



# Demonstrating Practical Use of Data Share and Secondary Analyses

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CTN WEB SEMINAR SERIES:  
A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

Produced by: CTN Training

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# Learning Objectives

- Review the structure of the NIDA Data Share website.
- Understand the information provided, how to navigate through the website, and obtain all the relevant information
- Demonstrate the technical procedures for using SAS or ASCII data sets for conducting secondary analyses.



# Polling Question

**Have you been to the  
Data Share website?**

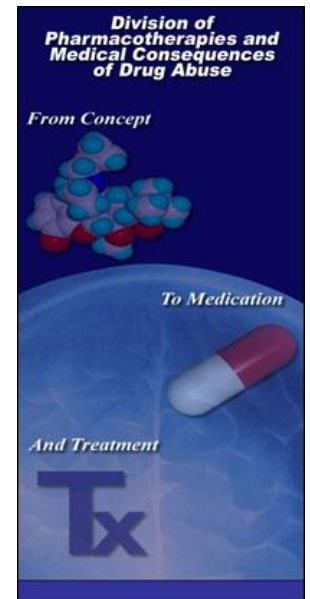
Yes

No

# Introduction to Data Share

## What is Data Share?

- Repository of publically available studies funded by NIDA
- CTN trials: ~34, plus 2 follow up studies
- Non-CTN trials: ~ 15 studies from the Division of Therapeutics and Medical Consequences (DTMC)



# Over 80 countries have downloaded data from Data Share

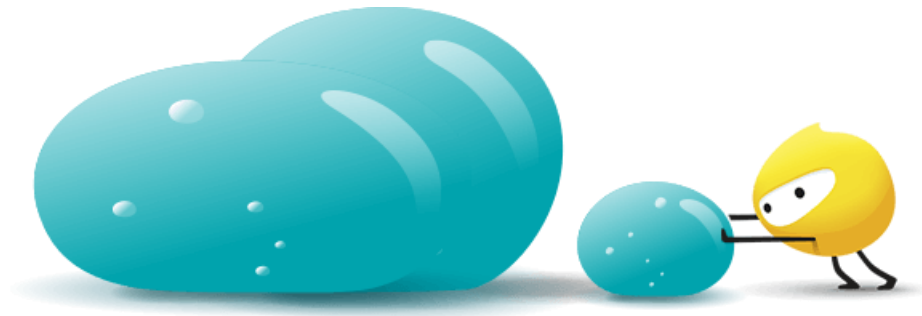


**United States • India • UK • Canada • China • Spain • France • Malaysia • Bangladesh • Turkey • Egypt • Poland • Nepal • Brazil • Afghanistan • Mexico • South Korea • Australia • Canary Islands • Croatia • Denmark • Ecuador • Netherlands • Pakistan • Singapore • South Africa •**



# Goals of Data Share

- Optimize research productivity and use of resources
- Promote new research and secondary analyses
- Facilitate career development



# Funding Opportunity for Data Share

## Accelerating the Pace of Drug Abuse Research Using Existing Data (R01)

- *“Of particular interest are analyses of data that have been harmonized and merged across multiple different datasets, such as those with PhenX measures... as well as data from NIDA Data Share for clinical trials...”*
- Deadline October 5, 2016 ☹️

<http://grants.nih.gov/grants/guide/pa-files/PAR-16-234.html>



# Goals of Data Share

For example, it can be used for:

- Grant applications:
  - Preliminary data
  - Power/sample size calculations
- Secondary analyses:
  - Subgroup analyses
  - Mediation and moderation
- Secondary outcomes:
  - Harm reduction
  - Quality of Life



# Data Share Policies

- Trial data posted 18 months after database lock or after primary manuscript published, whichever comes first
- All CTN studies are posted to Data Share
- Only de-identified data is included
- Only raw data are provided

# Data Share Policies

- Truly open access:
  - No proposal necessary
  - Must agree to terms and conditions of use
- When publishing or presenting, must recognize the data source (NIDA Data Share)



