

2010 Web Seminar Series

# The Value of Common Data Elements

Presented on December 7, 2010 by:

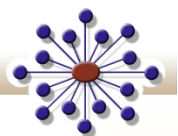
Dennis Donovan, Ph.D.

Paul VanVeldhuisen, Ph.D.

Paul Wakim, Ph.D.

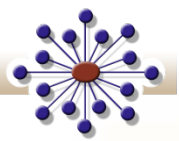
*Produced by Liz Buttrey, NIDA CTN CCC Training Office*

*"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."*

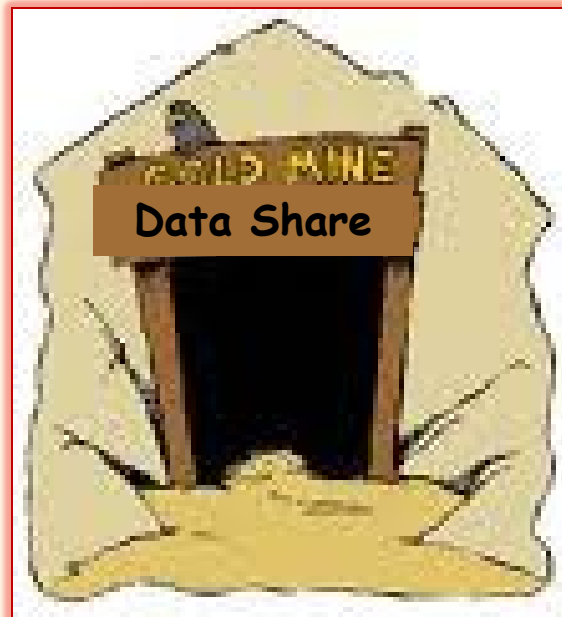


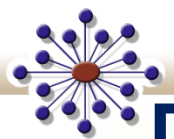
# Training Outline

- Factors enabling cross-study analyses
- Implementing and maintaining standardized biological measures, data collection forms and assessment instruments
- Combining self-report instruments with biological measures to capture drug use, its consequences and its reduction
- Maximizing the value of the CTN's Public Data Share



# Maximizing the Value of the CTN's Public Data Share

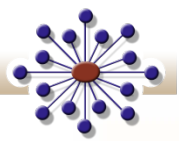




# Data Share Experience: *Case Example*

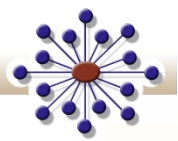
---

- 10 protocols
  - At least 4 diagnostic assessment instruments
  - Information included diagnostic criteria
- Disparate information pieces
  - ASI – use varied
- No consistent indicator of primary drug
- Lack of consistency in data elements across studies
- Extremely large time investment



# Consistency is Important

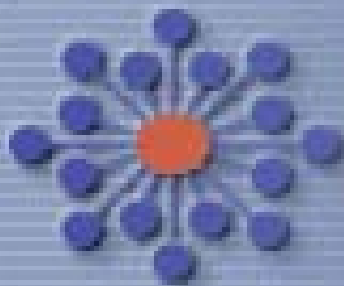
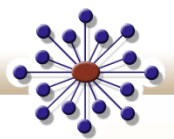
- Availability and useful resource in data share
- Improving future data through the 7 elements
- Expedite data share use
- Manuscripts using multiple protocols are increasing
  - Comparison of opiate-primary treatment seekers with and without alcohol use disorder.
    - Journal of Substance Abuse Treatment, 39(2), 114-123. Hartzler, B., Donovan, D.M., & Huang, Z. (2010).



# Why Standardize Across Trials?

---

- Facilitates comparisons of data collected across different populations, drugs, and protocols
- Allows secondary analyses of data merged across protocols



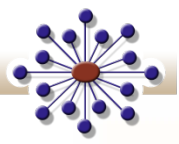
# CTN

Clinical Trials Network

DATA SHARE WEBSITE

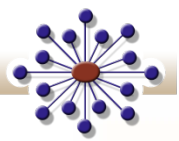
<http://www.ctndatashare.org/>

- The Clinical Trials Network (CTN) Data Share web site
  - An electronic environment that allows data from completed clinical trials to be distributed to investigators
  - To promote new research
  - Encourage further analyses
  - Disseminate information to the community
- Secondary analyses produced from data sharing multiply the scientific contribution of the original research
- *This site allows researchers to download de-identified data from completed CTN studies to conduct analyses that improve the quality of drug abuse treatment*
- **Currently 23 research studies included**



