

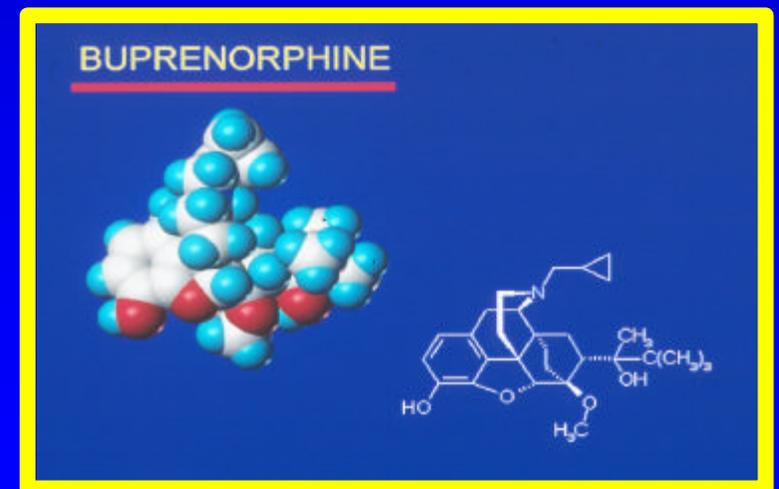
Buprenorphine in the Treatment of Opioid Addiction: Balancing Medication Access with Quality Care

Timothy P. Condon, Ph.D.
Deputy Director
National Institute on Drug Abuse
National Institutes of Health
Department of Health and Human Services

Washington, D.C.
February 21, 2008

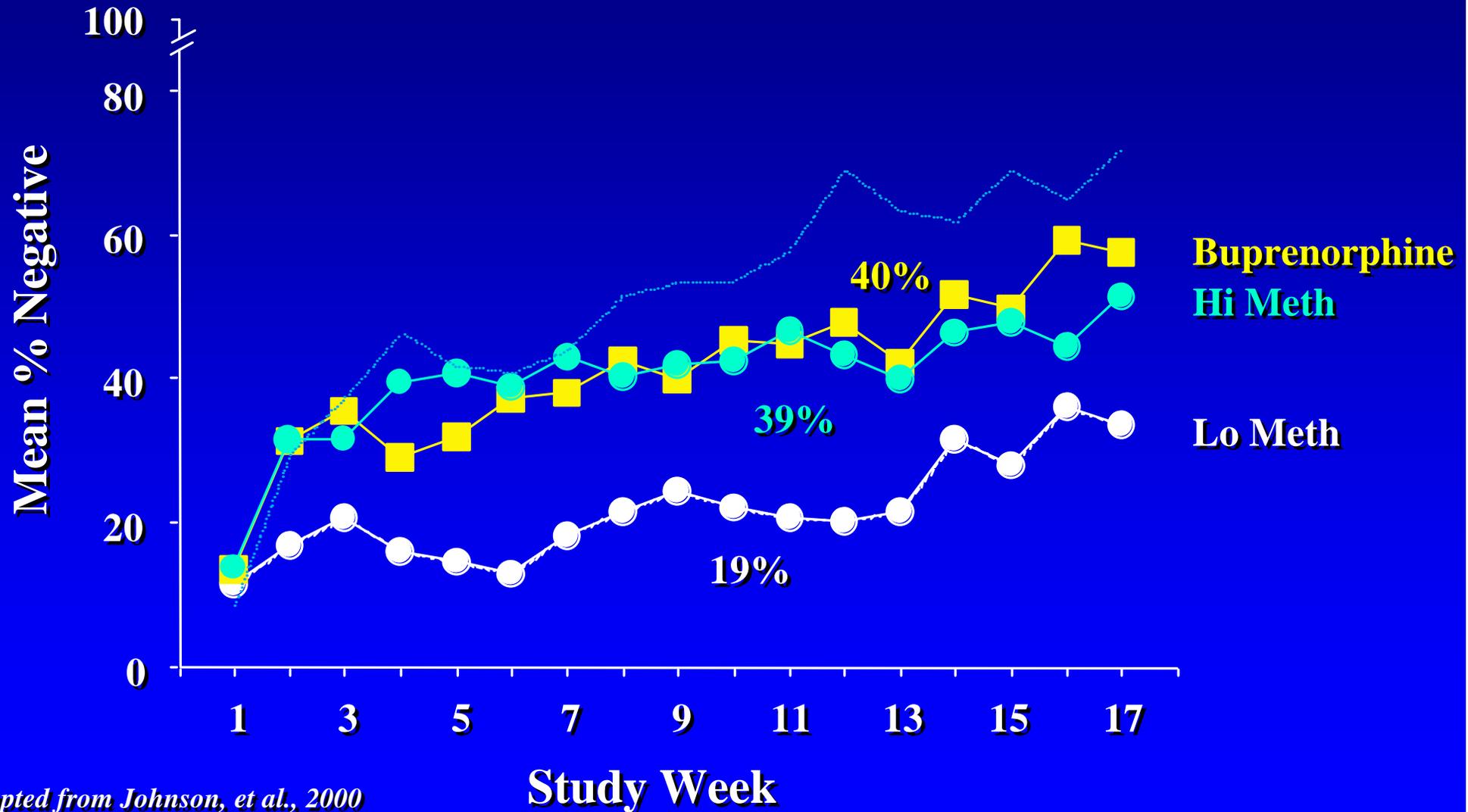
Buprenorphine

- Developed through a Cooperative Research & Development Agreement (CRADA) with Reckitt-Benckiser Pharmaceuticals, Inc.
- Partial agonist that functions on the same brain receptors as morphine – but does not produce the same high, dependence, or withdrawal syndrome
- Prevents morphine from binding to opiate receptors, thus blocking its pleasurable effects
- Blocks withdrawal discomfort by keeping the receptors occupied
- Is long-lasting, less likely to cause respiratory depression, well tolerated by addicts and, when combined with naloxone, has reduced diversion potential



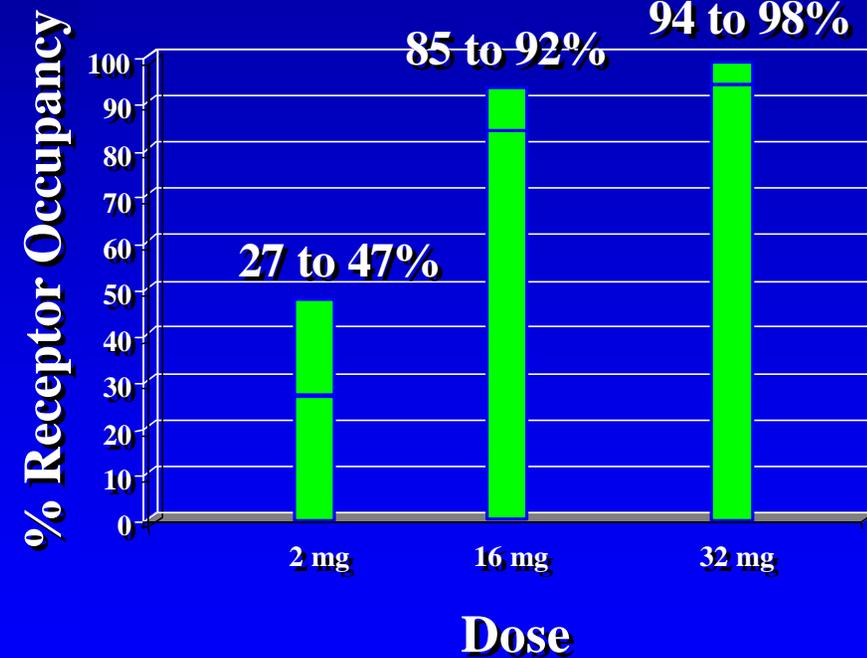
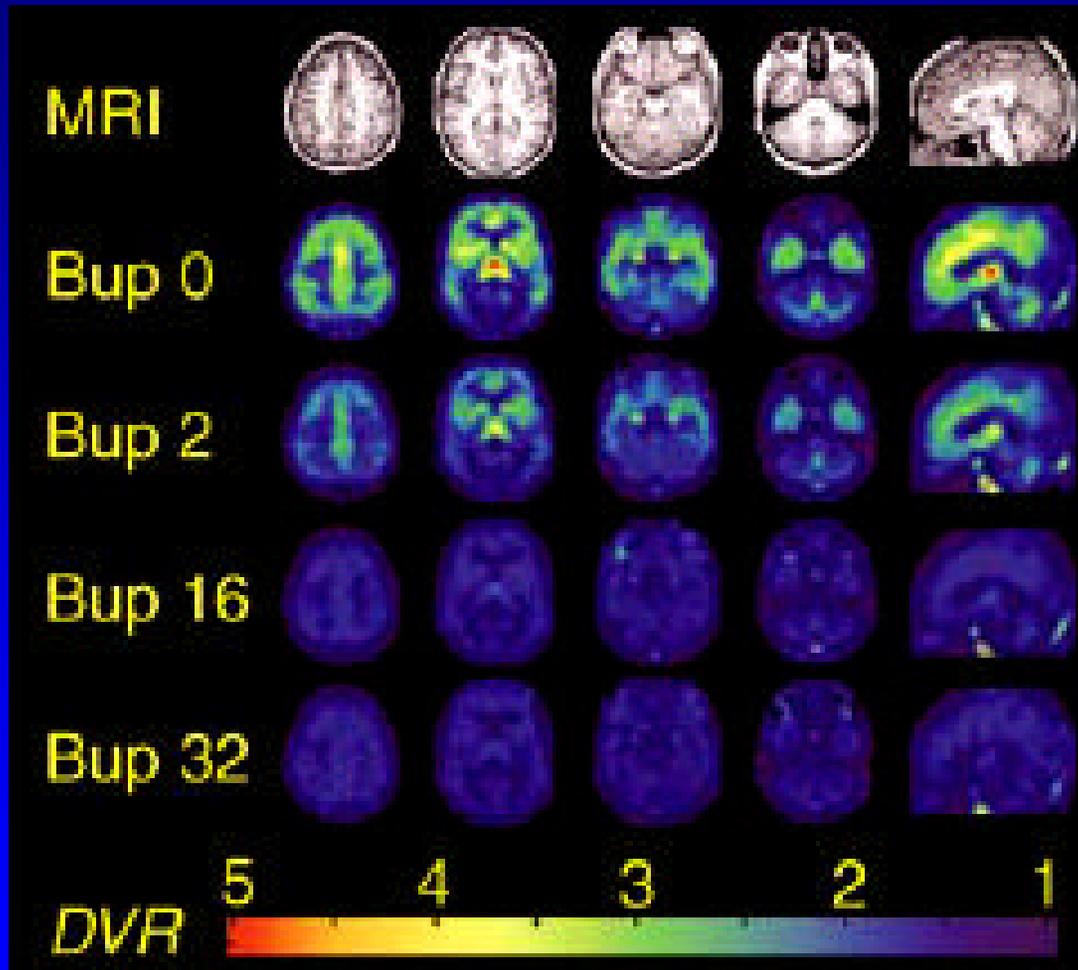
What Have We Learned?

