

2010 Web Seminar Series

The Importance of the CTN

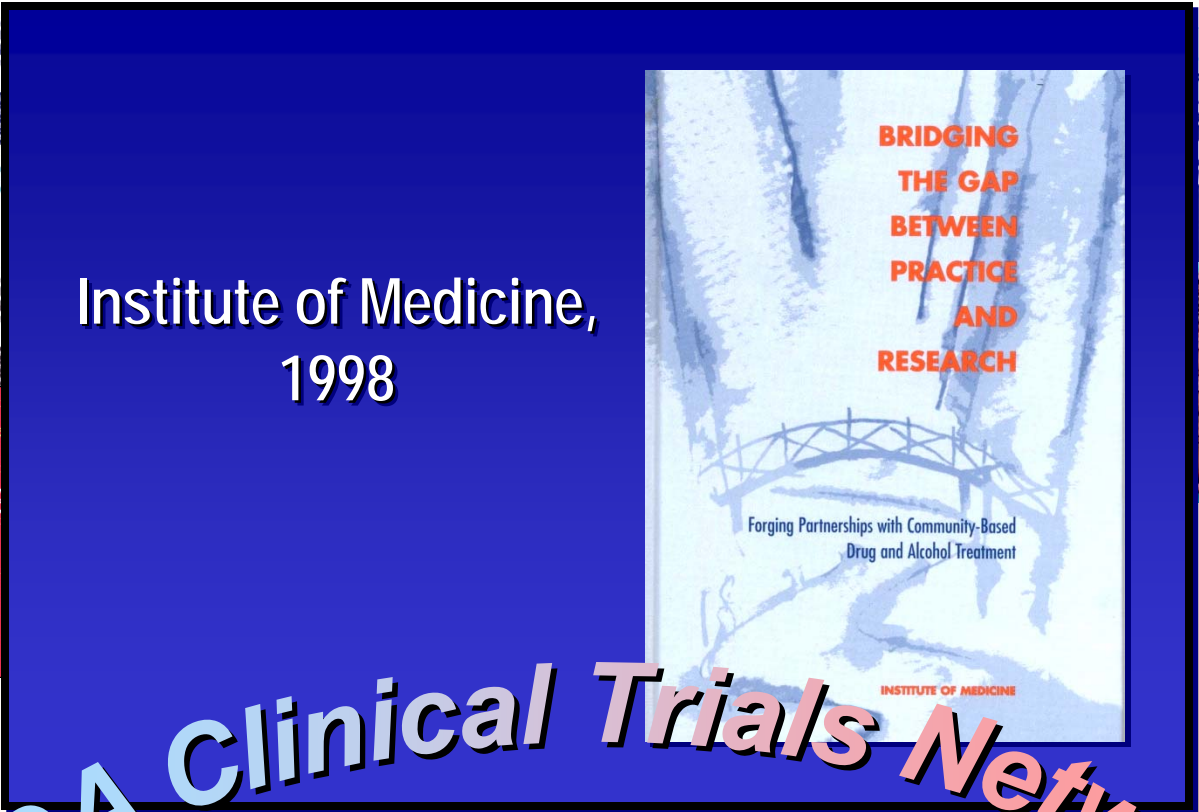
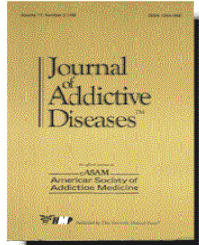
Betty Tai, Ph.D., Director

Center for the Clinical Trials Network

National Institute on Drug Abuse

Produced by Liz Buttrey, NIDA CTN CCC Training Office


"This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No.HHSN271200522081C."



NIDA Clinical Trials Network

Research
Bridging
the
Practice
Gap

CTN Premises

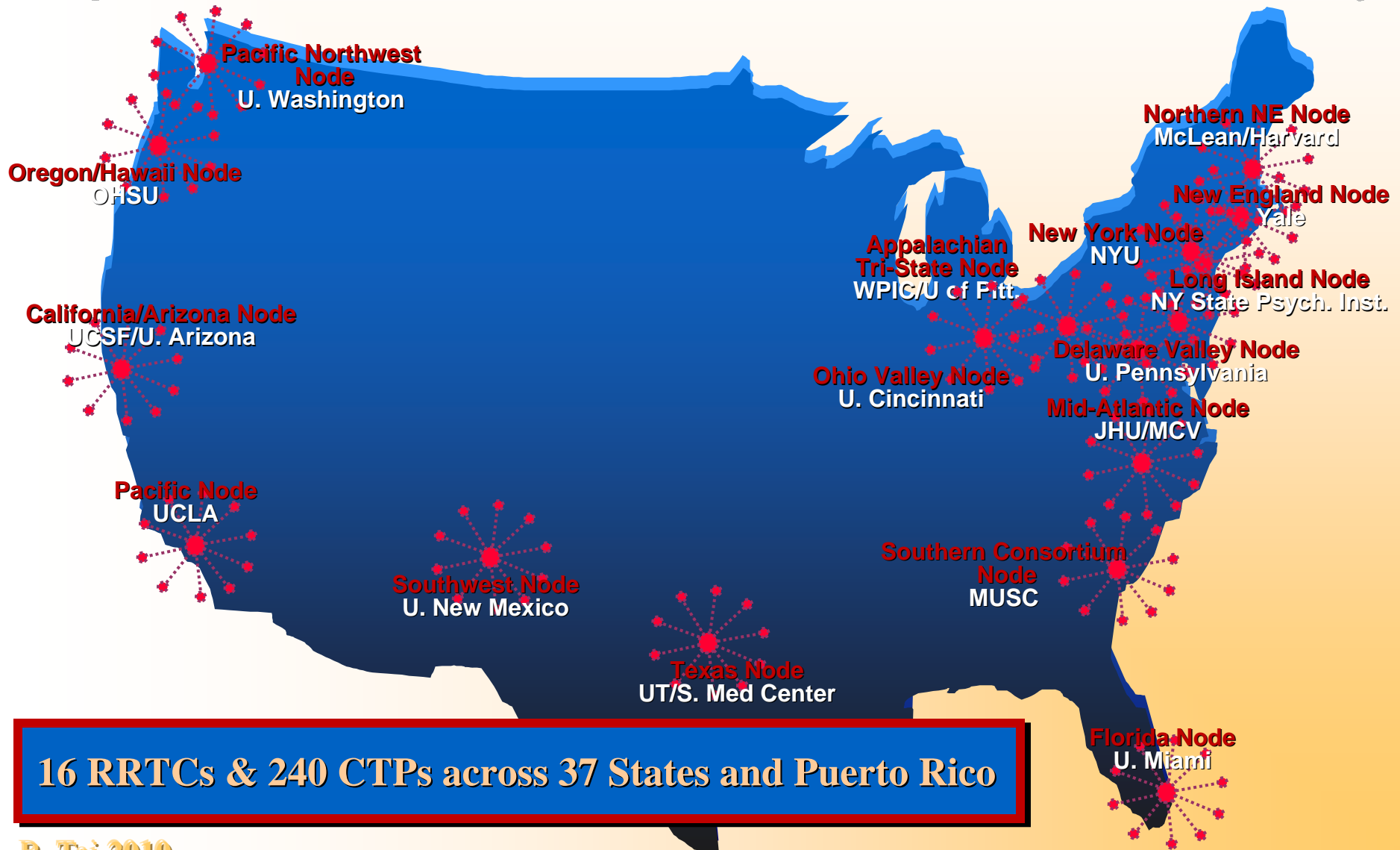
- 
- **Addiction treatment services will be improved as evidence-based treatments are broadly implemented in community-based treatment programs**
 - **Randomized, controlled clinical trials are the gold standard for generating evidence-based treatments**
 - **Engage the providers in the research process will improve the acceptability/adoption of research results**