# Overview of Posted Studies

- Most studies are:
  - Multi-site randomized controlled trials
  - Primary outcome usually substance-use related
  - Duration: intervention and follow-up are short (3-6 months)
  - Sample size: usually 100-500
- Types of interventions:
  - Behavioral (e.g., CTN-0037- Stimulant Reduction Intervention using Dosed Exercise (STRIDE))
  - Medication (e.g., CTN-0001- Buprenorphine/Naloxone versus Clonidine for Inpatient Opiate Detoxification)
  - Both behavioral and medication (e.g., CTN-0030- Buprenorphine/Naloxone Treatment Plus Individual Drug Counseling for Opioid Analgesic Dependence)



# Assessments

- Demographics
- Substance Use
- Mental Health
- Impulsivity and General Trait and Behavior Scales
- Interpersonal Relationships/Culture
- Physical/General Health
- Health Cognitions and QOL
- Clinical Measures
- Sexual Behavior/HIV
- Clinic Related Surveys





# Available Information



- Study documentation:
  - Brief study description
  - Protocol
  - Link to primary manuscript (available from CTN Dissemination Library)
- Data documentation:
  - Annotated CRFs
  - Data dictionary
  - De-identification notes



# Some examples

- Secondary analysis of individual studies
- Analysis of merged data from several CTN studies

# Examples

Journal of Substance Abuse Treatment 70 (2016) 73–80



Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment



## Mortality Rates Among Substance Use Disorder Participants in Clinical Trials: Pooled Analysis of Twenty-Two Clinical Trials Within the National Drug Abuse Treatment Clinical Trials Network<sup>☆,☆☆</sup>



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### ARTICLE INFO

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#### Keywords:

Substance use disorder

Clinical trial

Standardized mortality rate

Standardized mortality ratio

Pooled analysis

### ABSTRACT

**Background:** Most substance use disorders (SUD) treatment clinical trials are too short and small to reliably estimate the incidence of rare events like death.

**Objective:** The aim of this study is to estimate the overall mortality rates among a SUD treatment-seeking population by pooling participants from multiple clinical trials conducted through the National Institute on Drug Abuse (NIDA)-sponsored National Drug Abuse Treatment Clinical Trials Network (CTN).

**Participants:** Drug and or alcohol users (N = 9866) who sought treatment and participated in one of the twenty-two CTN trials.

**Measurements:** Data were collected through randomized clinical trials in national community treatment programs for SUD. Pooled analysis was performed to assess age- and gender-standardized mortality rate(s) (SM rate(s)), and mortality ratio(s) (SM ratio(s)) of CTN trial participants compared to the U.S. general population.

**Results:** The age- and gender-SM rate among CTN trials participants was 1403 (95% CI: 862–2074) per



## NIH Public Access

### Author Manuscript

*Subst Use Misuse*. Author manuscript; available in PMC 2012 October 05.

Published in final edited form as:

*Subst Use Misuse*. 2011 ; 46(14): 1716–1725. doi:10.3109/10826084.2011.611960.

## Depressive Symptoms, Substance Use and HIV-Related High Risk Behaviors among Opioid-Dependent Individuals: Results from the Clinical Trials Network

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### Abstract

The sample included 343 opioid-dependent adults enrolled in two national multisite studies of the National Drug Abuse Treatment Clinical Trials Network (CTN001-002). Opioid-dependent individuals were recruited from 12 sites across the United States from January 2001 to July 2002. We examined associations between depressive symptoms, co-occurring substance use (i.e. the use of substances other than opioids), and HIV-related sexual and injection risk behaviors. Data were collected using the Addiction Severity Index (ASI) and the HIV Risk Behavior Scale, and analyzed using linear regression. Depressive symptoms were associated with an increased level of injection risk behaviors, but were not associated with risky sexual behaviors. The co-occurring use of amphetamines also increased the likelihood of risky sexual behaviors. The study limitations and clinical implications are noted. The study was funded by the U.S. National Institute on Drug Abuse.



