All members of the BUP 0010 study team were delighted to see the primary outcome paper “Extended vs Short-term Buprenorphine-Naloxone for Treatment of Opioid-Addicted Youth: A Randomized Trial”, published as the lead article in the Nov. 5 edition of JAMA (vol. 300 [17]; 2003-2011) with a commentary by David Fiellin entitled “Treatment of Adolescent Opioid Dependence: No Quick Fix” (pp 2057-2059). Dr. Fiellin commented that one of the most important findings was the reduction in opioid use when medication was used, and the high rate of opioid use at all followup points after it was tapered. The findings do not show how long buprenorphine-naloxone should be continued, but they clearly show that clinicians should not be reluctant to start buprenorphine-naloxone simply because the patient is young and only recently addicted, and that there should be no hurry to stop it. The findings represent only the beginning of studies that are needed to map out the best ways to use MAT for treating opioid-addicted youth. However they do represent a new treatment paradigm that has the potential to expand access and improve outcomes in the outpatient settings where most patients are now being treated. The 0010 study is one that could not have been done without the support and resources of the CTN and has a real chance of changing the way opioid-addicted youth are treated.

Interested readers will also find a commentary by Chuck O’Brien in the same issue (pp. 2054-2055) entitled “The CAGE Questionnaire for Detection of Alcoholism”. Dr. O’Brien summarizes the value of the CAGE, and the lack of attention given to screening for alcoholism and other substance use disorders in general medical practice. His commentary has valuable ideas that will be helpful in designing the SBIRT protocol.

Research Involving Vulnerable Populations

Because prisoners may not be free to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, the regulations require additional safeguards for the protection of prisoners in research. These safeguards are found in 45 CFR 46, Subpart C.

Definitions Specific to Subpart C (46.303):
Prisoner - any individual involuntarily confined or detained in a penal institution encompassing: Individuals sentenced to such an institution under a criminal or civil statute; Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; Individuals detained pending arraignment, trial, or sentencing. Taken from: http://grants2.nih.gov/grants/policy/hs/prisoners.htm

DelVal Node Trial Progress:

CTN 0027 - START
Study Update by: Edgar Weiss, Assoc. Project Manager; Site: NET Steps, Phila, PA
Winding down a study is not as easy as it may sound. The START study stopped recruiting new participants last April and only now, Sunday, Nov. 23rd, did we conduct our last regular visit, a Week 32. We have seen some drama in the last months, such as client “anger issues,” incarceration, and the challenges of ‘detox.’ All in all, we feel good about being a positive part of helping clients take their lives back. Now we just have the required FDA safety follow up and our contact with clients ends.
Our contact with the documentation goes on. In mid November we hosted an EMMES monitoring visit. Andrea Dedier confirmed that we have maintained an excellent ‘handle’ on the record-keeping. We will have her back for two wrap-up sessions over the coming months. We have maintained high national ranking in many areas, such as recruitment, 117% of our target. We have been holding onto 89% of our clients through the additional two-month follow-up period, the top rate in the country. Our methadone retention has been near the top and our Suboxone retention, since major changes at the beginning of the year, improved markedly while the rates all the other sites have fallen.

In the coming months we will be concluding the documentation reviews for the study. Lin Denton has already been out to give us a heads-up on the next steps at Net-STEPs. This includes corroborating the dosing records in the study files with the source materials in the clinic’s records. We thank Tom Brown for heading up this effort, supported by Judi Bright. Devlin Hart is finishing the final entries into the InForm database, checking all study charts, and closing out the cash payments account with Annette Carroll. Dr. Walker continues to monitor the well being of our clients and signing casebooks. Dr. Taylor is helping verify the documentation from the beginning of the study. In all, a busy time interrupted by training, such as for the ASI, aimed at the expectation of the next project, likely to be in concert with both Net-STEPs and the prison.

At this time, we cannot help but notice the invaluable contribution of the Net-SETPS staff who have gotten us this far. The dosing nurses should be applauded for consistently caring and responsiveness. The counselors have determinedly championed all their clients, especially those on the study. There has been the commitment and constancy of the intake process, lead by Annette Carroll. The Doctors provided care and documentation in a study-timely way, often at odds with the sanity of the clinic. Even the support of the security staff, like Lou and John, should not go unnoticed. So, our hat is off to the Director, John Carroll, for giving us a home. We say thanks.

CTN 0028 - ADHD in Adolescents
Study Update by: Charlotte Royer-Malvestuto,
Project Manager; Site: Rehab After Work,
Paoli, PA

We are in the process of “clean-up” prior to data lockdown next month. Gretchen Friedberger and Laura Scott are continuing to help with resolution of data queries- thanks Gretchen and Laura! Charlotte and Lin are closing out the office space at Rehab after Work and are updating the Regulatory Binder to include close-out documentation.