Presentation Outline

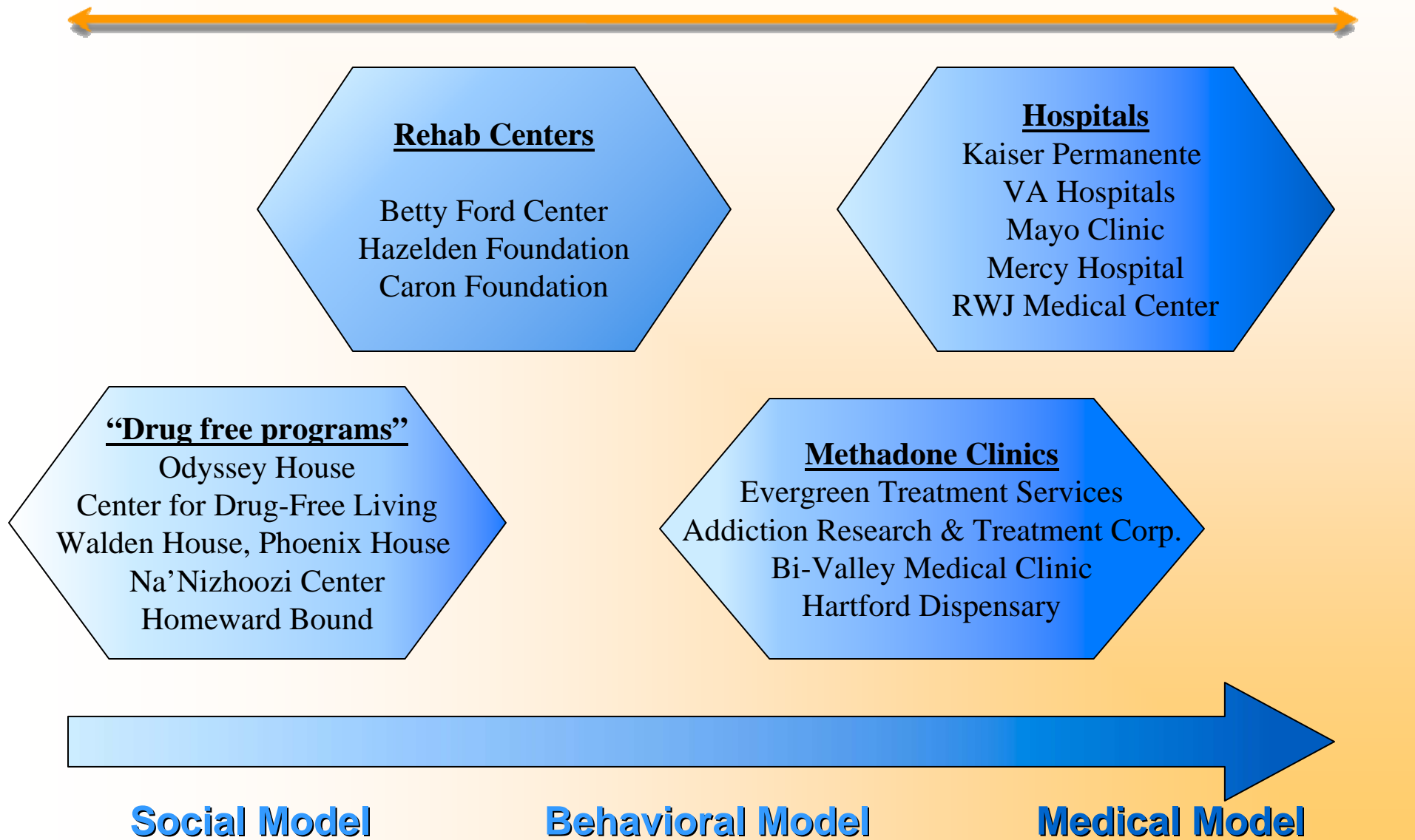


- ✓ Infrastructure
- ✓ Research
- ✓ Research utilization
- ✓ CTN impact

National Drug Abuse Treatment Clinical Trials Network



The Drug Abuse Treatment Community



CTN Coordinating Centers



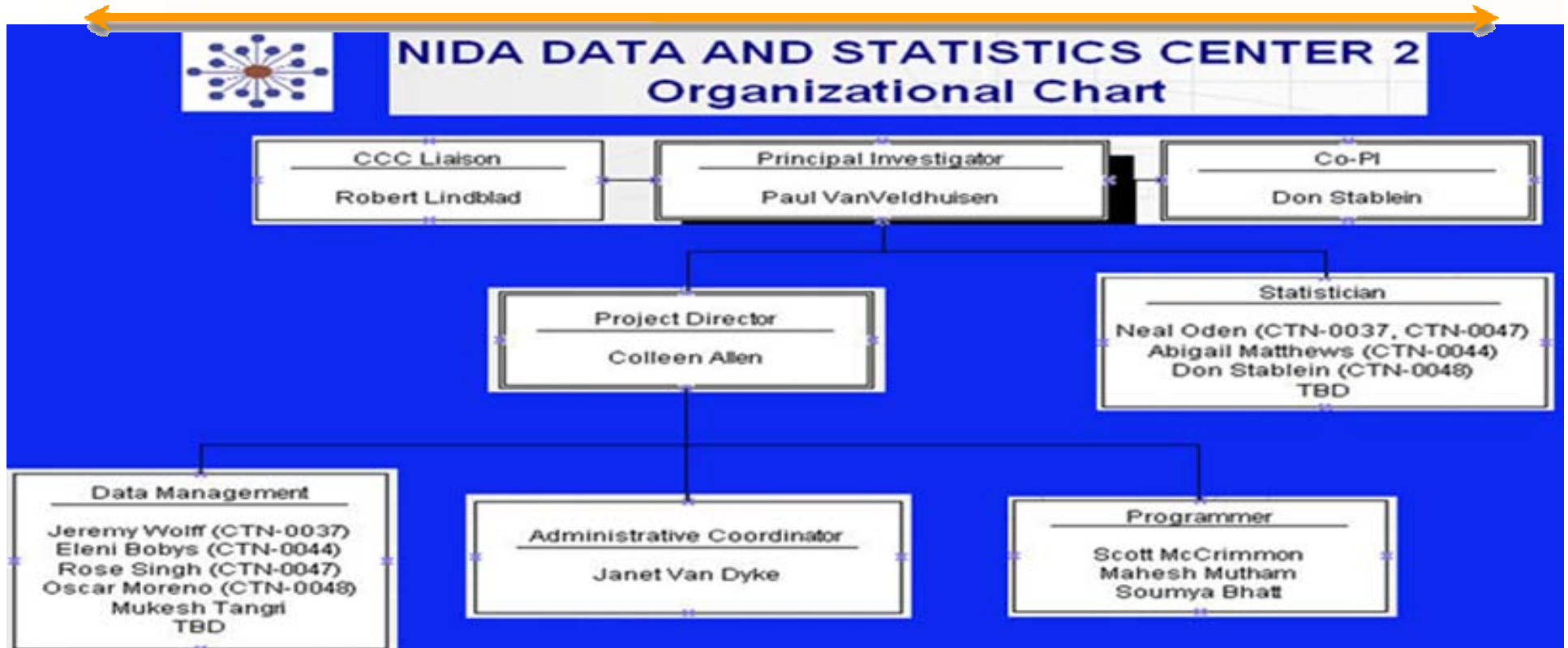
Organizational design of a multisite trial is as important to its success as is the experimental design.

Curtis Meinert, *Controlled Clinical Trials* 1, 305 (1981)

“Science and process are equally important to ensure success of large prospective studies.”