# Gender and racial/ethnic differences in addiction severity, HIV risk, and quality of life among adults in opioid detoxification: results from the National Drug Abuse Treatment Clinical Trials Network

This article was published in the following Dove Press journal:

Substance Abuse and Rehabilitation

1 December 2010

[Number of times this article has been viewed](#)

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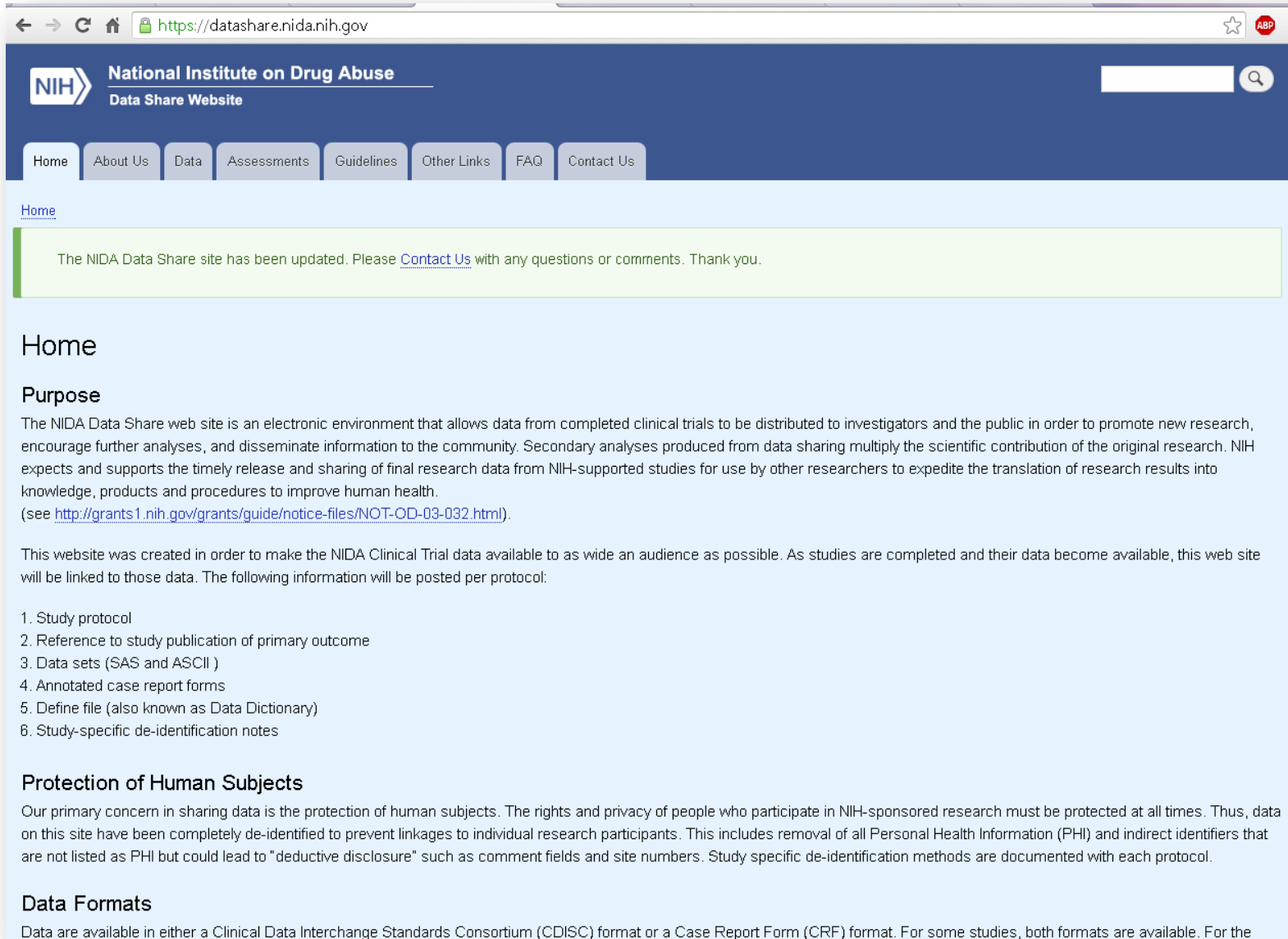
**Purpose:** Detoxification often serves as an initial contact for treatment and represents an opportunity for engaging patients in aftercare to prevent relapse. However, there is limited information concerning clinical profiles of individuals seeking detoxification, and the opportunity to engage patients in detoxification for aftercare often is missed. This study examined clinical profiles of a geographically diverse sample of opioid-dependent adults in detoxification to discern the treatment needs of a growing number of women and whites with opioid addiction and to inform interventions aimed at improving use of aftercare or rehabilitation.