# Factors Enabling Cross-study Analyses

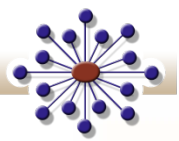




# Basic Terminology: Data Element

---

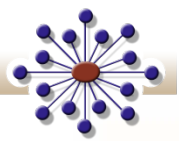
- A logical unit of data pertaining to information of one kind
- A data element has a
  - Name
  - Precise definition
  - Clear enumerated values (codes) if applicable
  - Occupies the space provided by field(s) on a case report form or in a database record



# Example of a Data Element

---

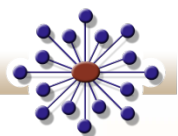
- Name: Race
- Definition: A study participant is asked to choose which racial category or categories he/she identifies
- Permissible values or codes:
  - American Indian or Alaska Native
  - Asian
  - Black or African-American
  - Native Hawaiian or Pacific Islander
  - White
  - Other



# Common Data Element (CDE)

---

- Data elements with standard definitions, code lists, and instructions
- Allows use in multiple clinical trials
- Typically determined by a working group of experienced researchers
- A lot of effort by NIH in CDE development, including NIDA!



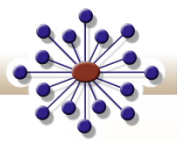
# Types of CDEs

## ■ General

- Data elements consistently collected in trials across all disease or therapeutic areas
- Examples: demographics, adverse events

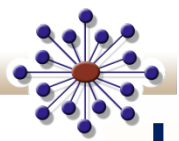
## ■ Disease-specific

- Data elements specific to a particular disease or therapeutic area
- Examples: drug use categories, time-line follow-back, Addiction Severity Index (ASI)



# Value of CDEs

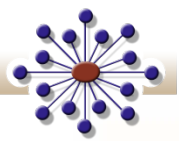
- Reduce the time and cost needed to develop data collection tools
- Promote standardized, consistent, and universal data collection
- Improve data quality
- Facilitate data sharing
  - Particularly when research standards for storage and access are met like in NIDA CTN Data Share
- Promotes discovery by providing opportunities for meta-analysis using participant-level data



# Long-terms Benefits of NIDA CTN CDE Efforts

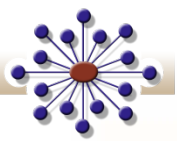
---

- Multi-study data analyses (meta-analysis) with CDEs can potentially answer substance-use questions not sufficiently addressed in single studies
  - Large sample sizes
  - Greater statistical power
  - Allows sub-group analyses when single trial may not provide sufficient numbers



# Implementing and Maintaining Standardization





# CTN Treatment Effect & Assessment Measures (TEAM) Task Force

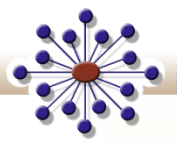
---

## Goal 1:

To recommend a clinically meaningful outcome on drug use to be used in CTN clinical trials, and a method to capture that outcome

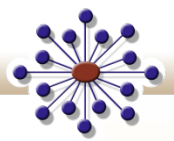
## Goal 2:

To recommend a set of key questions and instruments that would be used across CTN clinical trials



# Why is this Important?

- To collect and analyze data on ***clinically meaningful*** outcomes, at ***critical time points***, in the most ***cost-effective*** manner
- To compare treatment effectiveness across trials based on a common scale
- To conduct secondary analyses across trials based on common elements
- To avoid revisiting the same issues every time a new trial design is developed

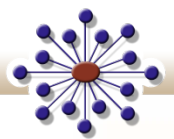


# CTN TEAM Task Force Recommendations

---

Goal 2: Use **seven** common instruments and key questions across CTN clinical trials:

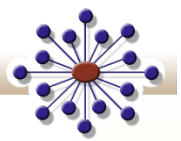
1. Qualitative Urine Drug Screening (UDS) test
2. Timeline Followback technique
3. A standardized demographics form
4. The CTN Addiction Severity Index (ASI) Lite (version 10/24/2000)
5. A question on primary drug of use
6. A question on age of first use (onset)
7. The World Health Organization's Quality of Life BREF instrument