Opioid Urine Results for Buprenorphine and Methadone



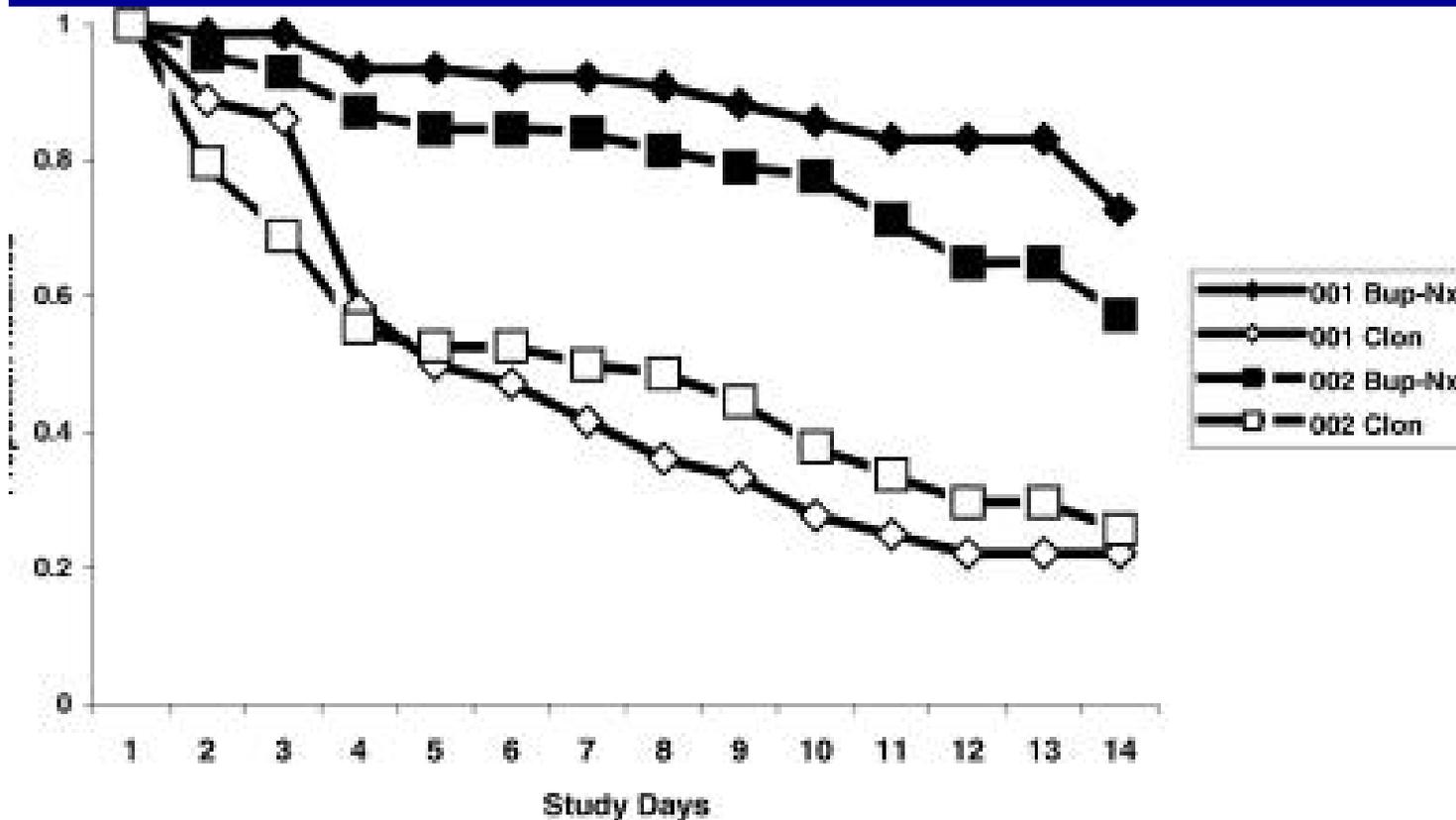
Adapted from Johnson, et al., 2000

Effects of Buprenorphine Maintenance Dose on μ -Opioid Receptor Availability



Source: Greenwald, MK et al, *Neuropsychopharmacology* 28, 2000-2009, 2003.

Buprenorphine-Naloxone Increases Patient Retention, Compared To Clonidine

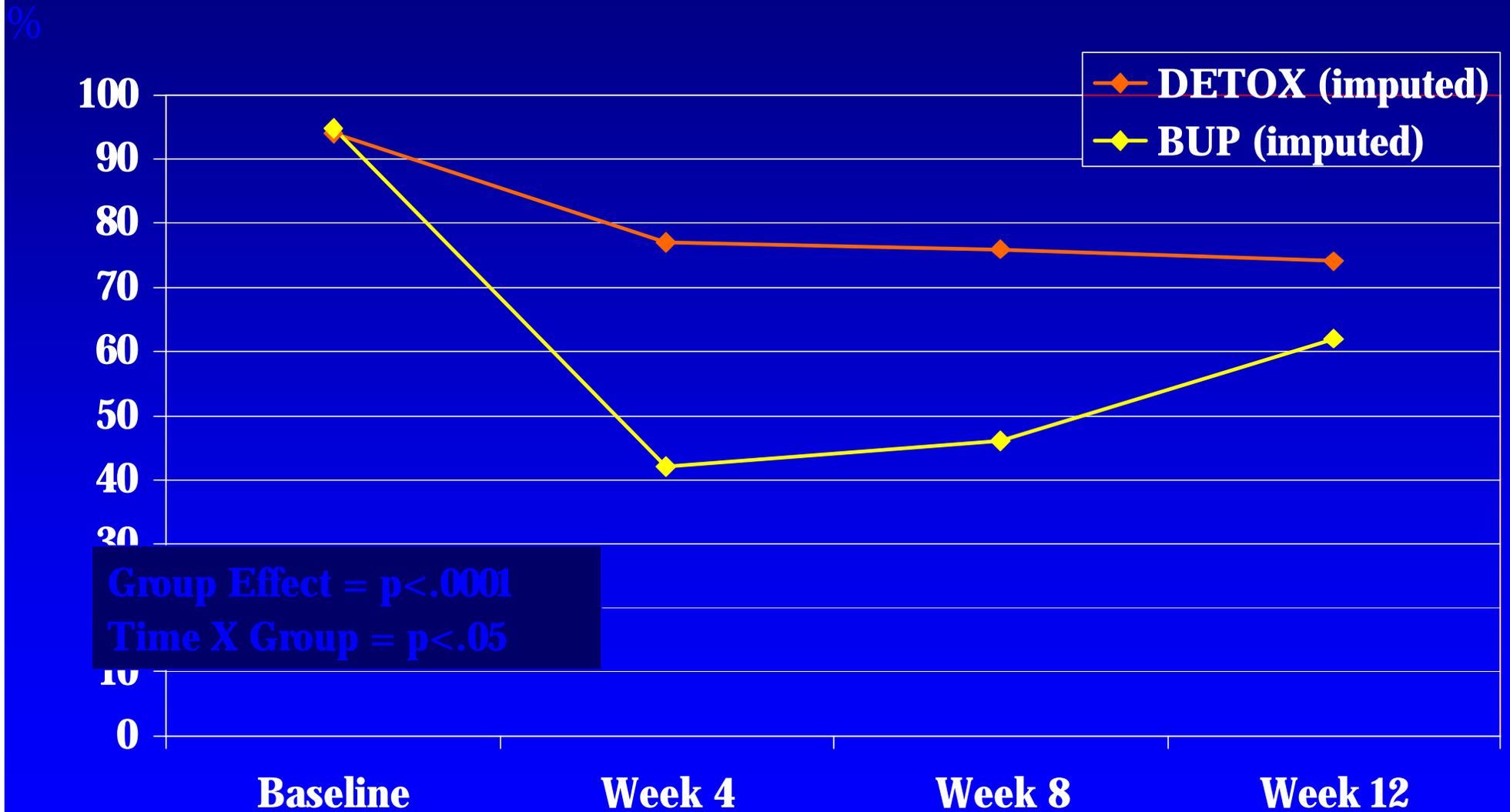


In a recent study, about 80% of those receiving buprenorphine continued in further treatment, compared to 30% receiving clonidine.