**Methods:** The sample included 343 opioid-dependent patients enrolled in two national multi-site studies of the National Drug Abuse Treatment Clinical Trials Network (CTN001-002). Patients were recruited from 12 addiction treatment programs across the nation. Gender and racial/ethnic differences in addiction severity, human immunodeficiency virus (HIV) risk, and quality of life were examined.

**Results:** Women and whites were more likely than men and African Americans to have greater psychiatric and family/social relationship problems and report poorer health-related quality of life and functioning. Whites and Hispanics exhibited higher levels of total HIV risk scores and risky injection drug use scores than African Americans, and Hispanics showed a higher level of unprotected sexual behaviors than whites. African Americans were more likely than whites to use heroin and cocaine and to have more severe alcohol and employment problems.

**Conclusions:** Women and whites show more psychopathology than men and African Americans. These results highlight the need to monitor an increased trend of opioid addiction among women and whites and to develop effective combined psychosocial and pharmacologic treatments to meet the diverse needs of the expanding opioid-abusing population. Elevated levels

# Website Home Page



← → ↻ 🏠 🔒 https://datashare.nida.nih.gov

**NIH** National Institute on Drug Abuse  
Data Share Website

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[Home](#)

The NIDA Data Share site has been updated. Please [Contact Us](#) with any questions or comments. Thank you.

## Home

### Purpose

The NIDA Data Share web site is an electronic environment that allows data from completed clinical trials to be distributed to investigators and the public in order to promote new research, encourage further analyses, and disseminate information to the community. Secondary analyses produced from data sharing multiply the scientific contribution of the original research. NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers to expedite the translation of research results into knowledge, products and procedures to improve human health. (see <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>).

This website was created in order to make the NIDA Clinical Trial data available to as wide an audience as possible. As studies are completed and their data become available, this web site will be linked to those data. The following information will be posted per protocol:

1. Study protocol
2. Reference to study publication of primary outcome
3. Data sets (SAS and ASCII )
4. Annotated case report forms
5. Define file (also known as Data Dictionary)
6. Study-specific de-identification notes


### Protection of Human Subjects

Our primary concern in sharing data is the protection of human subjects. The rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data on this site have been completely de-identified to prevent linkages to individual research participants. This includes removal of all Personal Health Information (PHI) and indirect identifiers that are not listed as PHI but could lead to "deductive disclosure" such as comment fields and site numbers. Study specific de-identification methods are documented with each protocol.

### Data Formats

Data are available in either a Clinical Data Interchange Standards Consortium (CDISC) format or a Case Report Form (CRF) format. For some studies, both formats are available. For the

# Guidelines Tab



The screenshot shows the 'Guidelines' page of the National Institute on Drug Abuse Data Share Website. The page has a dark blue header with the NIH logo and site name. A search bar is located in the top right. A navigation menu below the header includes links for Home, About Us, Data, Assessments, Guidelines (which is highlighted), Other Links, FAQ, and Contact Us. The main content area is light blue and features a breadcrumb trail 'Home > Guidelines', a 'Guidelines' heading, and two bullet points: 'Registration Agreement' and 'Data Share Policy'. The footer is dark blue and contains a navigation menu with links for Home, About Us, Contact Us, Privacy Policy, Accessibility, FOIA (NIH), and Site Map. Below the footer menu is a disclaimer: 'PDF documents require the free Adobe Reader Microsoft Word documents require the free Microsoft Word viewer Microsoft Excel documents require the free Microsoft Excel viewer'. At the bottom of the footer are the logos for NIH, the Department of Health and Human Services, and USA.gov.

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## Guidelines


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**NIH** 

# Data Share Registration Agreement



**National Institute on Drug Abuse**  
Data Share Website

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## Registration Agreement

Thank you for visiting the NIDA Data Share web site and reviewing our data sharing policy. Before downloading any data, you must first agree to the following terms and conditions (study documents can be viewed without registering). You will be prompted to complete the registration agreement once you attempt to access the data files.