# Biological Testing for Presence of Drugs as Outcome Measures

the gold standard





# Drug Use Biological Measures



Urine



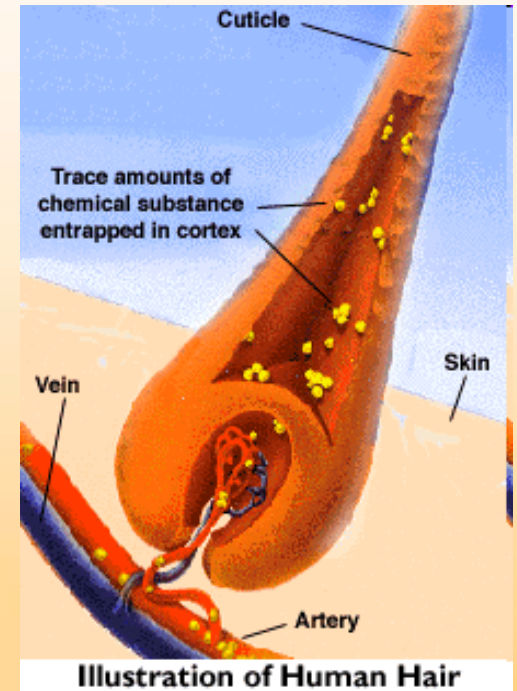
Sweat



Saliva



Nails



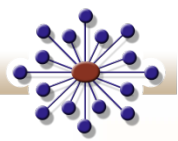
Hair



# 1. Qualitative Urine Drug Screening (UDS) test

---

Minimum of twice per week during the critical period covered by the primary outcome

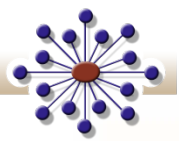


## 2. Timeline Followback

---

- Provides a continuous measure of substance use on a day-to-day basis
- Add: “How many occasions did you use on that day?”





# 3. Standardized Demographics Form

---

1. **Date of birth:** MM/DD/YYYY

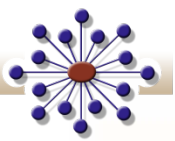
2. **Sex:** Male      Female      Participant chooses not to answer

3. **Ethnicity** (check only one)  
Hispanic or Latino  
Not Hispanic or Latino  
Participant chooses not to answer

4. **Race** (check all that apply)  
American Indian or Alaska Native  
Asian  
Black or African American  
Native Hawaiian or Pacific Islander  
White  
Other (specify \_\_\_\_\_ )

OR

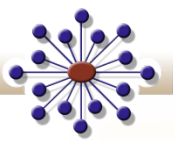
Participant chooses not to answer  
Unknown



# 4. CTN Addiction Severity Index (ASI) Lite

Composite scores on seven domains  
(142 questions,  $\approx$ 45 minutes):

- Medical Status
- Employment/Support Status
- Alcohol
- Drugs
- Legal Status
- Family/Social Relationships
- Psychiatric Status



## 5. Primary Drug of Use

---

Original question (in full ASI instrument):

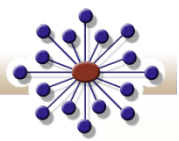
***D14: Which substance is the major problem?***

*Please code as above or 00-No problem; 15 Alcohol & Drug (Dual addiction); 16-Polydrug; when not clear, ask patient.*

Modified question (**recommended**):

***D14: Currently, which substance is the major problem?***

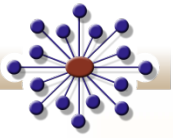
*Interviewer should determine the major drug of abuse (excluding Nicotine use). Please use the substance code 01-12 corresponding to questions D1-D12, and 00 for No Problem. When not clear, ask patient.*



## 6. Age of First Use (Onset)

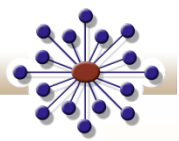
---

- A strong predictor of future drug dependence
- Describes an important characteristic of the sample being studied



# 7. WHO QoL BREF

- Composite scores on four domains (26 questions):
  - Physical health
  - Psychological
  - Social Relationships
  - Environment
  
- Administer at baseline *and* at a later time point (>6 months post-randomization)

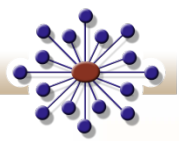


# CTN TEAM Task Force Report

---

Publicly available at:

<http://ctndisseminationlibrary.org/display/522.htm>

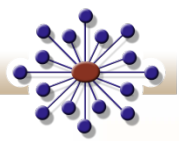


# Maintaining Standardization

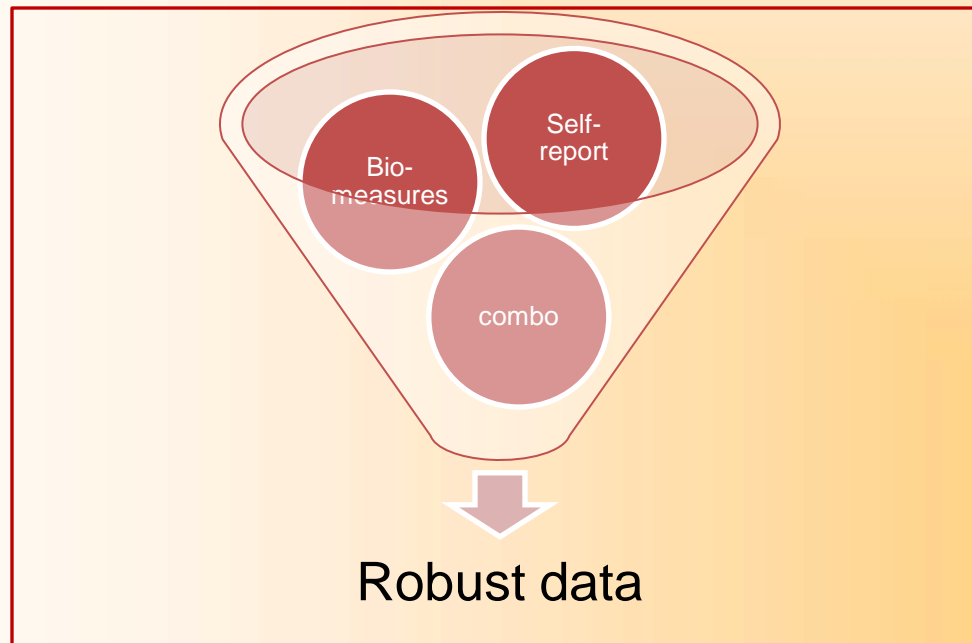
- It depends on...
- Rigidity vs. flexibility
- Benefits of process
  - Provides a starting point for the Protocol Development Team
  - Facilitates the thought process for variations
  - Helps the future development of a decision tree on which primary outcome should be used

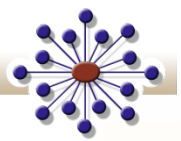


*Protocol Development Teams are asked to follow the Task Force recommendations.  
Send the justification for deviations in writing to Paul Wakim at the NIDA CCTN.*