Cite: Brigham et al., JSAT, 2007

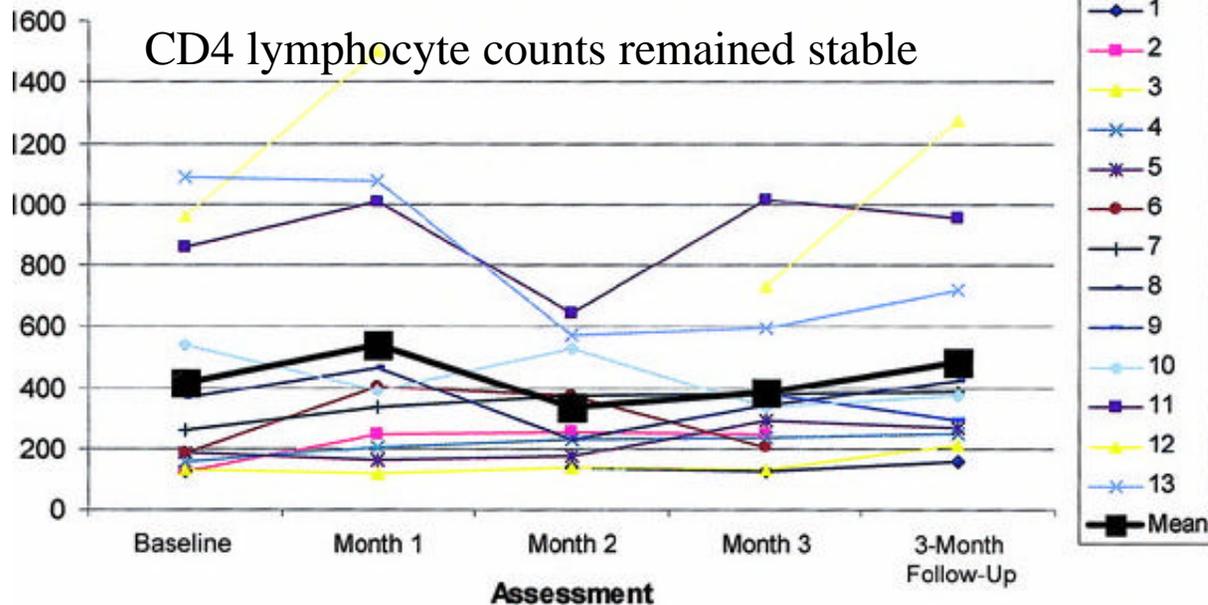
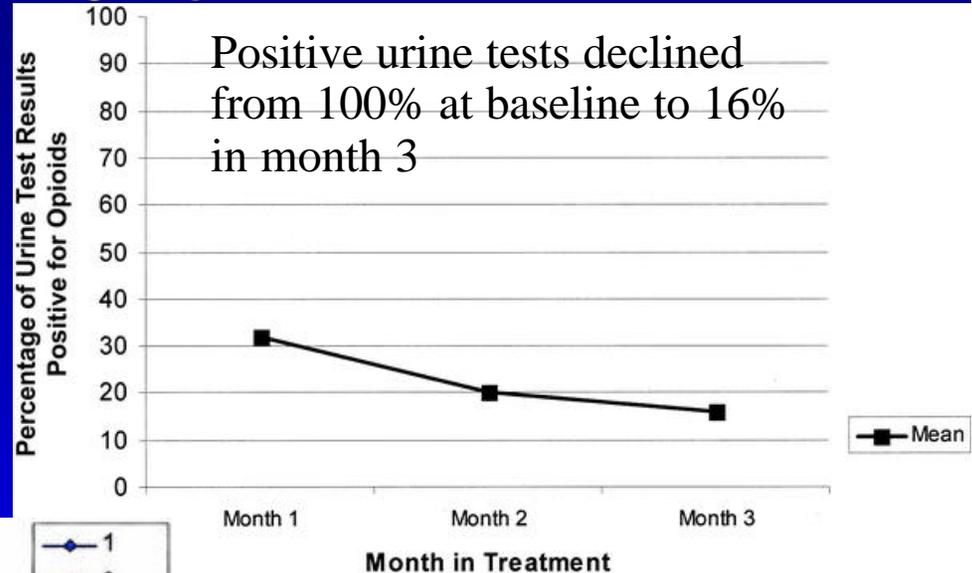
Have We Learned Anything New?

Buprenorphine/Naloxone-Facilitated Rehabilitation for Heroin Addicted Adolescents/Young Adults



HIV Patients Benefit From Buprenorphine/Naloxone Treatment

- 16 HIV-positive, opioid-dependent patients rcd bup/naloxone for 12 wks



- 81% of the patients completed the 12 weeks of treatment

Buprenorphine Interactions with Antiretroviral Medications

- Like methadone, **buprenorphine concentration** is significantly **reduced** when administered with the nonnucleoside reverse-transcriptase inhibitor efavirenz
- Unlike methadone, **no opioid withdrawal syndrome** observed in volunteers receiving buprenorphine/naloxone maintenance with efavirenz
- Findings from studies with the nucleoside reverse-transcriptase inhibitor zidovudine, with nonnucleoside reverse-transcriptase inhibitor delavirdine, and with protease inhibitors (nelfinavir, lopinavir/ritonavir and ritonavir) indicate that pharmacokinetic interactions occur, resulting in **altered buprenorphine exposure**; pharmacodynamically, however, these have not been of clinical significance
- **Antiretroviral medication concentrations not significantly affected** by buprenorphine/naloxone
- **Over sedation** and probable **opioid excess** was found in a case study with patients receiving buprenorphine/naloxone and ritonavir

Interaction Between Buprenorphine and Atazanavir or Atazanavir/Ritonavir

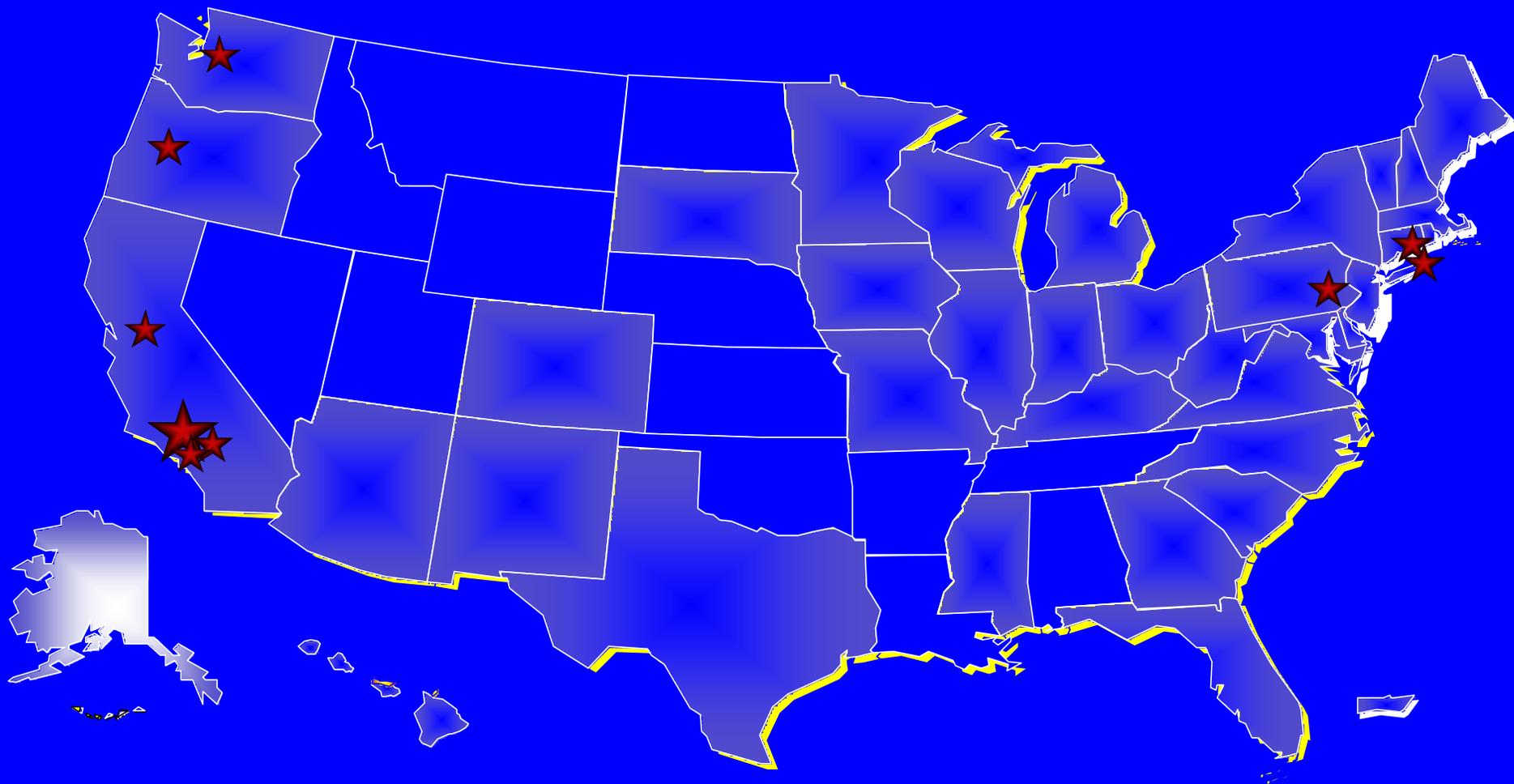
- Buprenorphine treatment did not significantly alter atazanavir or ritonavir concentrations
- Buprenorphine dose should be monitored as atazanavir/ritonavir may increase buprenorphine metabolite concentrations
- Increased sedation may occur with atazanavir/ritonavir