***The recipient of the data agrees:***

1. Not to use the received data, either alone or in conjunction with any other information, in any effort whatsoever to establish identities of any of the subjects from whom the data were obtained.
2. To retain control over the received data, and not to transfer any portion of the received data, with or without charge, to any other entity or individual
3. To notify the Recipient's Institutional Review Board (IRB) operating under an Assurance approved by the Office of Human Research Protections (OHRP) as required by the Recipient's affiliated university, and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46 of any new research projects based on the NIDA data. This requirement is university-specific and is not necessary for data uses such as teaching resources
4. To acknowledge the NIDA database and the specific trials accessed in all oral and written presentations and publications resulting from analyses of the received data. NIDA data should be cited as follows: "The information reported here results from secondary analyses of data from clinical trials conducted by the National Institute on Drug Abuse (NIDA). Specifically, data from NIDA – XXXX-XXXX (actual protocol number and title) were included. NIDA databases and information are available at (<https://datashare.nida.nih.gov>)."
5. To maintain security and privacy of the received data for as long as necessary per local and federal requirements.
6. That the NIDA or its affiliates may contact you concerning publications or other issues regarding use of the data.

***Role of the Sponsor:*** The National Institute on Drug Abuse (NIDA) has no role in the preparation, review, or approval of the manuscript.

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# Data Share Policy



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## Data Share Policy

The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers to expedite the translation of research results into knowledge, products and procedures to improve human health.

Data sets for CTN protocols will be available after (1) the primary paper has been accepted for publication, or (2) the data is locked for more than 18 months, whichever comes first.

In order to make the CTN data available to as wide an audience as possible, a Data Sharing link has been created on the CTN Homepage (link to be added). As studies are completed and their data become available, this site will be linked to that data.

The following will be posted per protocol:

1. Data set (SAS)
2. Data set (ASCII)
3. Annotated Case Report Forms, Define file (aka data dictionary)
4. Study protocol. The Investigators can provide an abbreviated protocol for sharing purposes, attached with the final study report
5. Reference to study publication of primary outcome


(DTMC data share policy is under development.)

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- [NIH Public Data Sharing Policy](#)
- [Clinical Trials.gov](#)
- [SDTM Information](#) 
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# FAQ Tab



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## Frequently Asked Questions

- 1. Do I need IRB approval to download data?**
  - The Recipient's Institutional Review Board (IRB) should be notified of any new research projects based on the NIDA data. This requirement is university-specific and is not necessary for data uses such as teaching resources. These data are good learning tools for new researchers and for those unfamiliar with clinical trials or SDTM data structures.
- 2. How do I download data?**
  - Click on the "Data" tab at the top of the web page.
  - Click on the the desired protocol number from the first table column.
  - The protocol description along with a box on the right will appear, that box will contain the primary manuscript, CRFs, data dictionary and the data files.
  - Click on "Data Files" from the box, this will take you to the data share agreement. Complete the boxes at the bottom of the page including your name, position, affiliation, e-mail, and country of origin. Select the preferred data file format (SAS, ASCII, or both). Click "submit" to proceed with download.
  - The data files will display at the top of the page in the format you requested. You may then save the WinZip files to your computer.
- 3. Can I open the CSV data files using Excel?**
  - The CSV data files are just comma delimited ASCII files that are in a format that you can open using any EXCEL version most of the time. However, for extremely large files (>65,536 records) you will need to use another method to view all data simultaneously such as the following:
    - Open all records at once in WordPad, NotePad, or EXCEL 2007
    - Import into an analysis software package such as SAS or SPSS
    - Open all records using a text file editor such as WordPad or NotePad and divide dataset into smaller files
- 4. Can I open/import SAS XPT files using SPSS?**
  - SAS transport files can easily be imported into SPSS as follows:
    - Open SPSS and select File-> Open -> Data
    - Choose option "SAS Transport (\*.xpt)"
    - Select desired dashare XPT file to open in SPSS



# LIVE DEMONSTRATION

# Assessments Tab



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## Assessments

[Main](#) [By Category](#)

Here you will find a collection of assessments used on NIDA studies found on the Data Share website. Records for individual assessments contain a brief description of the assessment, which category the assessment is classified in, related assessments, if any, links to other protocols using the assessment, and possibly a link to more information about the assessment. All of the links to additional information, found in the green boxes, are from sites outside of the NIDA Data Share website. Most of this information is from the [Alcohol and Drug Abuse Institute Library](#) at the University of Washington.

