at Maria Youth with the ultimate goal of sustaining a BSFT™ program in their agency.

The BSFT™ team at Maria Youth will participate in the Brief Strategic Family Therapy Conference at Karolinska Institute in Stockholm on September 10-11, 2009, which will be the first international conference dedicated to BSFT. For further information about this conference or the BSFT™ Training Institute, please e-mail bsft@med.miami.edu.

News from the Ohio Valley Node



Northern Plains Tribal Epidemiology Center Hosts Meeting on Substance Use Research and Treatment in Northern Plains Tribes

The Northern Plains Tribal Epidemiology Center of the Aberdeen Area Tribal Chairmen's Health Board (NPTEC-AATCHB; Ohio Valley Node) welcomed Dr. Nora Volkow and Dr. Betty Tai as honored guests at a meeting in Rapid City, South Dakota on June 10, 2009. The purpose of the meeting was to discuss the current state of substance abuse and other behavioral health concerns among Northern Plains Tribes, and to identify potential areas for intervention and research. In addition to the representatives from NIDA, the meeting brought together tribal health and alcohol directors, as well as representatives from the South Dakota Division of Alcohol and Drug Abuse, the South Dakota Division of Mental Health, the Aberdeen Area Indian Health Service, the Prairielands Addiction Transfer and Technology Center, the City/County Alcohol and Drug Program (CCADP; Ohio Valley Node), the Ohio Valley Node RRTC, and the AATCHB. The Ohio Valley Node wishes to thank Dr. Adeola Jaiyola and Dr. Maurine Orwa of the NPTEC-AATCHB for their outstanding work in organizing the meeting.

Dr. Art Zimiga (AATCHB) opened the meeting, followed by Dr. Don Warne (Executive Director, AATCHB) who spoke on the historical foundations for tribal healthcare and the current state of healthcare among the Northern Plains Tribes. Dr. Vicky Claymore-Lahammer (Aberdeen Area Indian Health Service), Gib Sudbeck (South Dakota Division of Alcohol and Drug Abuse), and Amy Iversen-Pollreisz (South Dakota Division of Mental Health) followed by discussing current substance use and mental health treatment efforts for Northern Plains Tribes. Next, Duane Silk (Standing Rock Sioux Tribe) and Terryl Blue White Eyes (Oglala Sioux Tribe) presented the challenges faced by reservation-based treatment providers. Donna Keeler (South Dakota Urban Indian Health) described current issues faced in providing treatment to urban-dwelling American Indians. She was followed by Dr. Duane Mackey (Prairielands Addiction Transfer and Technology Center), who discussed issues of importance in conducting contemporary research protocols with American Indian populations. Dr. Eugene Somoza (Ohio Valley Node RRTC) then discussed the CTN and the current study being conducted in the Northern Plains (CTN 0033). Dr. Nora Volkow then addressed the issues that had been brought forth, and discussed the potential role of NIDA research in seeking effective interventions for the Northern Plains Tribes.



As is customary among American Indians in the Northern Plains, special gifts were presented to the guests from NIDA and the Ohio Valley Node. A "Fancy Dance" shawl was handmade by Mary and Jennifer Irving especially for Dr. Volkow. The shawl depicts three horses, representing the journey from active addiction to recovery. Julie Cain (United Tribes Technical College) also presented Dr. Volkow with an art piece representing an eagle's feather. The eagle is a symbol of strength and bravery in Northern Plains tradition, and bestowing an eagle feather is a great honor. Gifts of beaded key chains were also presented to Dr. Tai, Dr. Somoza and Frankie Kropp (Ohio Valley Node).

Following the meeting, Dr. Tai, Dr. Somoza, and Ms. Kropp were given a tour of the Pine Ridge Reservation (Oglala Sioux) by Dr. Zimiga and Jennifer Richards (AATCHB). As part of the tour, the group visited Ms. Blue White Eyes and her staff at Anpetu Luta Otipi ("Living in a Red Day") treatment center in Kyle, SD. The tour was very beneficial in helping to illustrate many of the challenges faced in preventing and treating substance abuse on the Pine Ridge Reservation.

Thanks to all who helped make these visits a success!

Recovery Corner



*Thanks to Mandy Owens for sharing this story. **Court Mandated vs. Self-Referred: STAGE-12 Success Stories***

Among the participants in STAGE-12 at the Recovery Centers of King County (RCKC), two continue to shine although each traveled a completely different path to treatment: court-mandated vs. self-referred.



One participant, Richard*, is a 45 year old African-American man who has a history of cocaine and heroin use, with thirteen years of intravenous use. During these years Richard was homeless at times and served over seven years in prison for drug-related charges. After his most recent delivery charge in 2008, the courts decided to offer Richard an alternative to incarceration—enrollment in Drug Court. The King County Drug Court Program requires full compliance with alcohol and drug treatment including two random urine analyses a week for one year or more.

After leaving work release, Richard moved into sober housing and continued to attend Intensive Outpatient treatment and STAGE-12 groups. Since completing the study, Richard is on track for advancement to phase three of treatment (monthly groups). He still attends one or more 12-step meetings every day, except Sunday when he goes to church. He is active in his AA home group and stays in regular contact with a fellow member who acts as his sponsor. He comments that the STAGE-12 groups “helped me” and “kept me focused”, noting that he “does not think [anyone] can recover unless you take the 12 steps seriously.” He has been sober since August 2008. With only three months remaining before he completes the Drug Court Program, Richard is focused on his new life that is just beginning and has no desire to return to his past ways.

A second participant, Michelle*, is a 54 year-old African-American woman. Since her introduction to drug use at age 12, she had never been abstinent until July 2008. With no skills or work experience, Michelle supported herself and her 28-year cocaine habit by selling drugs, interrupted by drug-related prison and jail terms. However, last year something suddenly changed for Michelle. For the first time in her life she decided that she wanted to get sober for herself and her family. At RCKC, Michelle participated in Intensive Outpatient

as well as the STAGE-12 interventions. During this process, she demonstrated her commitment to the 12-step program by attending two meetings almost every day and obtaining a sponsor. She has served as secretary for an AA meeting for the past six months.

Earlier this year, Michelle traveled to California for an annual Narcotics Anonymous convention for women—an experience that she was proud to share with her fellow group members back home at RCKC. Currently, Michelle is studying for her GED and recently got her driver’s license. She is re-establishing her relationship with her daughter and granddaughter. She looks back at the STAGE-12 intervention with gratitude, saying that it is “a good program to look at yourself” and was a “big help.” She enthusiastically recommends the STAGE-12 groups to other clients at the agency and for “anyone looking to recover.”

Thanks to the RCKC staff for sharing these success stories!

**Names were changed to protect the confidentiality of STAGE-12 participants*

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