Buprenorphine appears to be safe and effective in individuals with acute Hepatitis C

- Previous studies have raised concerns about hepatotoxicity by BUP, particularly among those with Hepatitis C
- Most of these studies had mitigating factors (consuming alcohol, other psychoactive meds)
- In one case study, four opioid dependent patients with acute Hepatitis C tolerated BUP treatment and had improved liver transaminases during their treatment

National Drug Abuse Treatment Clinical Trials Network (CTN)

Starting Treatment with Agonist Replacement Therapies - START



 Study Lead - Drs. A. Saxon, W.Ling et al.

 Participating Site

CTN-0027

Design

A randomized, open-label, parallel-group, multicenter study, Phase 4 study to compare changes in liver enzymes related to treatment with BUP/NX to changes in liver enzymes related to treatment with MET

Main Aims

Compare changes in liver enzymes related to treatment with BUP/NX to changes related to MET over 24 week maintenance period of 600 opioid dependent pts.

Identify risk factors at baseline and during treatment that could contribute to interactions with BUP/NX or MET causing liver dysfunction

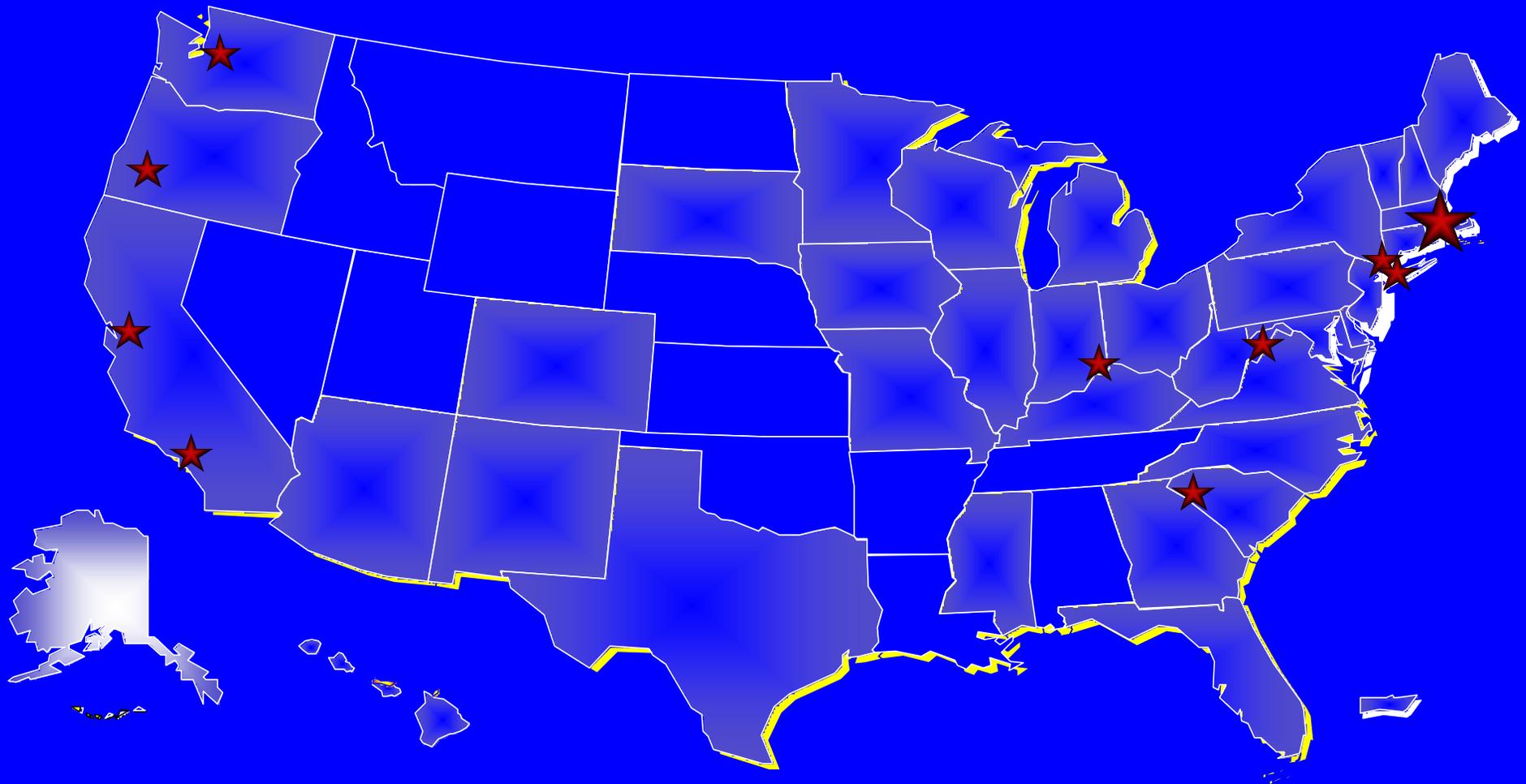
Assess abstinence from illicit substances and alcohol

Ancillary Genetics Study

- To study the frequency of gene variants that have primarily been associated with addiction.
- To examine the relationship between treatment drug plasma concentrations and gene variants associated with drug disposition and transport.

National Drug Abuse Treatment Clinical Trials Network (CTN)

Prescription Opioid Addiction Treatment Study



Study Lead – Drs. R. Weiss, W. Ling et al.



Participating Site

CTN-0030

Rationale

- Prescription opioid dependence is a growing problem, esp. in some areas of U.S.
- Population consists of a continuum, from legitimate pain pts to street/Internet buyers.
- TAU varies widely from brief detox to maintenance, with associated wide ranging psychosocial interventions.

This is the first national study that examines

Main Questions

- Office-based opioid treatment model vs. Drug abuse treatment program model
- What is the optimal length of BUP/NX treatment for this population: 1 month? 3 months? Maintenance? And for whom?
 - Do chronic pain patients do better or worse?
 - Do patients who have ever used heroin do worse?

**ROADBLOCK : Although Treatments
For **Addiction** Are Available, They Are Not
Being Widely Used By Those Who Need Them**

In 2006, An Estimated
22.6 Million Americans
Were Dependent On or Abused
Any Illicit Drugs or Alcohol

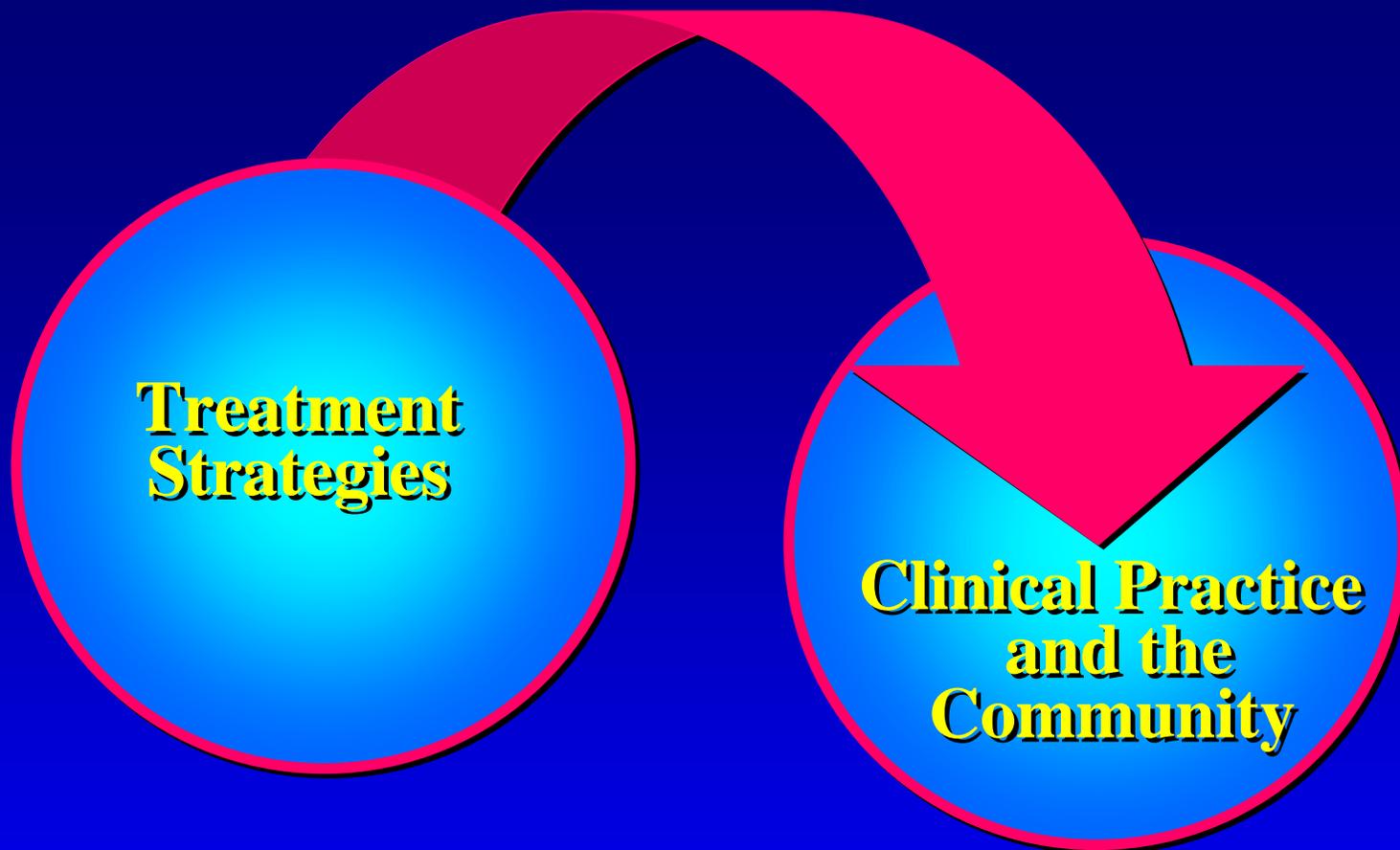
But...Only **4 Million (17.7%)**
of These Individuals
Had Received Some Type of
Treatment In the Past Year