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A

[Abuse Experiences Questionnaire](#)

[Addiction Recovery Scale](#)

[Addiction Research Center Inventory](#)

[Addiction Severity Index Lite](#)

[Adherence / Competence Rating Scales](#)

[Adjective Rating Scale for Withdrawal](#)

[Adult ADHD Investigator Symptom Rating Scale](#)

[Adult ADHD Self Report Rating Scale](#)

[Adult Clinician Diagnostic Scale](#)

[Alcohol Use Disorders Identification Test](#)


[Attitudes Toward Condom Use](#)

[Attitudes Towards the Female Condom](#)

B

[Barratt Impulsiveness Scale](#)

# Assessments- Main



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## Addiction Severity Index Lite

Submitted by administrator on Thu, 02/25/2016 - 10:38

**Abbreviation**  
ASI

**Catalog Link**  
[Addiction Severity Index Lite Information](#)

**Description**  
The Addiction Severity Index - Lite version (ASI-Lite) is a shortened version of the Addiction Severity Index (ASI). The ASI is a semi-structured instrument used in face-to-face interviews conducted by clinicians, researchers or trained technicians. The ASI covers the following areas: medical, employment/support, drug and alcohol use, legal, family/social, and psychiatric. The ASI obtains lifetime information about problem behaviors, as well as problems within the previous 30 days. The ASI-Lite contains 22 fewer questions than the ASI, and omits items relating to severity ratings, and a family history grid. It can be administered in approximately 30 minutes.


**Category**  
Substance Use

**Subcategory**  
Drugs

### Studies Using This Assessment

- [NIDA-CSP-1018](#)
- [NIDA-CSP-1025](#)
- [NIDA-CSP-1026](#)
- [NIDA-CTN-0001](#)
- [NIDA-CTN-0002](#)
- [NIDA-CTN-0003](#)
- [NIDA-CTN-0004](#)
- [NIDA-CTN-0005](#)
- [NIDA-CTN-0006](#)
- [NIDA-CTN-0009](#)
- [NIDA-CTN-0011](#)
- [NIDA-CTN-0013](#)
- [NIDA-CTN-0014](#)

# Assessments- by category


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## Assessments

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**Category**  **Subcategory**


- Any -
- Any -
- Mental Health
- Substance Use
- Clinic Related Surveys
- Demographics (incl employment)
- Health Cognitions & QOL
- Impulsivity and General Trait & Behavior Scales
- Interpersonal Relationships/Culture
- Physical/General Health
- Clinical Measures
- Sexual Behavior/HIV

- [Adult ADHD Investigator Symptom Rating Scale](#)
- [Adult ADHD Self Report Rating Scale](#)
- [Adult Clinician Diagnostic Scale](#)
- [Alcohol Use Disorders Identification Test](#)
- [Attitudes Toward Condom Use](#)
- [Attitudes Towards the Female Condom](#)

B

- [Barratt Impulsiveness Scale](#)
- [Barriers to Treatment Inventory](#)
- [Beck Anxiety Inventory](#)
- [Beck Depression Inventory](#)

# Mental Health Assessments


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## Assessments

Main
By Category

Category	Subcategory		
<div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;">                     Mental Health                 </div> <p>A</p> <p><a href="#">Adult ADHD Self Report Rating Scale</a></p> <p><a href="#">Adult Clinician Diagnostic Scale</a></p> <p>B</p> <p><a href="#">Beck Anxiety Inventory</a></p> <p><a href="#">Beck Depression Inventory</a></p> <p><a href="#">Brief Symptom Inventory</a></p> <p><a href="#">Brief Psychiatric Rating Scale</a></p> <p>C</p> <p><a href="#">Center for Epidemiologic Studies-Depression Short Depression Scale</a></p> <p><a href="#">Children's Global Assessment Score</a></p> <p><a href="#">Clinical Global Impression Scales</a></p> <p><a href="#">Clinician Administered PTSD Life Events Checklist</a></p> <p><a href="#">Clinician-Administered PTSD Scale for DSM-IV</a></p> <p><a href="#">Composite International Diagnostic Interview for DSM-IV</a></p> <p><a href="#">Concise Associated Symptoms Tracking</a></p> <p><a href="#">Concise Health Risk Tracking Scale</a></p> <p>D</p>	<div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;">                     - Any -                 </div> <ul style="list-style-type: none"> <li style="background-color: #007bff; color: white; padding: 2px;">- Any -</li> <li>Depression</li> <li>ADHD</li> <li>PTSD</li> <li>Eating Disorders</li> <li>Dementia</li> <li>Suicidal Intent</li> <li>Antisocial Personality</li> <li>General/Multiple Disorders</li> <li>Anxiety</li> <li>Diagnostic</li> <li>Tobacco</li> <li>Alcohol</li> <li>Drugs</li> </ul>	<input type="button" value="Apply"/>	<input type="button" value="Reset"/>