Timothy Sprosen, UK Biobank
NIH New Models for Large Prospective Studies symposium (1/22/2010)

CTN Coordinating Centers



CTN Data and Statistics Centers

- Provide statistical support for protocol design/analysis
- Provide data management via electronic data capture
- Monitor integrity and security of data

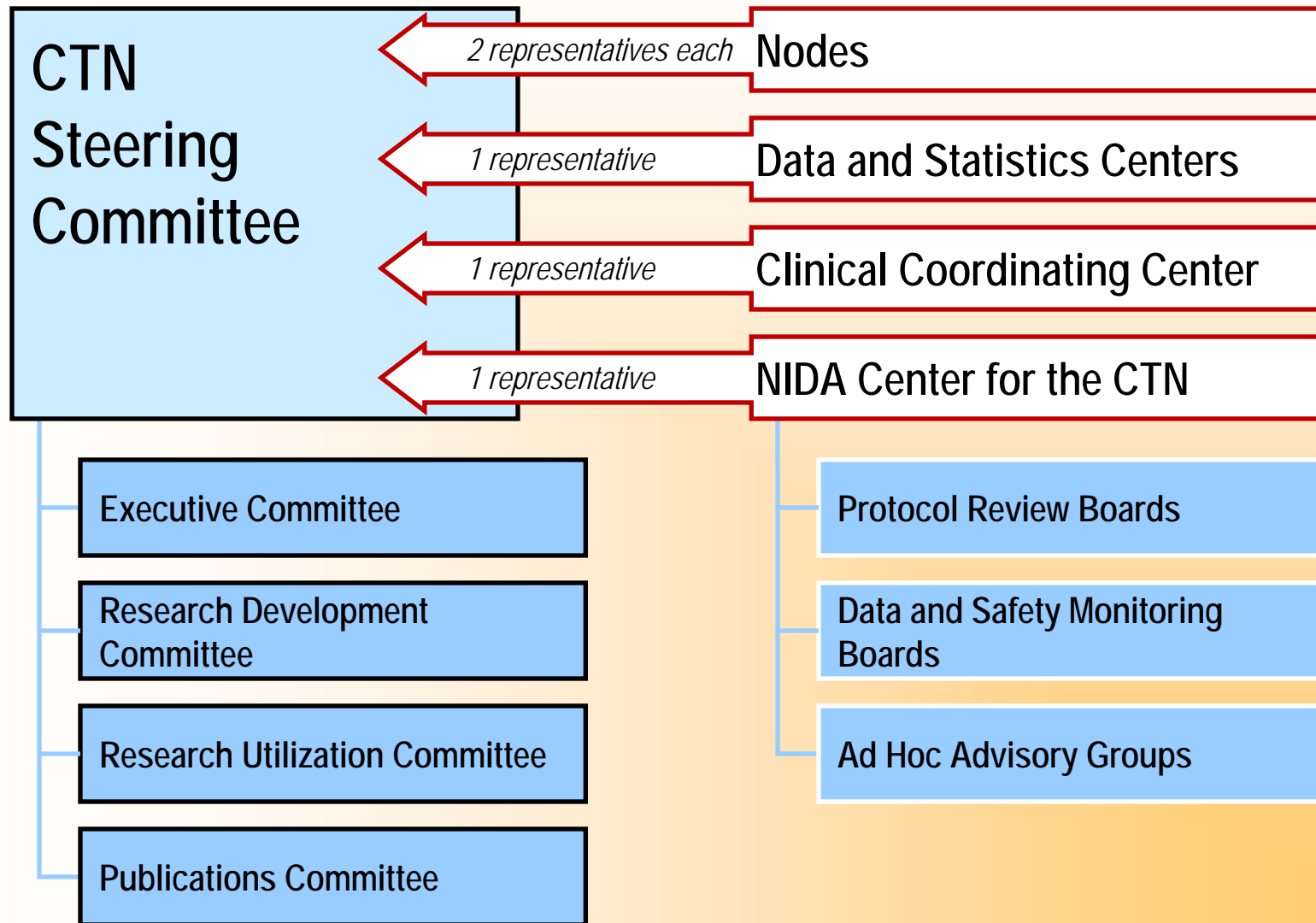
CTN Clinical Coordinating Center

- Provide centralized regulatory support, trial monitoring, training in clinical trials implementation procedures
- Uniform handling of pharmaceuticals, laboratory and clinical supplies

Center for the Clinical Trials Network



CTN Governance Infrastructure

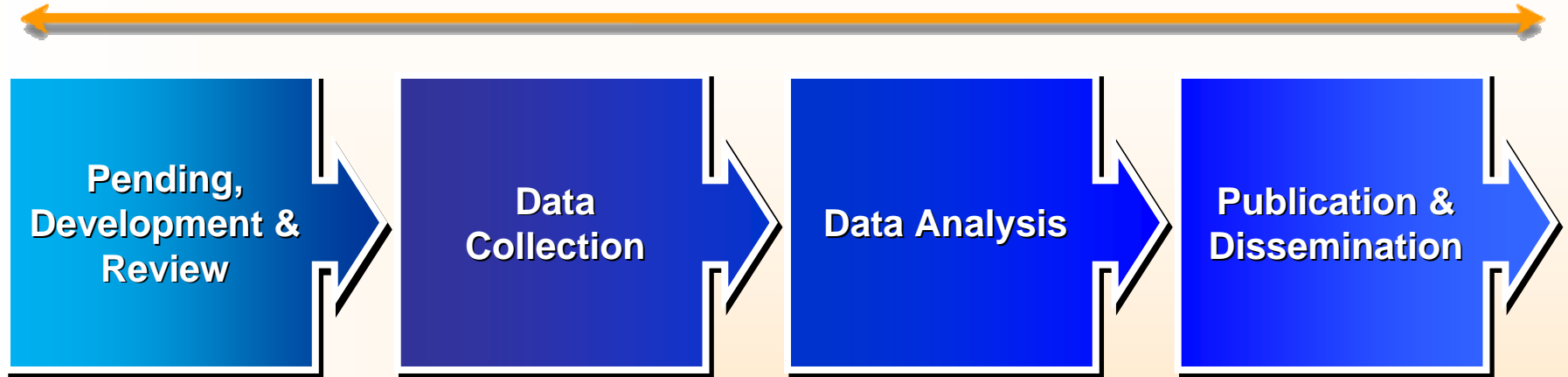


Presentation Outline



- ✓ Infrastructure
- ✓ Research
- ✓ Research utilization
- ✓ CTN next decade

The CTN Trials (1999-now)



CTN 0037
CTN 0047
CTN 0048

CTN 0027
CTN 0044
CTN 0046

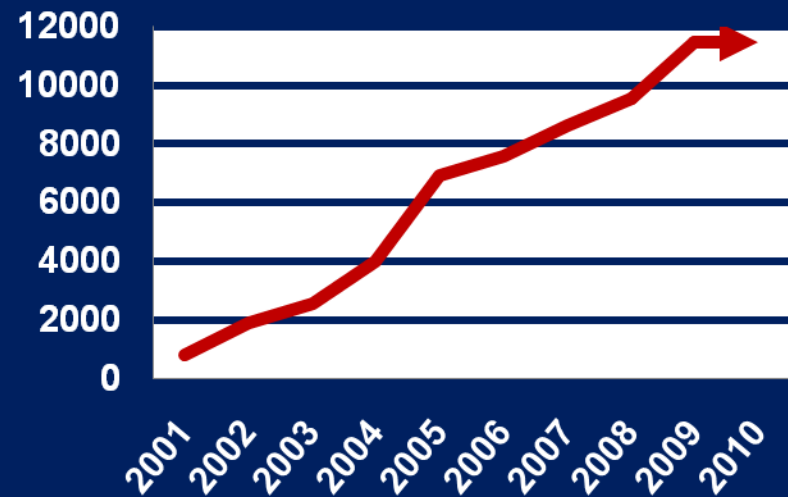
CTN 0014
CTN 0028
CTN 0030
CTN 0031
CTN 0032

CTN 0001 **CTN 0012**
CTN 0002 **CTN 0013**
CTN 0003 **CTN 0015**
CTN 0004 **CTN 0016**
CTN 0005 **CTN 0017**
CTN 0006 **CTN 0018**
CTN 0007 **CTN 0019**
CTN 0008 **CTN 0020**
CTN 0009 **CTN 0021**
CTN 0010 **CTN 0029**
CTN 0011