Community

Bedside

Bench



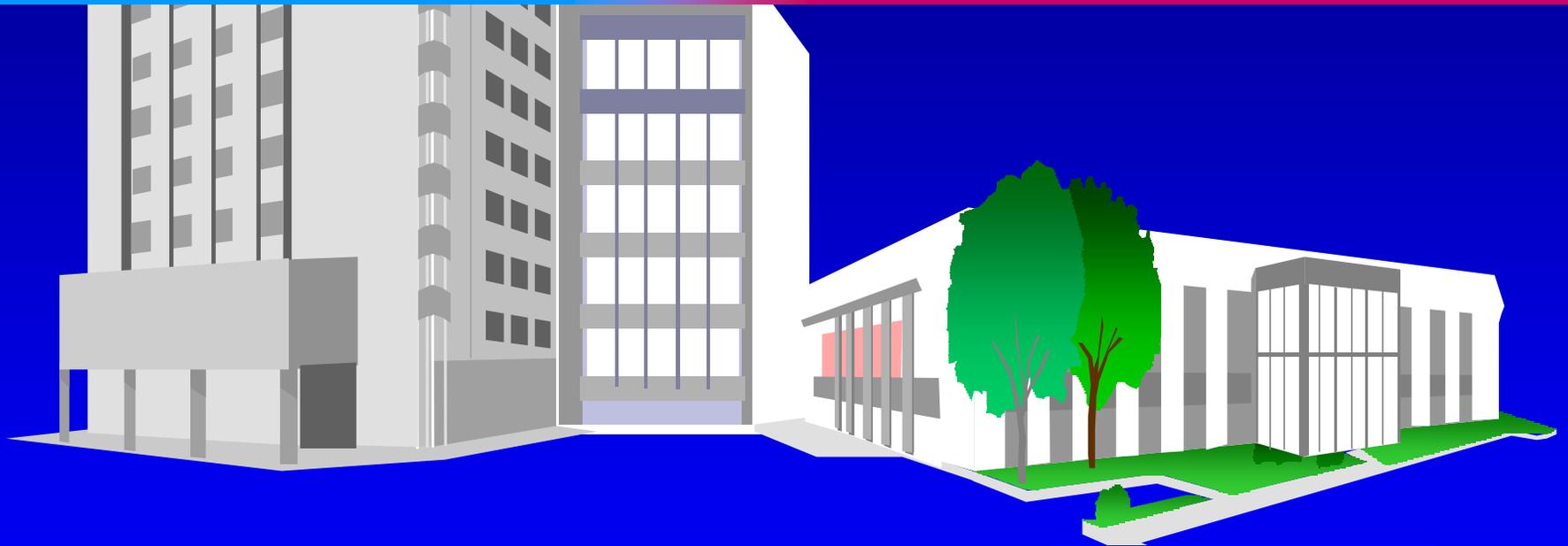
As we strengthen our *knowledge* on treatment of addiction it becomes increasingly urgent to... expand our research on strategies to optimize their *translation* into clinical practice and the community

*Our Strategy Involves **BLENDING***

RESEARCH

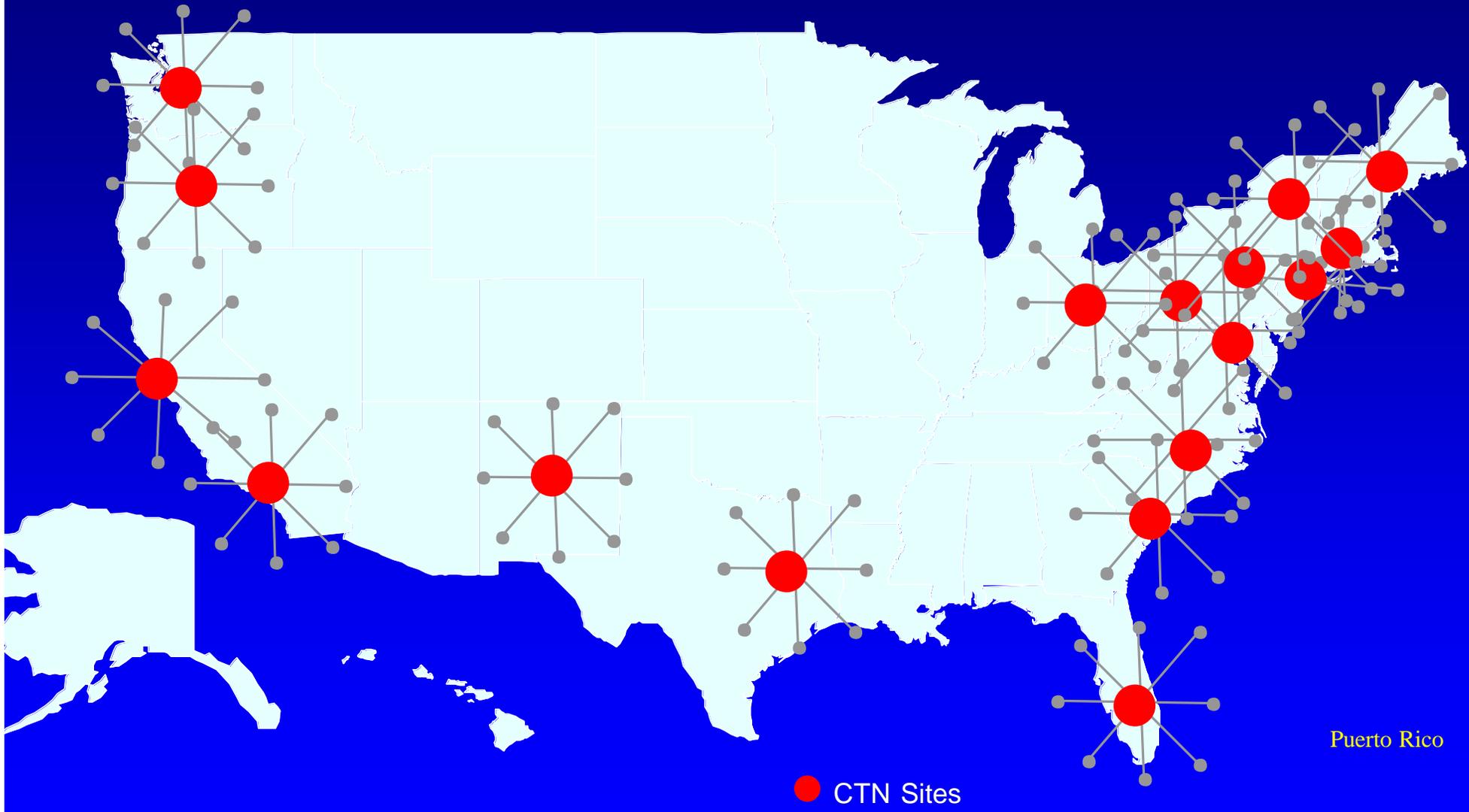
and

PRACTICE



*Bringing User-friendly Science-Based
Technologies
Into Ongoing Community Practice*