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## Beck Depression Inventory

Submitted by administrator on Thu, 02/25/2016 - 10:38

**Abbreviation**

BDI

**Description**

The Beck Depression Inventory was developed to measure the behavioral manifestations of depression in adolescents and adults. It was designed to standardize the assessment of depression severity in order to monitor change over time or to simply describe the illness. The BDI is a 21-item test presented in multiple choice format which is used to measure presence and degree of depression in adolescents and adults. Each of the 21-items of the BDI attempts to assess a specific symptom or attitude associated with depression, that association being consistent with descriptions of the depression contained in the psychiatric literature. The test takes 5-10 minutes to complete. Reading age of about 10 is required for a patient who is self-administering the test. In 1978, the scale was revised (BDI-IA) to eliminate duplicate severity descriptors and to reword certain items. In addition, the time frame for assessment was lengthened to the "last week, including today." In 1996, a new version of the BDI (BDI-II) with a modification of items to reflect DSM-IV criteria and to simplify wording was published. The time frame was extended to include the "last 2 weeks." The BDI-II is a 21 item measure (Beck et al., 1996) self-report measure. Although psychometric data presented in the manual for the new BDI-II look promising, the time frame extension to 2 weeks makes this instrument less useful for assessing patterns of change over time. There is evidence that the BDI-II performs well in treatment-seeking substance abusers.

**Category**

Mental Health

**Subcategory**

Depression

### Studies Using This Assessment

[NIDA-CTN-0009](#)[NIDA-CTN-0029](#)[NIDA-CTN-0030](#)[NIDA-CTN-0046](#)[NIDA-CTO-0004](#)

# A Research Example

- A researcher interested in the comorbidity, between **drug addiction** and **depression**...





# Questions

**Any questions so far before we  
move on to the next section ...**



# TIPS AND TRICKS



# Documentation

- Read each protocol to understand:
  - Eligibility criteria
  - Visit timing/windows
  - Procedures for data collection
- Review annotated CRFs to:
  - Determine data elements
  - Evaluate codelists (commonality/harmonization)
  - Identify corresponding data files
- Read de-identification notes/nulled values docs
  - What information has been deleted\*
  - What fields have been removed

*\* Contact study PI for access to raw data*

# Data Structure

- **CRF Level** – wide data files
  - One dataset per case report form
  - Each question/variable is a separate column
  - Requires substantial merging of different datasets
- **CDISC** – long and narrow data files
  - One row per question on CRF
  - Variable name/question described in one or more columns
  - All values/answers in one column
  - Minimizes amount of merging
  - Data from one case report form can be mapped to more than one dataset

# CRF-level data (CTN-0052)

PROT	PATID	VISNO	UDTSTPRF	UDCOLDT	UD1TMP	UD1ADULT	UD1THC	UD1OPI	UD1COC	UD1MDMA	UD1OXY	UD1MTD	UD1BAR
0052	193369	30	1	100	1	0	0	0	0 0	0	0	0	0
0052	193369	29	1	98	1	0	0	0	0 0	0	0	0	0
0052	193369	28	1	93	1	0	0	0	0 0	0	0	0	0
0052	193369	27	1	91	1	0	0	0	0 0	0	0	0	0
0052	193369	26	1	87	1	0	0	0	0 0	0	0	0	0
0052	193369	25	1	85	1	0	0	0	0 0	0	0	0	0
0052	193369	24	1	80	1	0	0	0	0 0	0	0	0	0
0052	193369	23	1	77	1	0	0	0	0 0	0	0	0	0
0052	193369	22	1	72	1	0	0	0	0 0	0	0	0	0
0052	193369	21	1	70	1	0	0	0	0 0	0	0	0	0
0052	193369	20	1	67	1	0	0	0	0 0	0	0	0	0
0052	193369	19	1	65	1	0	0	0	0 0	0	0	0	0
0052	193369	18	1	60	1	0	0	0	0 0	0	0	0	0
0052	193369	17	1	56	1	0	0	0	0 0	0	0	0	0
0052	193369	16	1	51	1	0	0	0	0 0	0	0	0	0
0052	193369	15	1	49	1	0	0	0	0 0	0	0	0	0
0052	193369	14	1	44	1	0	0	0	0 0	0	0	0	0
0052	193369	13	1	42	1	0	0	0	0 0	0	0	0	0
0052	193369	12	1	37	1	0	0	0	0 0	0	0	0	0