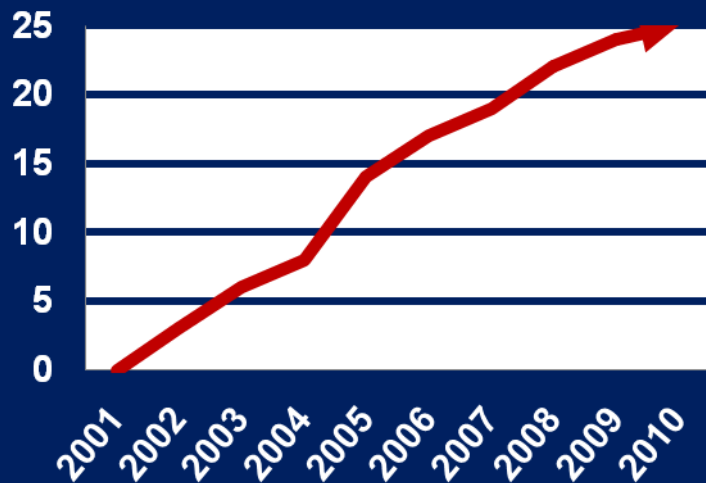
32 Studies address:
Pharmacotherapies: 15
Behavioral Interventions: 16
HIV/HCV Interventions: 4
Others: 3

A Decade of Growth: CTN by the Numbers

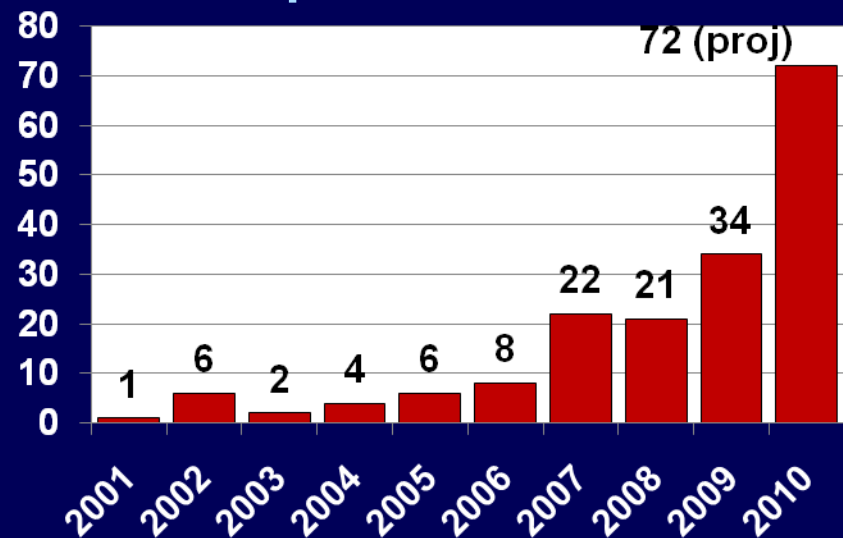
Randomized Participants



Completed Trials



Papers Published



CTN Trials in Development



- **STRIDE (CTN 0037):**
 - Stimulant Reduction Intervention Using Dosed Exercise
- **SMART-ED (CTN 0047)**
 - Screening, Motivational Assessment, Referral and Treatment in Emergency Departments
- **CURB (CTN 0048)**
 - Cocaine Use Reduction with Buprenorphine

Current CTN Trials in Recruitment



- **CTN-0044**
 - Web-delivery of Evidence-Based, Psychosocial Treatment for Substance Use Disorders.
- **S-CAST (CTN-0046)**
 - Smoking-Cessation and Stimulant Treatment Evaluation of the Impact of Concurrent Outpatient Smoking-Cessation and Stimulant Treatment on Stimulant-Dependence Outcomes.

Highlighting CTN Pharmacotherapy Trials



- Buprenorphine (Suboxone®)
 - CTN 0001, 0002 Bup/Nx vs Clonidine in detox
 - CTN 0003 Bup/Nx detox
 - CTN 0027 Bup/Nx vs Methadone in maintenance
 - CTN 0010 Bup/Nx for adolescents tapering
 - CTN 0030 Bup/Nx for prescription opiate dependence
- Osmotic-Release Methylphenidate (Concerta®)
 - CTN 0029 Adult smokers
 - CTN 0028 Adolescents Substance users
- Nicotine replacement in drug treatment
 - CTN 0009
 - CTN 0029
- Bupropion
 - CTN 0046

CTN Pharmacotherapy Trials: CTN 0010

JAMA[®]

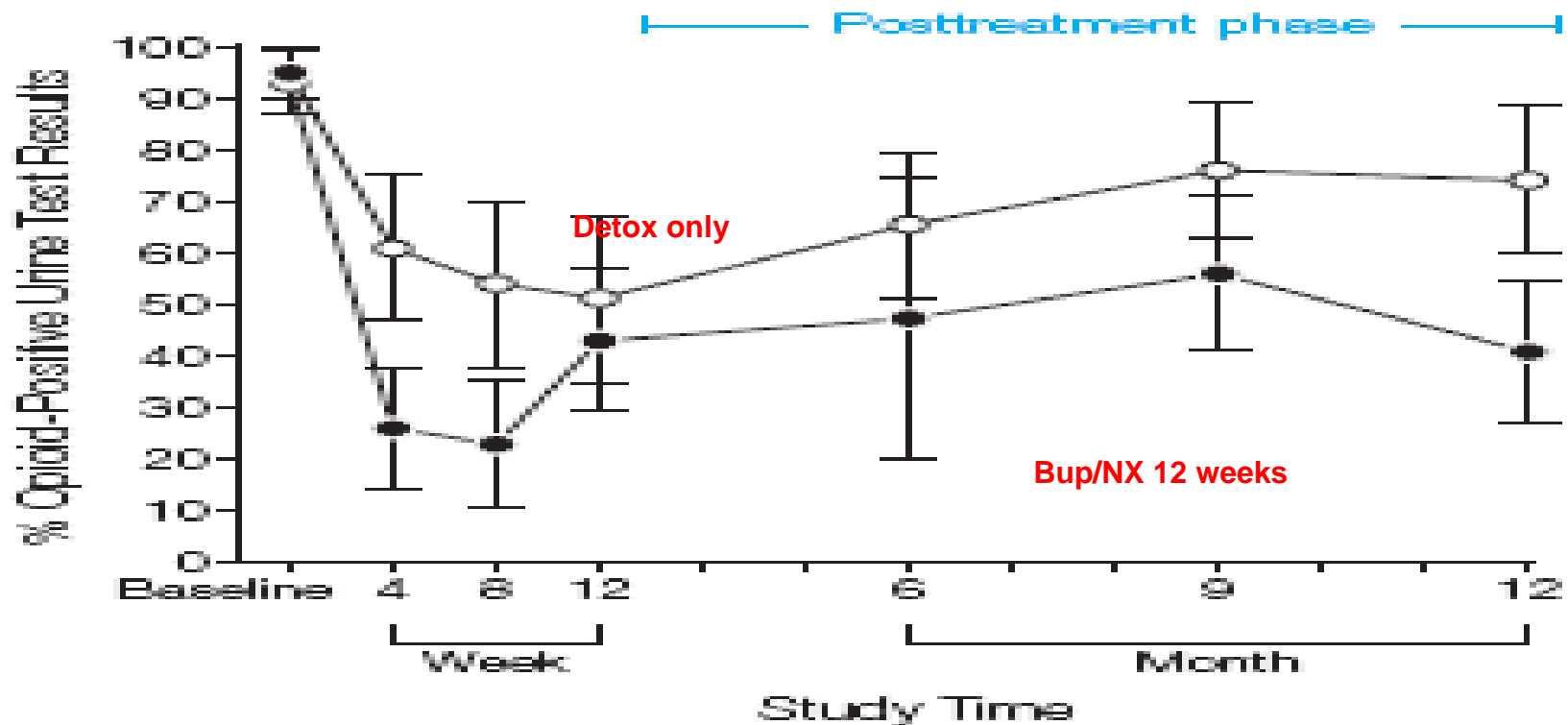
Online article and related content
current as of December 18, 2008.

Extended vs Short-term Buprenorphine-Naloxone for Treatment of Opioid-Addicted Youth: A Randomized Trial

George E. Woody; Sabrina A. Poole; Geetha Subramaniam; et al.