National Drug Abuse Treatment Clinical Trials Network

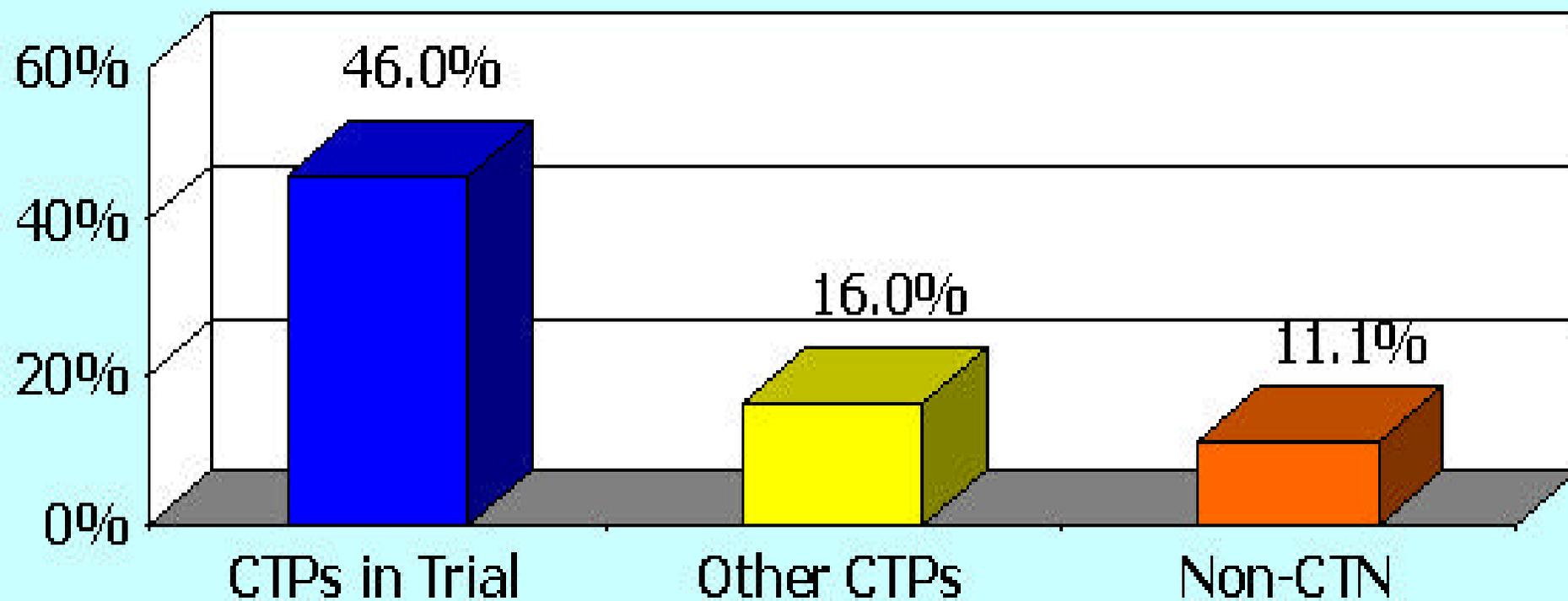


Puerto Rico

As of February 20, 2008

Research Utilization

An Example with Adoption of Buprenorphine

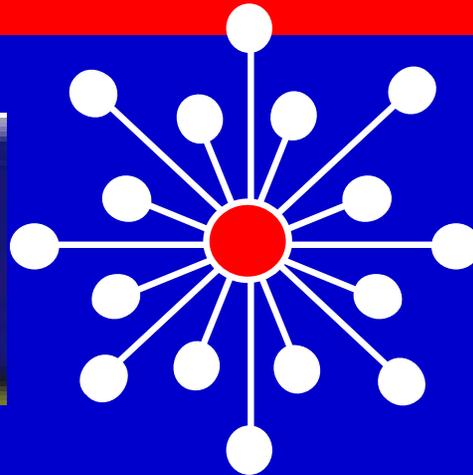


Source: Roman et al Presented 2006

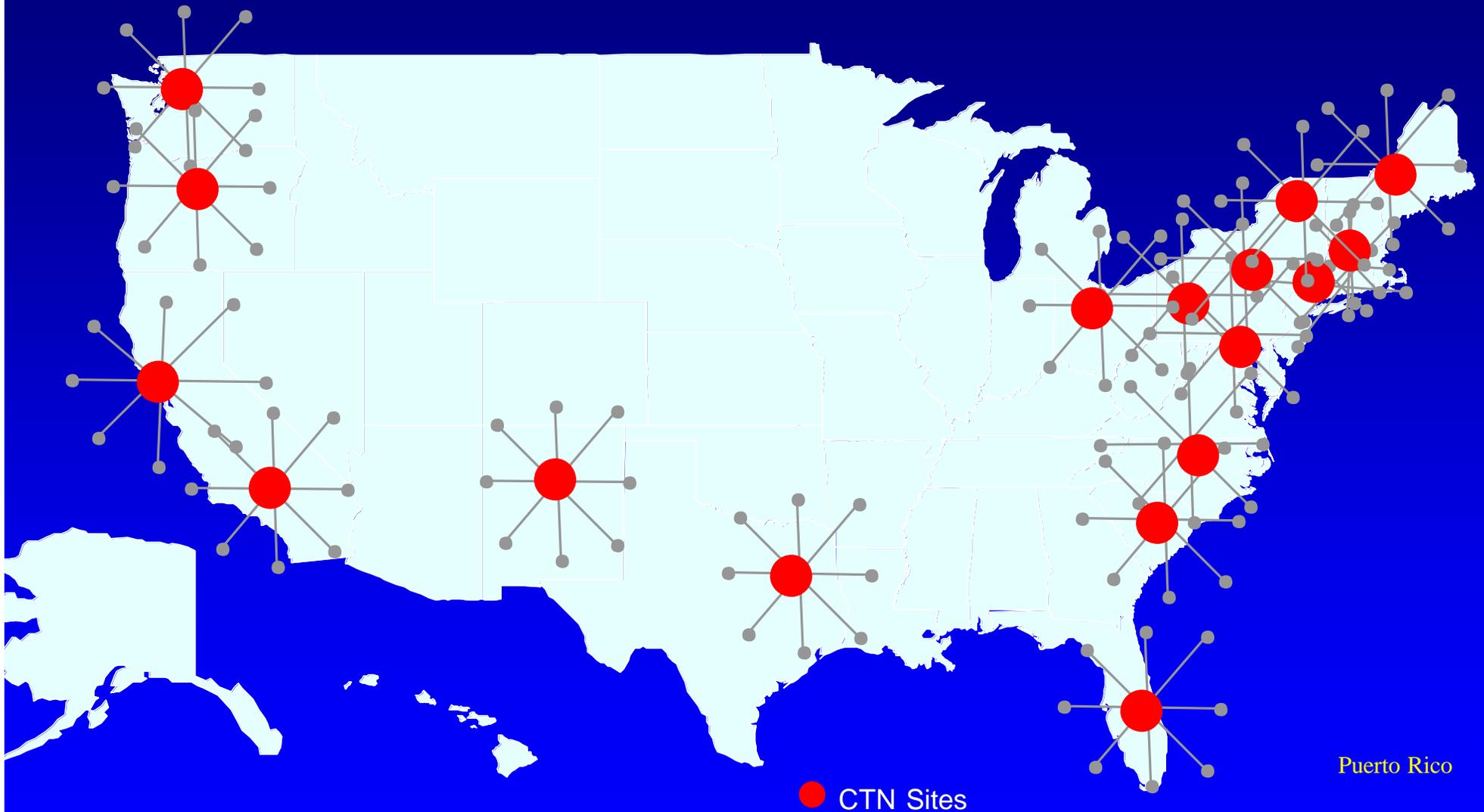
**NIDA & SAMHSA have partnered
to conduct and disseminate
research findings for application in
the community**



***Partnerships Are Essential In
Advancing the Science of Addiction
and in Translating Promising
Strategies into Practice***