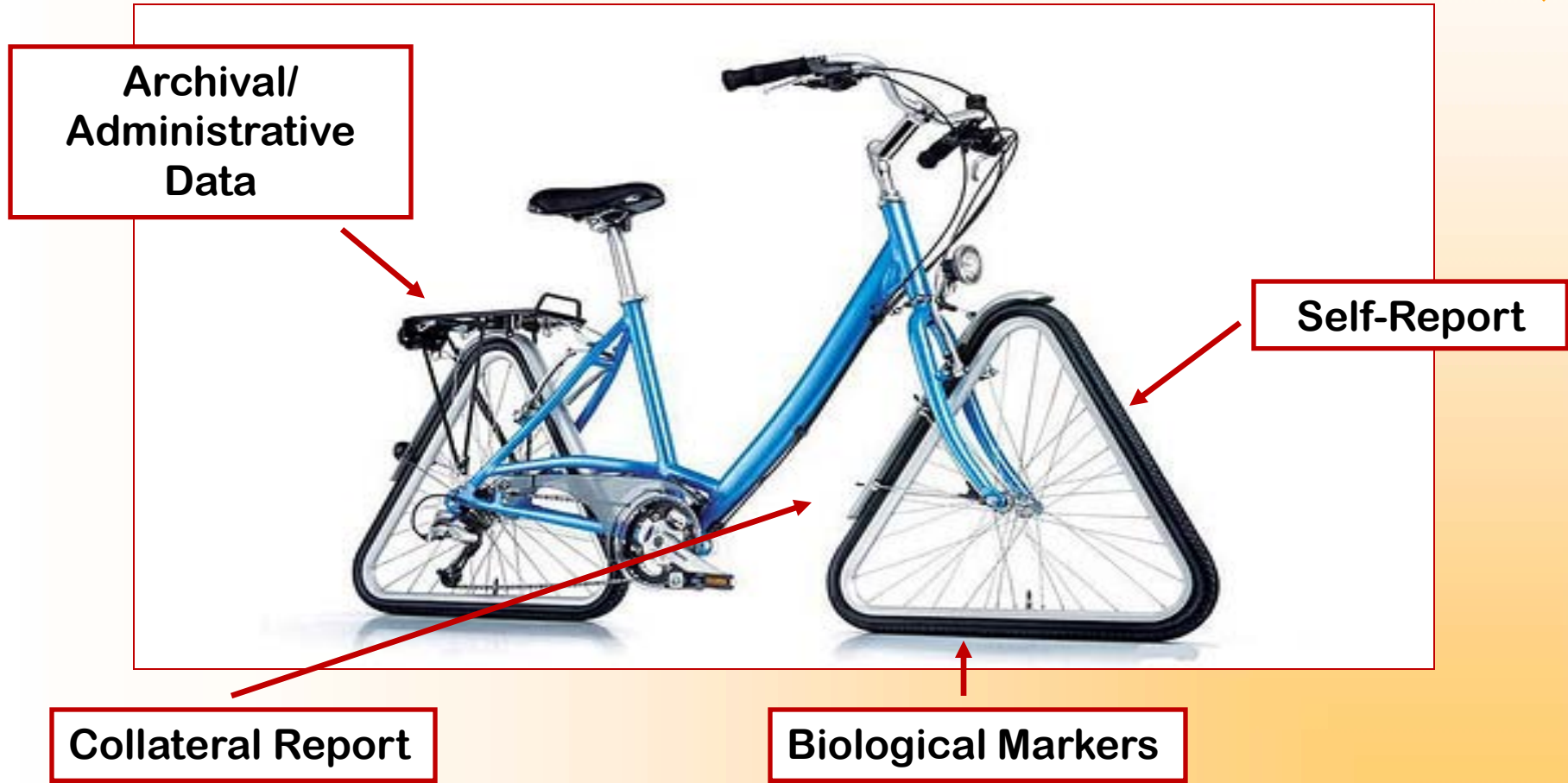


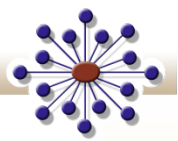
# Combining self-report instruments with biological measures





# Issues in Combining Sources of Data





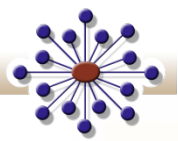
# Why Combine Self-Report and Biological Measures?

---

- Self-reports can be accurate given appropriate context, but veracity of drug users' reports is often questioned
- Biological measures are used as
  - Independent indicators of drug use
  - A way to corroborate self reports
- Each provides different aspects of drug use (e.g., any use, frequency of use, quantity used)

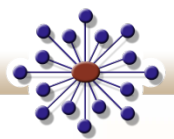
# The Goal is a More Consistent Method of Outcome Assessment that Combines Self-Report and Biological Measures in Tandem





# How to Combine Self-Report and Biological Measures?

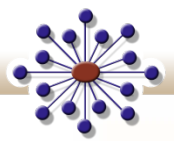
- Self-report corroborated by biological measure over the corresponding time window
- A positive toxicology result overrules self-reported abstinence for the period covered by the toxicology procedure
- Combinatorial algorithms, e.g., SRPHK1 outcome measure for cocaine-dependence trials combines self-report, urine benzoylecgonine levels, and the concordance between the two to determine a cocaine-use status for each study day (Somoza, et al., 2008)



# CTN TEAM Task Force Recommendations

---

- Define the primary outcome as the number of days of drug use during the last 30 days of active treatment
  - Based on self-report
  - Corroborated with qualitative urine analysis.
- Consider a co-primary outcome that captures well-being, functioning, satisfaction or quality of life.



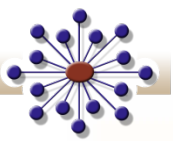
# Clinical Trials Outcome Determination Decision Tree

---

- IF .....

  - Target Drug
  - Behavioral or Pharmacological Therapy
  - Abstinence or Drug Use Reduction Goal
  - Biological and/or Self-Report Measures
  - Drug-focused and/or Function-focused
  - Short-term or Long-term Time Frame

- THEN .....



# *Clinical Trials Network · Dissemination Library*

National Drug Abuse Treatment

**A copy of this presentation will be available  
electronically after the meeting from:**

**CTN Dissemination Library**

<http://ctndisseminationlibrary.org>

**and**

**NIDA Livelink**

<https://livelink.nida.nih.gov>