JAMA. 2008;300(17):2003-2011 (doi:10.1001/jama.2008.574)

<http://jama.ama-assn.org/cgi/content/full/300/17/2003>



Highlighting CTN Behavioral Therapy Trials



- **MI or CM: Lower cost motivational incentives**
- **MI/MET: Motivational interviewing & enhancement**
 - Adults, pregnant women, Spanish speakers
- **Seeking Safety: trauma counseling for women**
- **BSFT: Brief Strategic Family Therapy**
 - Adolescent
- **STAGE-12: Twelve Step Facilitation Therapy**
- **Reducing HIV/HCV risk behavior**
 - Injection drug use, sex risks for women & men
- **Exercise: To reduce stimulant use**

MET for Spanish-Speaking Substance Users: CTN 0021



Journal of Consulting and Clinical Psychology
2009, Vol. 77, No. 5, 993–999

© 2009 American Psychological Association
0022-006X/09/\$12.00 DOI: 10.1037/a0016489

A Multisite Randomized Effectiveness Trial of Motivational Enhancement Therapy for Spanish-Speaking Substance Users

Kathleen M. Carroll, Steve Martino, Samuel A. Ball,
Charla Nich, Tami Frankforter, Luis M. Anez,
and Manuel Paris
Yale University School of Medicine

Lourdes Suarez-Morales and José Szapocznik
University of Miami

William R. Miller
University of New Mexico

Carmen Rosa
National Institute on Drug Abuse

Julie Matthews
Advanced Behavioral Health

Chris Farentinos
Changepoint, Inc.



Study Challenges and Opportunities: CTN 0021



- Recruited 436 representative population of US Hispanics across 5 CTP sites
- Bilingual investigators/therapists/RAs
- Translation of 70% of project materials
 - Consent forms
 - CRFs
 - Assessment instruments
 - Intervention manual
- Bilingual training and fidelity monitoring
- Shovel-ready project for Spanish language international collaboration

HIV Rapid Testing and Counseling in Drug Treatment: CTN 0032



What is the more effective

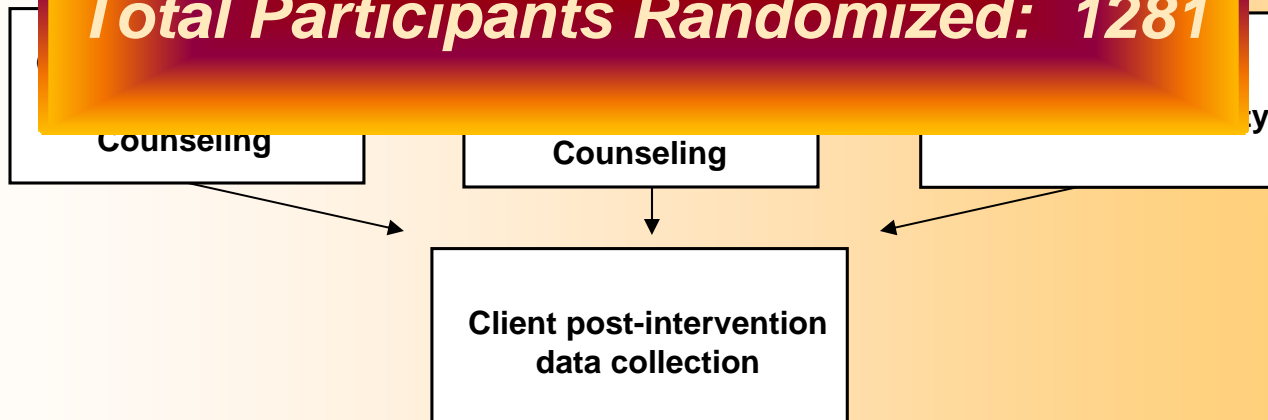
Recruitment and Enrollment

What is the more effective

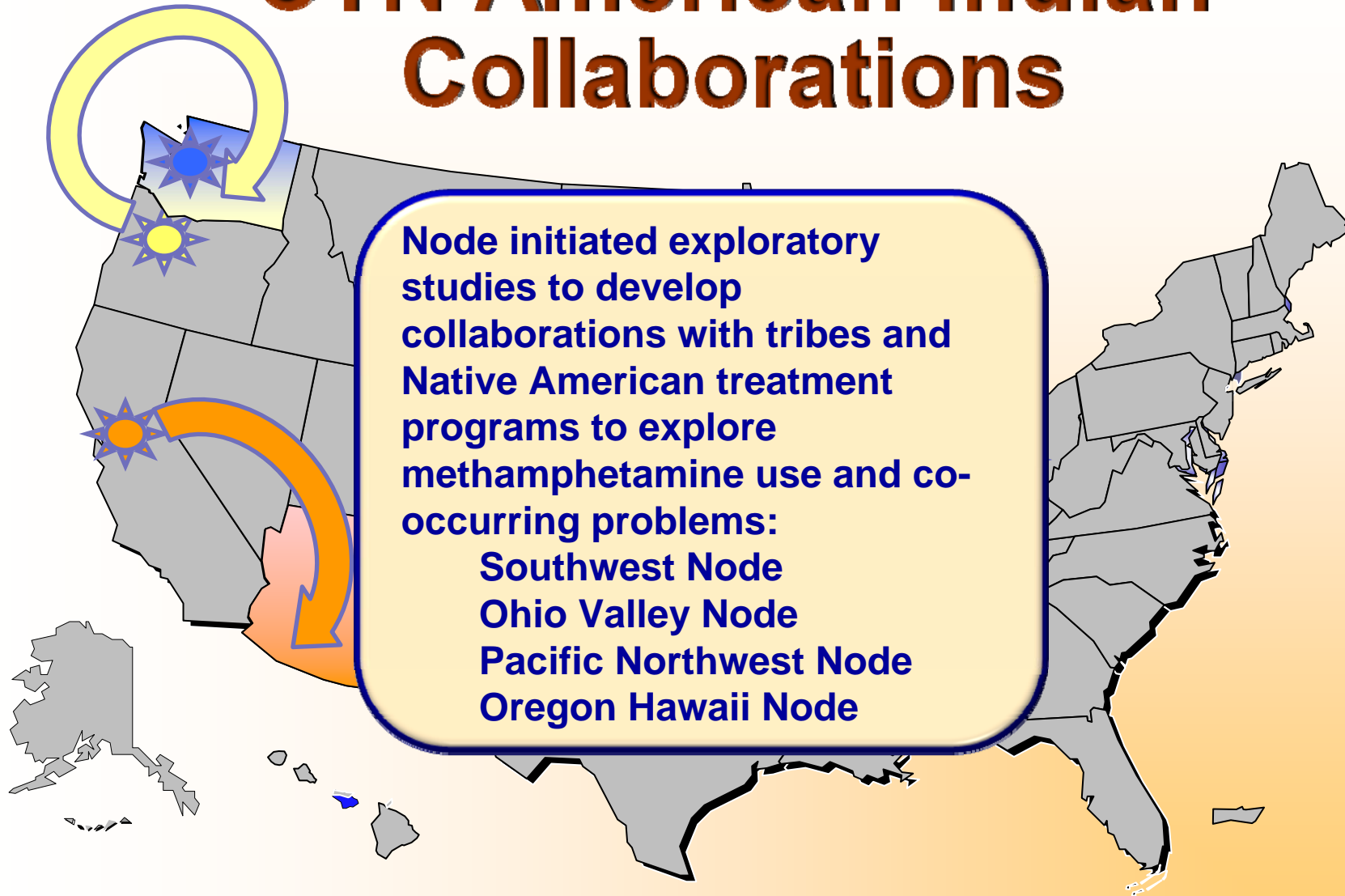
testing strategy to ensure that people who get HIV test and receive their results

First participant randomized: 01/05/2009
Last participant completed 12/31/2009
Total Participants Randomized: 1281

to their
rs?