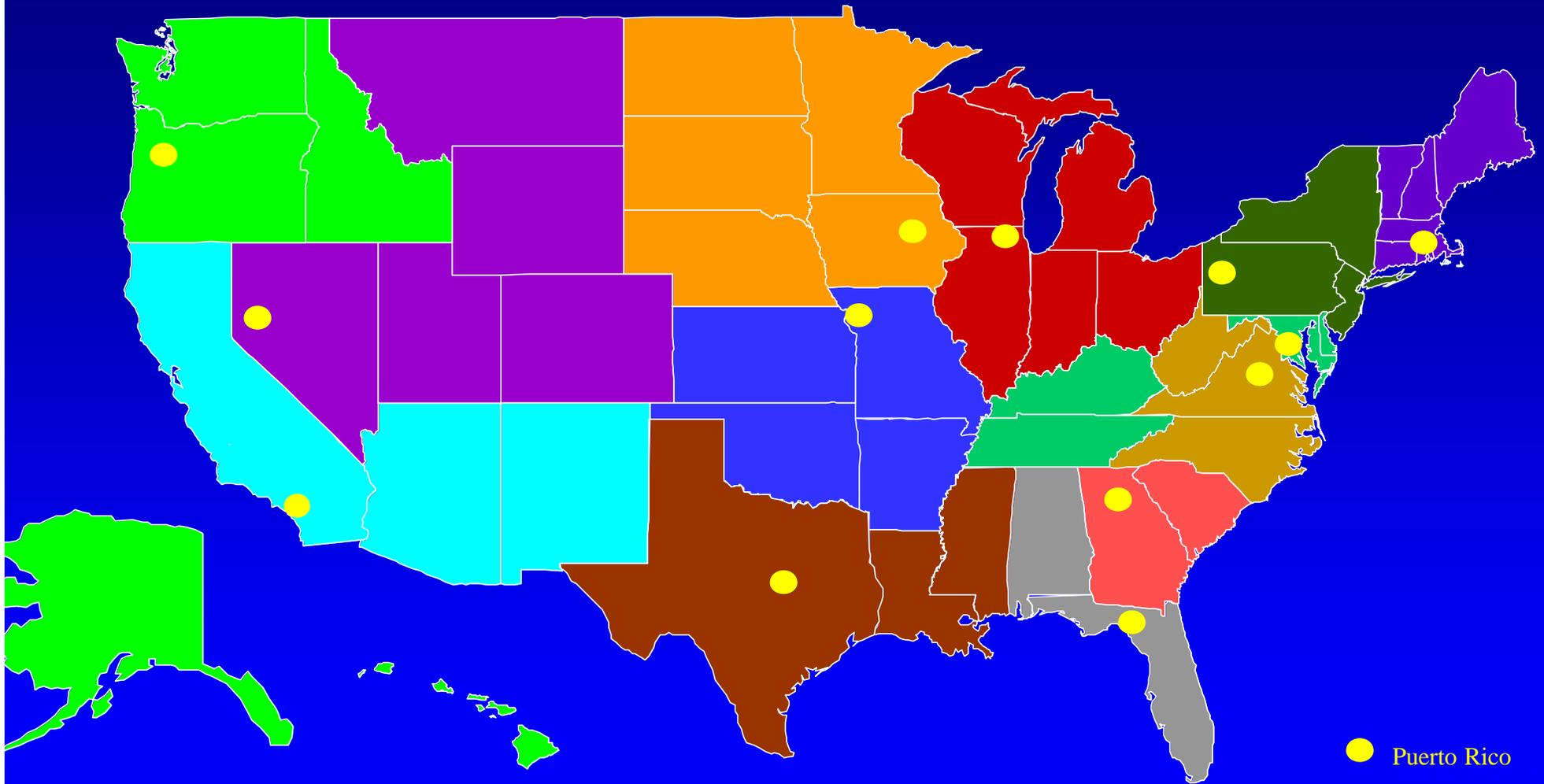


National Drug Abuse Treatment Clinical Trials Network



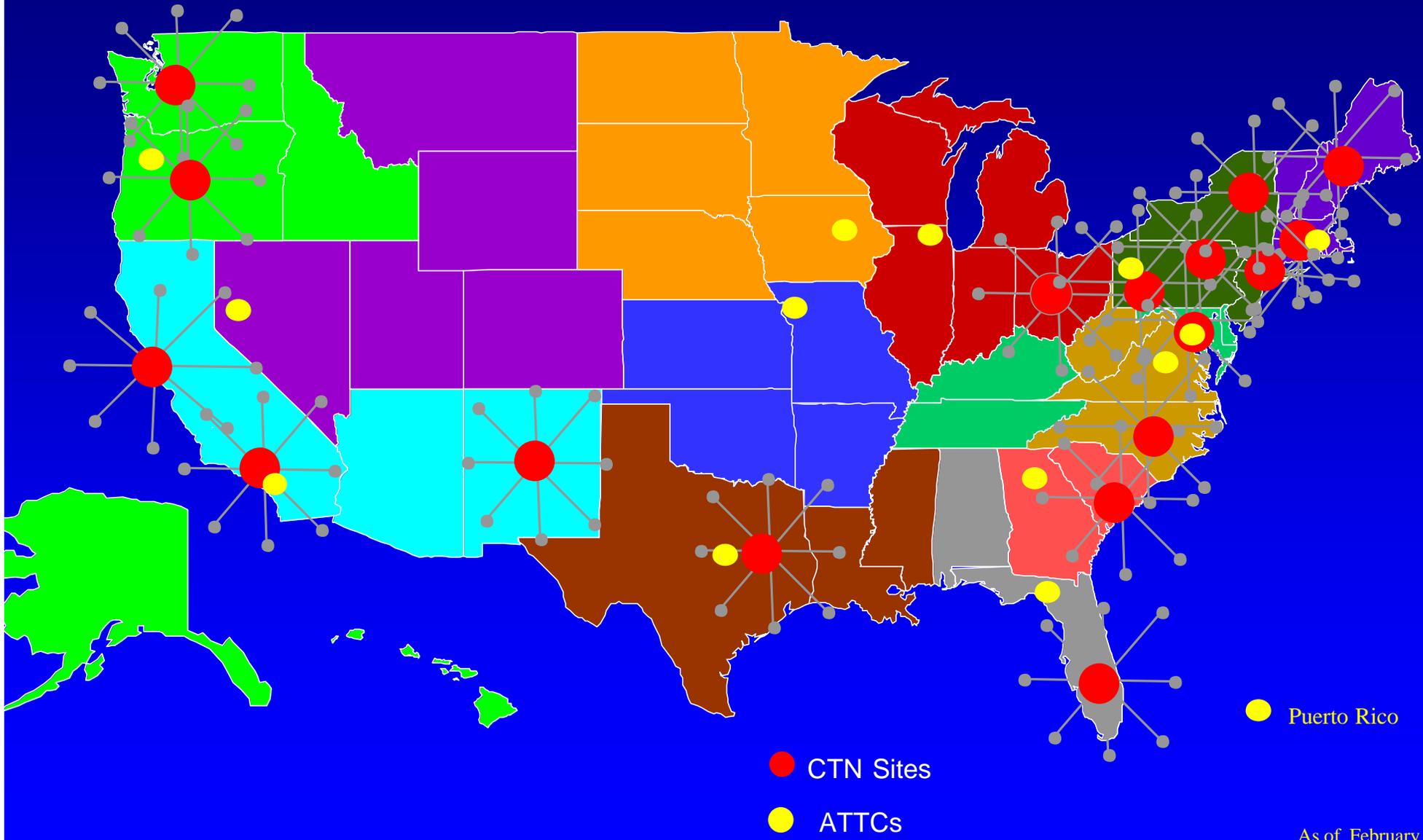
As of February 20, 2008

SAMHSA/CSAT Addiction Technology Transfer Centers



As of February 20, 2010

National Drug Abuse Treatment Clinical Trials Network and The Addiction Technology Transfer Centers



As of February 20, 2000

Second Component: NIDA-SAMHSA Blending Team

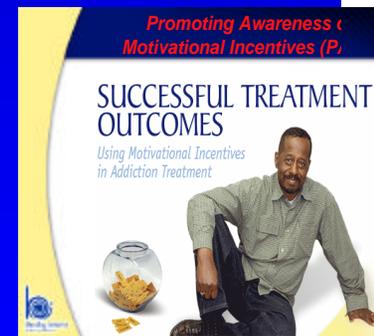
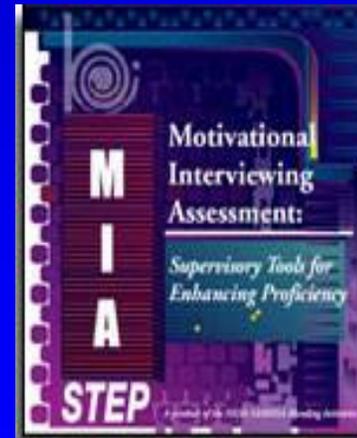
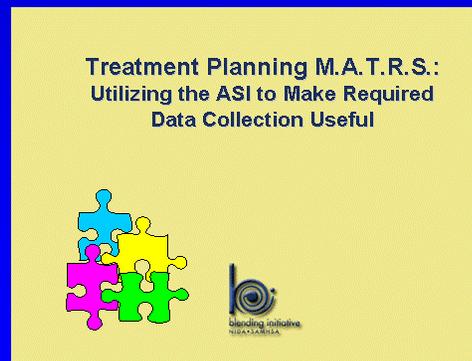
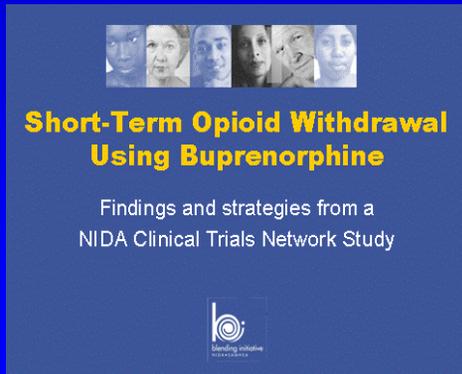
Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals

Short-Term Opioid Withdrawal Using Buprenorphine

Treatment Planning: MATRS: Utilizing the Addiction Severity Index (ASI) to Make Required Data Collection Useful

Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency (MIA-STEP)

Promoting Awareness of Motivational Incentives (PAMI)



Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals – Available Training Materials

- 6-hour classroom training program providing an overview of buprenorphine treatment
- Self-paced CD-ROM awareness course on buprenorphine treatment
- Annotated bibliography
- Research articles
- Brochure

Buprenorphine Treatment:
A Training for
Multidisciplinary
Addiction Professionals

The primary goal of this training package is to create awareness about buprenorphine among multidisciplinary addiction professionals. The materials include information designed to increase motivation for bringing buprenorphine to local communities, as well as information about what to expect when someone is treated with this medication.



blending initiative
NIDA • SAMHSA

Additionally, materials discuss legislation that permits office-based buprenorphine treatment, the science of addiction, the mechanism of buprenorphine, patient selection issues, and various patient, counseling, and therapeutic issues.