Devlin Hart, a member of the 0027 research team, completed requirements for ASI Interviewer certification.

Sabrina and Charlotte are assessing ways to support the next CTN round of ASI TTT and Interviewer Training initiatives in consultation with Liz Buttery and other CTN’ers.

Upcoming Meetings/Conferences

ACNP 47th Annual Meeting
Dec 7-11, 2008
Scottsdale, Arizona
For meeting and registration information, go to:
https://www.acnp.org/annualmeeting/registration.aspx

Save the Date

The NIDA CTN Steering Committee Meeting is scheduled to take place at the Bethesda North Marriott Hotel and Conference Center, Bethesda, Maryland, on March 24-26, 2009. More information, including registration, and agenda and logistical information will be posted starting January 19, 2009 at www.sei2003.com/NIDA/CTN/meetings.
Delaware Valley Node
Steering Committee

The next meeting of the Delaware Valley Node Steering Committee will be held on Tuesday, March 31, 2009 at 2 PM at TRI.

CTN Dissemination Library

The CTN Library is web-based, and includes all the CTN related publications (under What’s New). The web site is maintained by the Washington Node of the Clinical Trials Network. The address is: http://ctndisseminationlibrary.org

For a detailed list of upcoming conferences, click on “Upcoming Conferences” under “Dissemination Opportunities”

Grants Corner

The following grant opportunities may be of interest to researchers:

RFAs

Central Nervous System Intersections of Drug Addiction, Chronic Pain and Analgesia (R01) (RFA-DA-09-017)
National Institute on Drug Abuse
National Institute of Neurological Disorders and Stroke
Application Receipt Date(s): January 28, 2009 http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-09-017.html

*Central Nervous System Intersections of Drug Addiction, Chronic Pain and Analgesia (R21) (RFA-DA-09-018)
National Institute on Drug Abuse
National Institute of Neurological Disorders and Stroke

*Central Nervous System Intersections of Drug Addiction, Chronic Pain and Analgesia (R03) (RFA-DA-09-019)
National Institute on Drug Abuse
National Institute of Neurological Disorders and Stroke
Application Receipt Date(s): January 28, 2009 http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-09-019.html

*Interactions between Physical Activity and Drug Abuse (R01) (RFA-DA-09-013)
National Institute on Drug Abuse

*Interactions between Physical Activity and Drug Abuse (R03) (RFA-DA-09-014)
National Institute on Drug Abuse
Application Receipt Date(s): January 28, 2009 http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-09-014.html

Links to DelVal Node CTPs/Collaborators

Caron Treatment Centers http://www.caron.org/
Consortium http://www.consortium-inc.org/
Fresh Start Foundation http://www.freshstartfoundation.org

Jonathan Lax Center http://www.fight.org/
NET http://www.net-centers.org/
PHMC http://www.phmc.org/
Presbyterian http://pennhealth.com/behav_health/addiction/presyby/
PRO-ACT www.proact.org
RAW http://www.rehabafterwork.com/contact.htm
Seabrook House http://www.seabrookhouse.org/
Thomas Jefferson University http://www.jeffersonhospital.org/psychiatry/article4821.html
Treatment Research Institute www.tresearch.org
The University of Pennsylvania, Center for Studies on Addiction http://www.uphs.upenn.edu/trc/
Van Horn Consulting http://www.vanhornconsulting.com
**Program Announcements**

*Diversity-promoting Institutions Drug Abuse Research Program (DIDARP) (R24). (PAR-09-011)*

National Institute on Drug Abuse
Application Receipt/Submission Date(s):

*Pre-Application for the 2009 NIH Director’s Pioneer Award Program (X02)
(PAR-09-012)*

NIH Roadmap Initiatives
Application Receipt/Submission Date(s):
December 17, 2008

*Pre-Application for the 2009 NIH Director’s New Innovator Award Program (X02)
(PAR-09-013)*

NIH Roadmap Initiatives
Application Receipt/Submission Date(s):
January 15, 2009

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**Word Search Puzzle**

Theme: Philadelphia Streets

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N I I E K C X W T W
S R E T A W Z T I F
K C B C G Y Y E J P
N L A H U G W G H I
E C U R P S X D G M
T B C D Y X J I A I
U N A I T S I R H C
N J Q U G B K B O R
T B V U M E Q N S J
S R U P T H B I O U
E G O P I N E A U N
H C A M A C H B T I
C D R A B M O L H P
W U T S U C O L Q E
L T U N L A W W U R
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Bainbridge, Camac, Chestnut, Christian, Fitzwater, Juniper, Locust, Lombard, Market, Pine, South, Spruce, Walnut

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Updates for this newsletter should be sent to Doreen Cardillo dcardillo@tresearch.org