CTN American Indian Collaborations



Types of CTN Ancillary Studies



- **Cost analysis – (NIDA DESPR: Services Research Branch)**
 - CTN 0004, 0005, 0006, 0007, 0010, 0030, 0032, 0044
- **Genetics – (NIDA Genetics Consortium)**
 - CTN 0027
- **Training methods – (NIDA DCNBR: Behavioral & Integrative Treatment Research Branch)**
 - CTN 0014
- **Psychometric study – (NIAAA)**
 - CTN 0031
- **Brain Imaging study – (NIDA DCNBR: Clinical Neuroscience Branch)**
 - CTN 0030

CTN Secondary Analysis Studies



■ Scientific Rationale

- Secondary clinically useful information
 - E.g. Who drops out when and why?
- Mediators and moderators and their interactions at baseline

■ Scientist Rationale

- Investigators (especially junior) benefit
- A platform for independent research support
- Training opportunities (e.g., K Awards)

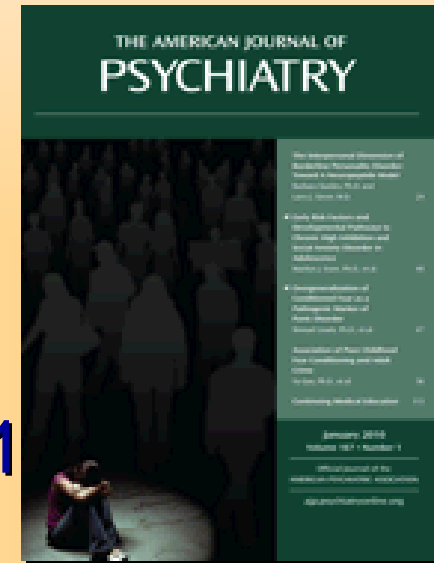
■ Economic Rationale

- *Inexpensive methods to address important questions*
- More precisely define future research steps
- Shorten measures to save future costs

CTN Secondary Analysis Studies

Do Treatment Improvements in PTSD Severity Affect Substance Use Outcomes? A Secondary Analysis From a Randomized Clinical Trial in NIDA's Clinical Trials Network

Denise A. Hien et al.
American Journal of Psychiatry
January 2010, Vol. 167, No. 1, 95-101

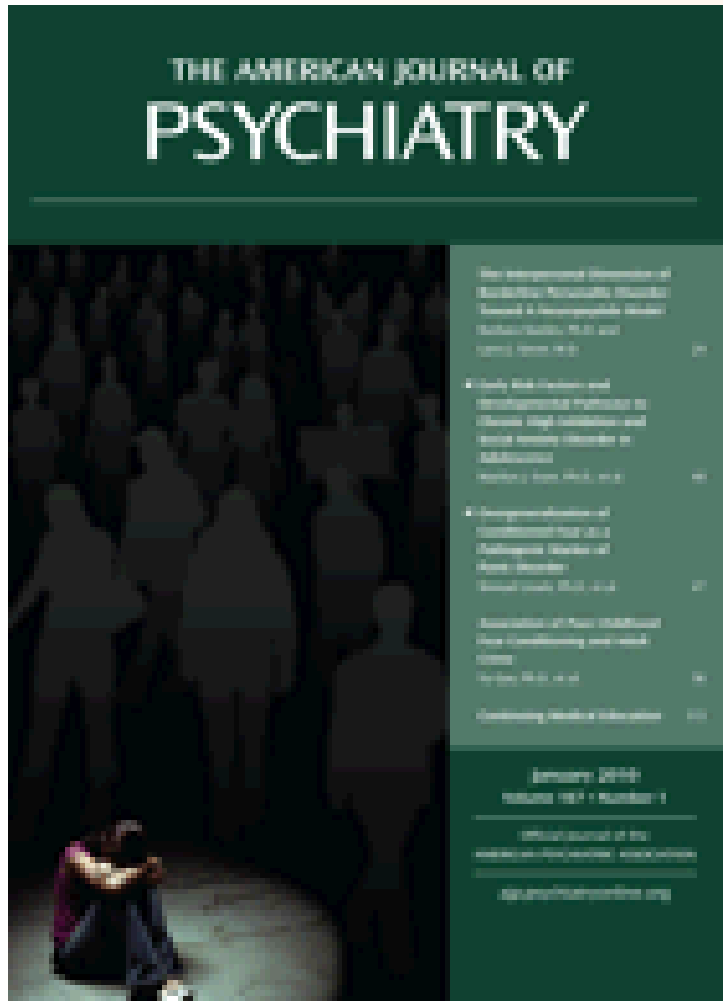


Conclusions/Implications



- PTSD severity reductions were associated with SUD improvement
- Integrated PTSD/SUD treatments may be advantageous for patients with severe symptoms
- For further study:
 - Men, mixed populations
 - Combat/military trauma
 - Other forms of integrated treatment

Providing Implications for Practice



Editorial

Toward an Improved Model of Treating Co-Occurring PTSD and Substance Use Disorders

“Findings bring into question the common practice of requiring patients with PTSD and substance use disorders to be abstinent from alcohol or drugs before commencing trauma work.”

Presentation Outline



- ✓ Infrastructure
- ✓ Research
- ✓ Research utilization
- ✓ CTN next decade

Research Utilization



Process through which research findings are put in use in the form of programs and policies

- Difficult
- Slow
- Not an action that begins when research is completed
- Rather a two way concurrent process

CTN Research Utilization Activities



- Led by CTN Research Utilization Committee
- Support and monitor the CTN dissemination library utilization
- Serve as point of contact for
 - NIDA Blending Conference
 - SAMHSA ATTC Program
- Major regional workshops in 2009, 2010
 - June 2009 Pacific NW/Oregon HI (Portland OR)
 - October 2009 Appalachian Tri-state (Pittsburgh PA)
 - November 2009 Southern Consortium (Charlotte SC)
 - June 2010 Mid Atlantic (Baltimore MD)
 - August 2010 Pacific Region (Los Angeles CA)

The CTN Dissemination Library

<http://ctndisseminationslibrary.org>

NIDA CTN Dissemination Library Home Page

National Drug Abuse Treatment

Clinical Trials Network • Dissemination Library

[Main](#) • [What's New](#) • [Search](#) • [Implementation](#) • [Resources & Policies](#) • [About](#) • [Site Map](#)

The **CTN DISSEMINATION LIBRARY** is a digital repository of resources created by and about NIDA's [National Drug Abuse Treatment Clinical Trials Network \(CTN\)](#). It provides CTN members and the public with a single point of access to research findings and other materials that are approved for dissemination throughout the CTN and to the larger community of providers, researchers and policy-makers.

Browse the Library



- Journal Articles
- Blending Team Products
- Presentations
- Manuals / Reports
- Videos **NEW**
- View All Items (Newest First)
- Publications Catalog (.pdf)

Search the Library



- [Advanced Search](#)
- [Need help? Ask a Librarian!](#)

Dissemination Opportunities



- [Send a Document to the Library](#)
- [Upcoming Conferences](#)

About the CTN



- [Protocols \(Studies\) in the CTN](#)
- [CTN Nodes & Community Treatment Programs \(CTPs\)](#)
- [NIDA's CTN web site](#)
- [CTN Public Data Share](#)
- [CTN Directory \(2009\)](#) **NEW**

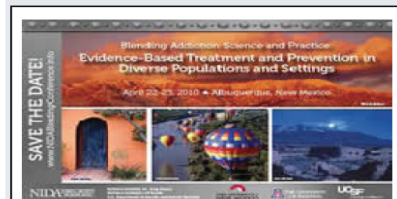
New in the Library [RSS](#)



Workshop on Disseminating Evidence-Based Treatments. Video of the March 2009 workshop organized by the RUC; NAADAC CE available from the National Office of the ATTC.



The Alliance in Motivational Enhancement Therapy and Counseling as Usual for Substance Use Problems by Crits-Cristoph, Gallop, Temes, et al. *Journal of Consulting and Clinical Psychology* 2009;77(6):1125-1135.