Short-Term Opioid Withdrawal Using Buprenorphine: Available Training Materials

- 4-hour classroom training providing step-by-step instructions on using buprenorphine for opioid dependent patients
- PowerPoint slides and CD
- Brochure
- Resources and bibliography

Short-Term Opioid Withdrawal
Using Buprenorphine: Findings
and Strategies from a NIDA
Clinical Trials Network Study

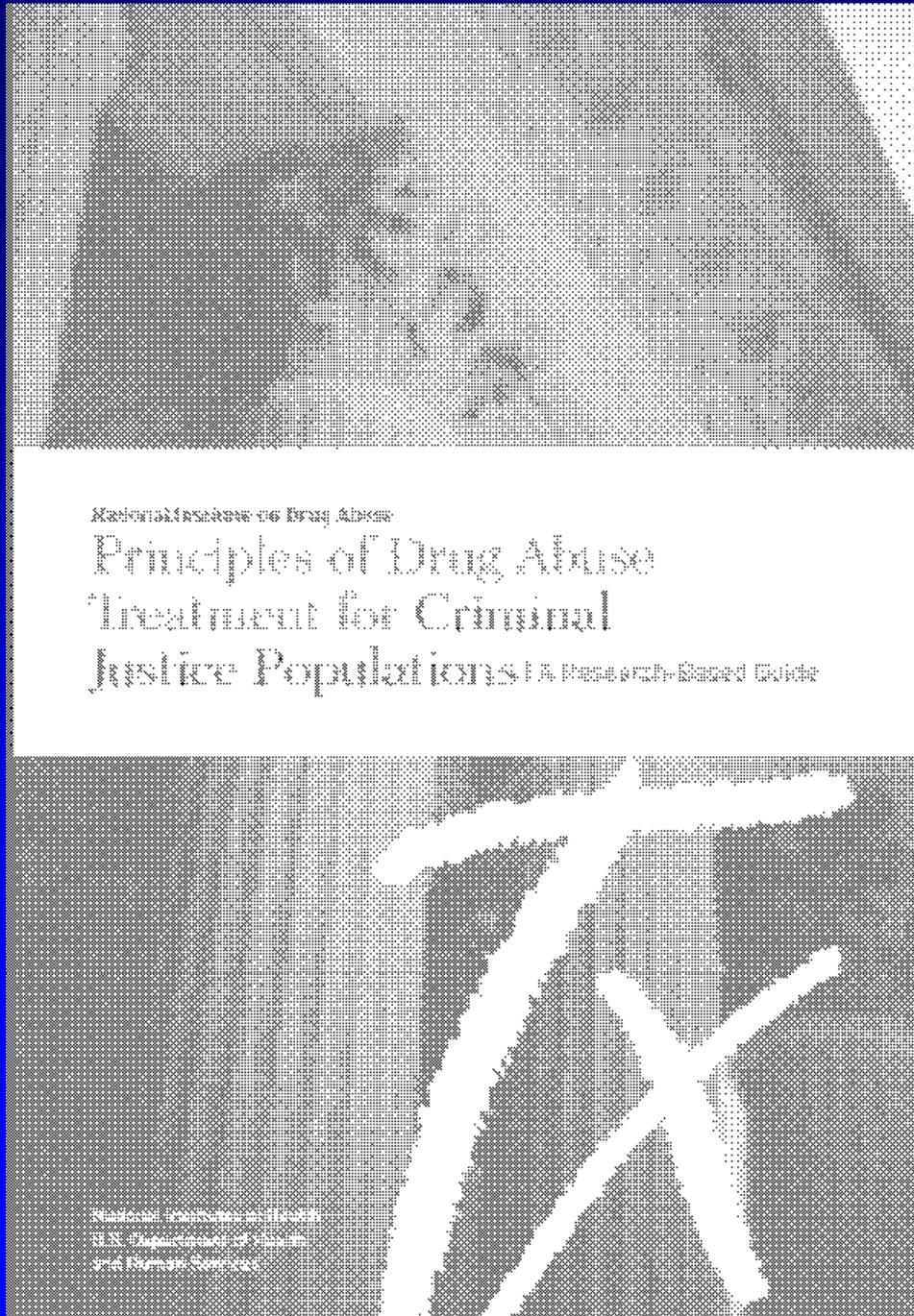
The primary goal of this training package is to instruct providers on the administration of a 10-day buprenorphine taper for opioid dependent patients. The training will review the results from research conducted by the NIDA Clinical Trials Network comparing buprenorphine versus clonidine in both inpatient and outpatient settings. The training will then provide instruction for implementing this protocol into treatment settings. Topics will include methods of evaluation and induction, the taper schedule, and use of ancillary medications during treatment. 4





**NIDA is Reaching Out to the Criminal
Justice Community**

**The Primary goal is to stop the vicious cycle
of drug abuse and criminal involvement**



National Institute on Drug Abuse

Principles of Drug Abuse
Treatment for Criminal
Justice Populations: A Research-Based Guide

National Institutes of Health
U.S. Department of Justice
Office of Human Services

**NIDA released
Publication as
Part of Its
Criminal Justice
Initiative**

Buprenorphine for Prisoners

Timothy W. Kinlock, Friends Research Institute
R01DA021579

Will examine:

- Effectiveness of buprenorphine administration to previously-addicted male *and* female inmates
- Effect of post-release treatment setting [opioid treatment program (OTP) vs. a community health center (CHC)]
- Outcome measures include: treatment entry and retention in the community, heroin use, cocaine use, HIV infection, HIV-risk behaviors, criminal activity, and employment

Buprenorphine: Where We Are Going Next

- We will continue to test the safety and efficacy of buprenorphine in other affected populations, including pregnant women, adolescents, and patients addicted to opiate analgesics.
- Working with SAMHSA's Addiction Technology Transfer Centers (ATTCs), State Directors, and other stakeholders, we are continuing to disseminate research information about buprenorphine to more proactively address the urgent needs of drug addiction.
- We are striving to increase the use of this and other addiction medications in different settings and locales, including in the U.S. criminal justice system and in countries where injection drug use is still a primary mode of HIV transmission.

SAVE THE DATE!

June 2-3, 2008 • Cincinnati, Ohio

Blending Addiction Science and Treatment:

*The Impact of Evidence-Based Practices
on Individuals, Families and Communities*

www.NIDABlendingConference.info



NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

National Institute on Drug Abuse
National Institutes of Health
U.S. Department of Health and Human Services

UNIVERSITY OF
UC
Cincinnati

 University of Pittsburgh

Visit Our Website @



The screenshot shows the homepage of the National Institute on Drug Abuse (NIDA). The header includes the NIDA logo, the text "NATIONAL INSTITUTE ON DRUG ABUSE", the tagline "The Science of Drug Abuse & Addiction", and the National Institutes of Health logo. A navigation bar contains links for HOME, ABOUT NIDA, NEWS & EVENTS, FUNDING, and PUBLICATIONS. Below this is a search bar and a "SELECT A TOPIC..." dropdown menu. The main content area is divided into several sections: "Drug Abuse Treatment for Criminal Justice Populations" with an icon of a hand holding a key; "News & Events" with a list of recent announcements; "Students & Young Adults" with education resources; "Parents & Teachers" with curriculum guides; "Researchers, Physicians & Other Health Professionals" with grants and funding information; "Drugs of Abuse" with a list of substances including Acid/LSD, Alcohol, Club Drugs, Cocaine, Ecstasy/MDMA, Heroin, Inhalants, Marijuana, Methamphetamine, PCP/Phencyclidine, Prescription Medications, Smoking/Nicotine, and Steroids (Anabolic); and "Related Topics" with links to Divisions, Centers, Offices, Clinical Trials Network, and Crime & Drug Abuse Treatment. A large blue banner with the website URL "www.drugabuse.gov" is overlaid on the bottom half of the page.

NIDA NATIONAL INSTITUTE ON DRUG ABUSE
The Science of Drug Abuse & Addiction

NATIONAL INSTITUTES OF HEALTH

keep your body healthy

HOME | ABOUT NIDA | NEWS & EVENTS | FUNDING | PUBLICATIONS

RESEARCHERS & HEALTH PROFESSIONALS | PARENTS & TEACHERS | STUDENTS & YOUNG ADULTS | EN ESPAÑOL

SELECT A TOPIC... GO

Drug Abuse Treatment for Criminal Justice Populations

News & Events

- NIDA Announces Recommendations To Treat Drug Abusers. Save Money.

Students & Young Adults

Education resources & materials on drugs of abuse, marijuana, ecstasy, smoking, steroids, ([more](#))

Parents & Teachers

Drug information & facts, education materials, curriculum guides, classroom tools, ([more](#))

Researchers, Physicians & Other Health Professionals

Grants & funding, treatment prevention research.

Drugs of Abuse

- Acid/LSD
- Alcohol
- Club Drugs
- Cocaine
- Ecstasy/MDMA
- Heroin
- Inhalants
- Marijuana
- Methamphetamine
- PCP/Phencyclidine
- Prescription Medications
- Smoking/Nicotine
- Steroids (Anabolic)

Related Topics

- Divisions, Centers, Offices
- Clinical Trials Network
- Crime & Drug Abuse Treatment

Prescription Drugs (3/04)

- HIV/AIDS and Drug Abuse (11/05)
- Stress and Drug Abuse (9/05)
- Methamphetamine Abuse (4/05)

View and order publications produced by NIDA

NIDA Sites

- backtoschool.drugabuse.gov

www.drugabuse.gov