2010 NIDA Blending Conference, CTN 10th Anniversary Symposium, & CTN Steering Committee Meeting

April 19-23, 2010, Albuquerque, NM

For details see: [Blending Conference](#) | [CTN Meetings](#)

Featured Resources

- [Implementation for Clinicians](#)
- [Training Resources](#) **new!**
- [CTN Data Share for Researchers](#)
- [Read/Search the CTN Bulletin](#)

[\[More Resources & Policies\]](#)

Supported by a grant from the National Institute on Drug Abuse to the University of Washington Alcohol and Drug Abuse Institute.
The materials on this site have neither been created nor reviewed by NIDA.
Updated 1/2010 | <http://ctndisseminationslibrary.org>
info@ctndisseminationslibrary.org


B, Tai 2010



Journal of Substance Abuse Treatment

Volume 38

Number 4

Supplement 1

June 2010

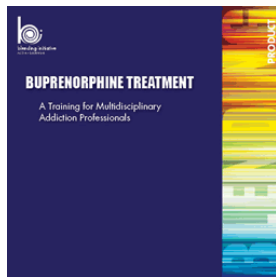
**A Decade of
Research by the
National Drug Abuse Treatment
Clinical Trials
Network**

ISSN 0740-5472

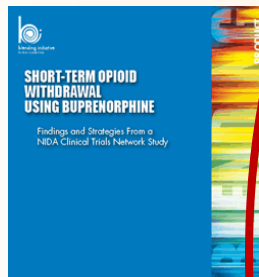
<http://www.journalofsubstanceabusetreatment.com>

NIDA-SAMHSA Blending Products

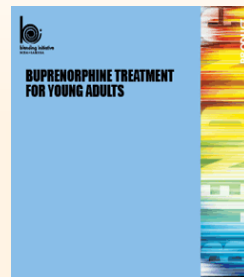
www.attcnetwork.org/explore/priorityareas/science/blendinginitiative/index.asp



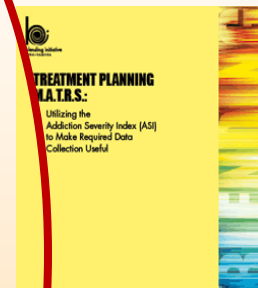
Buprenorphine Treatment: A Training for Multi-disciplinary Addiction Professionals



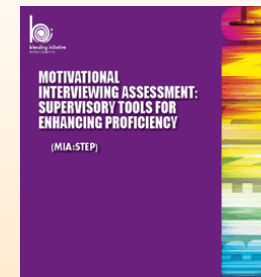
Short-Term Opioid Withdrawal Using Buprenorphine



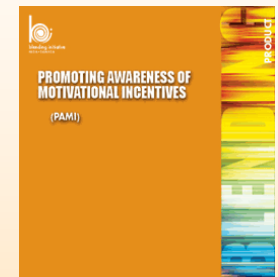
Buprenorphine Treatment for Young Adults



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)



CTN Data Share

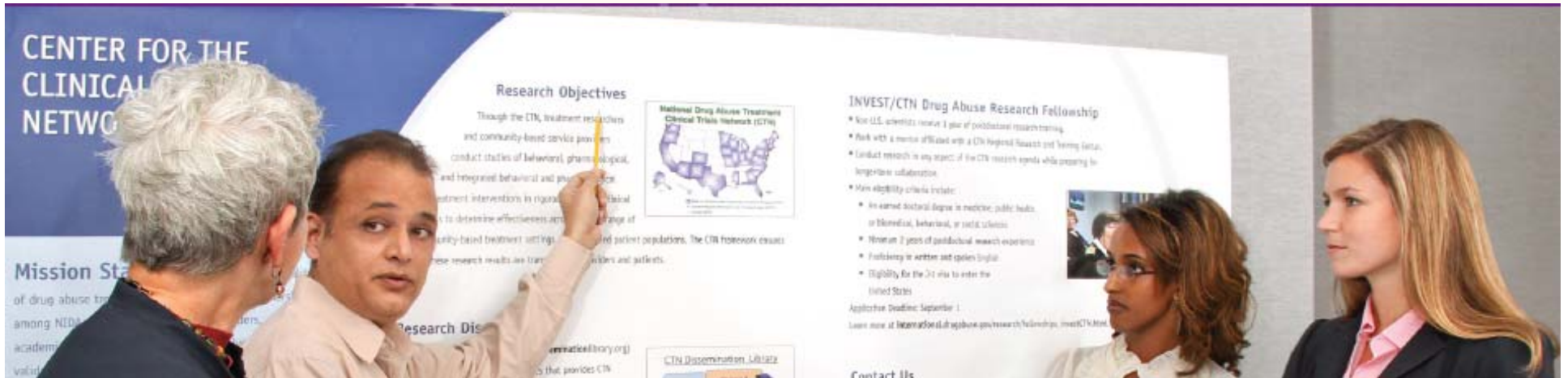
<http://www.ctndatashare.org>



CTN 0001, 0002, 0003, 0004, 0005, 0006, 0007, 0008, 0009, 0010, 0011, 0012, 0013, 0014, 0015, 0016, 0017, 0018, 0019, 0020, 0021, 0029

- CDISC standardized
- HIPAA Compliant
- CTN Public data/documents include:
 - Data sets (SAS and ASCII)
 - Defined file (aka data dictionary)
 - Annotated Case Report Forms
 - Study protocol and reference to study publication of primary outcomes

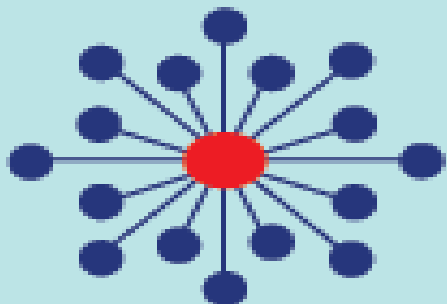
International Outreach: NIDA CTN INVEST Fellows



- Create an international network of scientists
- CTN serves as the training platform
- Senior non-U.S. scientists and health administrators
 - 2007 (1), 2008 (3), 2009 (2) and 2010 (3)

http://international.drugabuse.gov/research/fellowships_investCTN.html

International Outreach: Meet Global Patients Needs



Clinical Trials Network



- Export CTN expertise/technology globally
- Ongoing collaboration:
 - Mexico, China
- Potential international study sites:
 - Cocaine intervention study: Italy, Brazil, Canada
 - HIV prevention study: China

http://international.drugabuse.gov/research/fellowships_investCTN.html

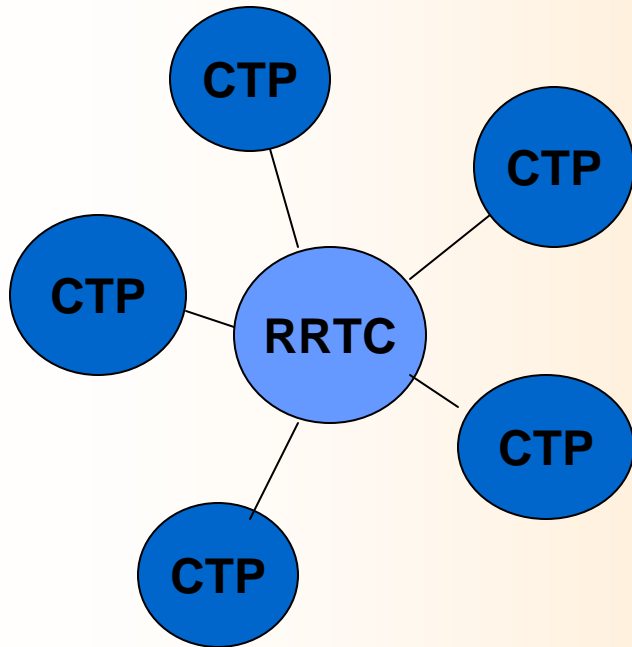
Presentation Outline



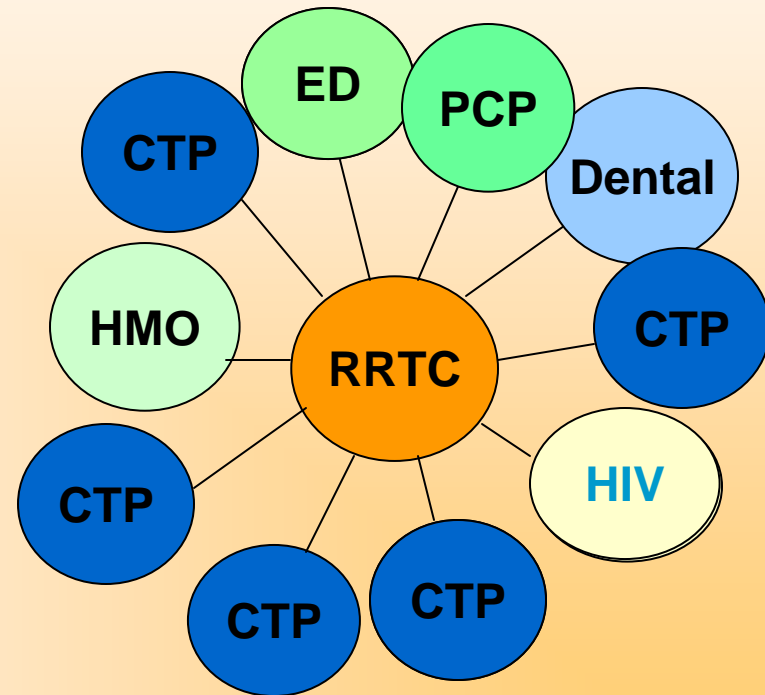
- ✓ Infrastructure
- ✓ Research
- ✓ Research utilization
- ✓ CTN next decade

Future of the CTN: Infrastructure

■ Current



■ Future expansion



Optimal ratio of research \$/infrastructure \$

Future of the CTN: Challenges and Opportunities



- **Information Technology**
 - **Novel approaches to data collection, processing & storage**
 - **Development and deployment of digitized patients medical records –currently ongoing**
 - **Standardized vocabulary/terminologies**
 - **Common core data elements**
 - **Data privacy & confidentiality**
 - **Approaches to accommodate physiologic and genetic information**
 - **Interventions to use web/wireless technology**

Future of the CTN: Challenges and Opportunities



- **New trial paradigms**
 - Large, simple trials
 - Pragmatic trials , comparative effectiveness trials
 - Subgroup analysis
- **Chronic Disease management model**
 - Treatment algorithm for continuing care
 - Approaches for effective longitudinal follow-up of patients

Future of the CTN: Challenges and Opportunities

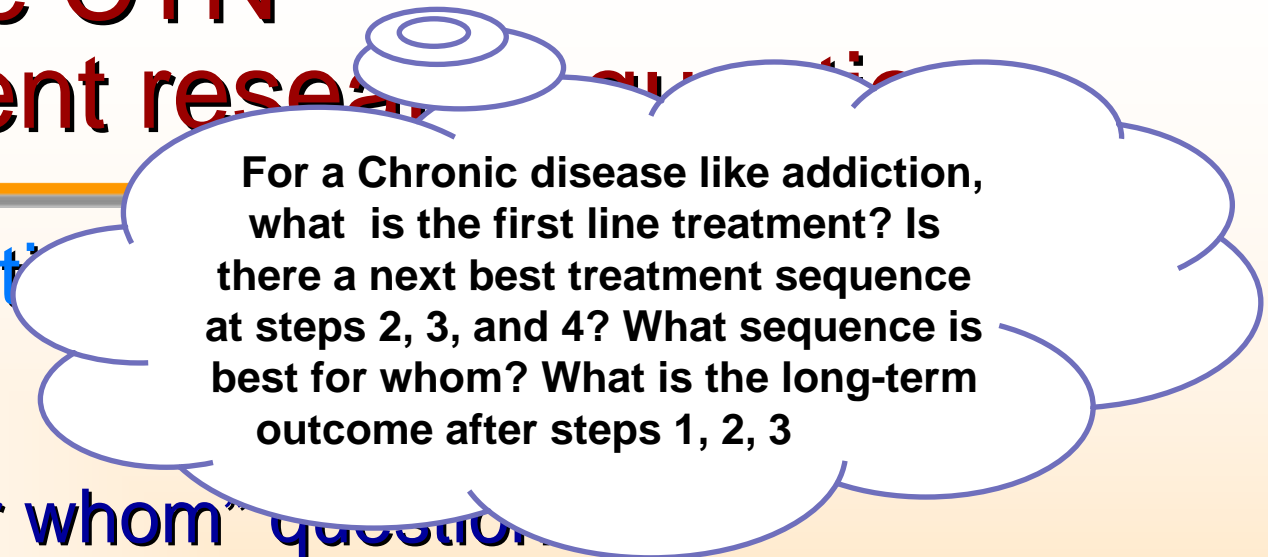


- Innovative trial/study designs
 - New statistical tools and techniques
 - Adaptive design
 - Simulation and modeling
 - Large database mining
 - Process Improvement –currently ongoing
 - Building consensus on meaningful trial outcome measures and success criteria
 - Standardizing and harmonizing tools/instruments
 - Training in instrument administration

Future of the CTN

Ask a different research question

Research question



For a Chronic disease like addiction, what is the first line treatment? Is there a next best treatment sequence at steps 2, 3, and 4? What sequence is best for whom? What is the long-term outcome after steps 1, 2, 3

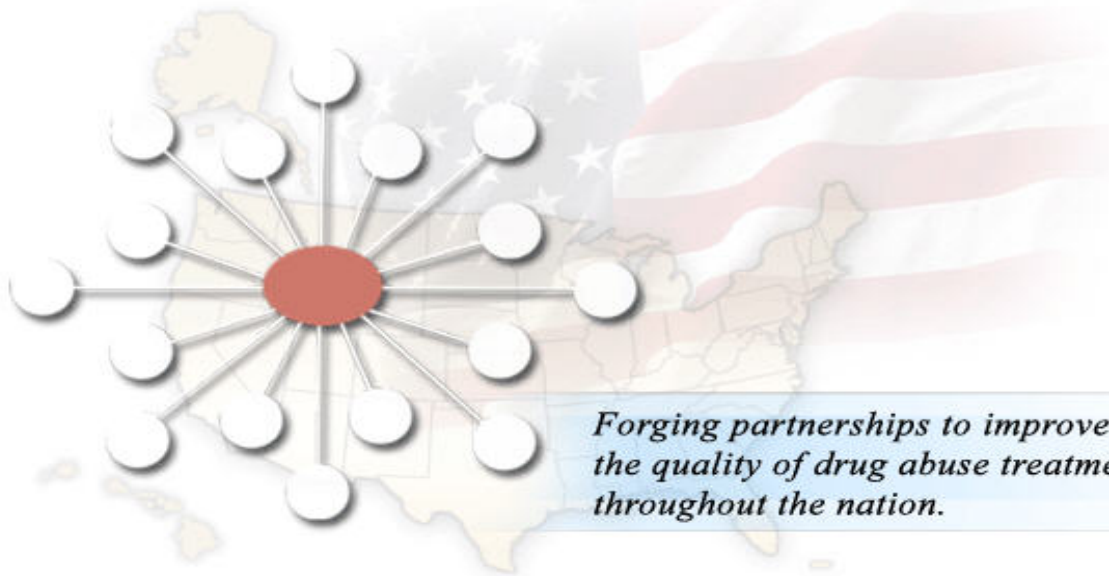
- “What” and “for whom” questions
- “How” questions
 - How to best practice based on efficacy and side effects,
- Decision questions
 - How much time, training, and cost is entailed in the new treatment? Is the clinical benefit worth the cost? Is there a cost offset?

Future CTN Goals

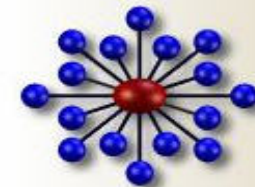


- **Treat Addiction as a disease, realize the promise of medication assisted recovery**
- **Engage medical settings/systems in the treatment of addiction disease**
- **Link addiction specialty treatment settings/systems with the primary care and other medical settings/systems**
- **Ascertain addiction treatment be included in the health care reform**

*National Drug Abuse Treatment
Clinical Trials Network*



*Forging partnerships to improve
the quality of drug abuse treatment
throughout the nation.*



- About the CTN
- Network Organization
- Research Studies
- CTN Library
- Data Share
- Meetings
- Resources
- En español

**CTN Funding
Opportunity**



www.nida.nih.gov/CTN/Index.htm

Q&A