# CDISC Data (CTN-0009)

DOMAIN	USUBJID	EPOCH	VSTESTCD	VSTEST	VSORRES	VSORRESU	VISIT	VISITNUM	VSDY
VS	09_000748	SCREENING	DBP	DIASTOLI	76	MMHG	SCREENING	-3	-23
VS	09_000748	BASELINE	DBP	DIASTOLI	86	MMHG	BASELINE	-2	-14
VS	09_000748	PRETQD	DBP	DIASTOLI	77	MMHG	PRE-TDQ	-1	6
VS	09_000748	TREATMENT	DBP	DIASTOLI	71	MMHG	TREATMENT	1	14
VS	09_000748	TREATMENT	DBP	DIASTOLI	79	MMHG	TREATMENT	2	21
VS	09_000748	TREATMENT	DBP	DIASTOLI	83	MMHG	TREATMENT	3	27
VS	09_000748	TREATMENT	DBP	DIASTOLI	74	MMHG	TREATMENT	4	34
VS	09_000748	TREATMENT	DBP	DIASTOLI	71	MMHG	TREATMENT	5	42
VS	09_000748	TREATMENT	DBP	DIASTOLI	79	MMHG	TREATMENT	6	49
VS	09_000748	TREATMENT	DBP	DIASTOLI	74	MMHG	TREATMENT	7	57
VS	09_000748	TREATMENT	DBP	DIASTOLI	84	MMHG	TREATMENT	8	63
VS	09_000748	FOLLOW UP	DBP	DIASTOLI	84	MMHG	FOLLOW UP	9	69
VS	09_000748	FOLLOW UP	DBP	DIASTOLI	83	MMHG	FOLLOW UP	13	105
VS	09_000748	SCREENING	PULSE	PULSE	93	BEATS/MIN	SCREENING	-3	-23
VS	09_000748	BASELINE	PULSE	PULSE	88	BEATS/MIN	BASELINE	-2	-14
VS	09_000748	PRETQD	PULSE	PULSE	87	BEATS/MIN	PRE-TDQ	-1	6
VS	09_000748	TREATMENT	PULSE	PULSE	83	BEATS/MIN	TREATMENT	1	14
VS	09_000748	TREATMENT	PULSE	PULSE	90	BEATS/MIN	TREATMENT	2	21
VS	09_000748	TREATMENT	PULSE	PULSE	82	BEATS/MIN	TREATMENT	3	27
VS	09_000748	TREATMENT	PULSE	PULSE	72	BEATS/MIN	TREATMENT	4	34
VS	09_000748	TREATMENT	PULSE	PULSE	86	BEATS/MIN	TREATMENT	5	42
VS	09_000748	TREATMENT	PULSE	PULSE	79	BEATS/MIN	TREATMENT	6	49
VS	09_000748	TREATMENT	PULSE	PULSE	95	BEATS/MIN	TREATMENT	7	57
VS	09_000748	TREATMENT	PULSE	PULSE	84	BEATS/MIN	TREATMENT	8	63
VS	09_000748	FOLLOW UP	PULSE	PULSE	65	BEATS/MIN	FOLLOW UP	9	69



# Data Formats

- **ASCII**
  - Text files
  - CSV – comma separated values
  - Can be read into SAS, SPSS, Excel, Stata, etc.
- **SAS**
  - Usually SAS transport file (.xpt)
    - Can be read into SPSS, SAS, DBMS Copy, and other programs
    - Some studies have formats catalogue
  - Sometimes standard SAS file (.sas7bdat)
    - Can be read into SPSS and SAS

# Notes on De-identification



- Participant IDs are *not* those of the actual study
- Site is dropped
- All free text fields removed
- Dates converted to study day or days since informed consent

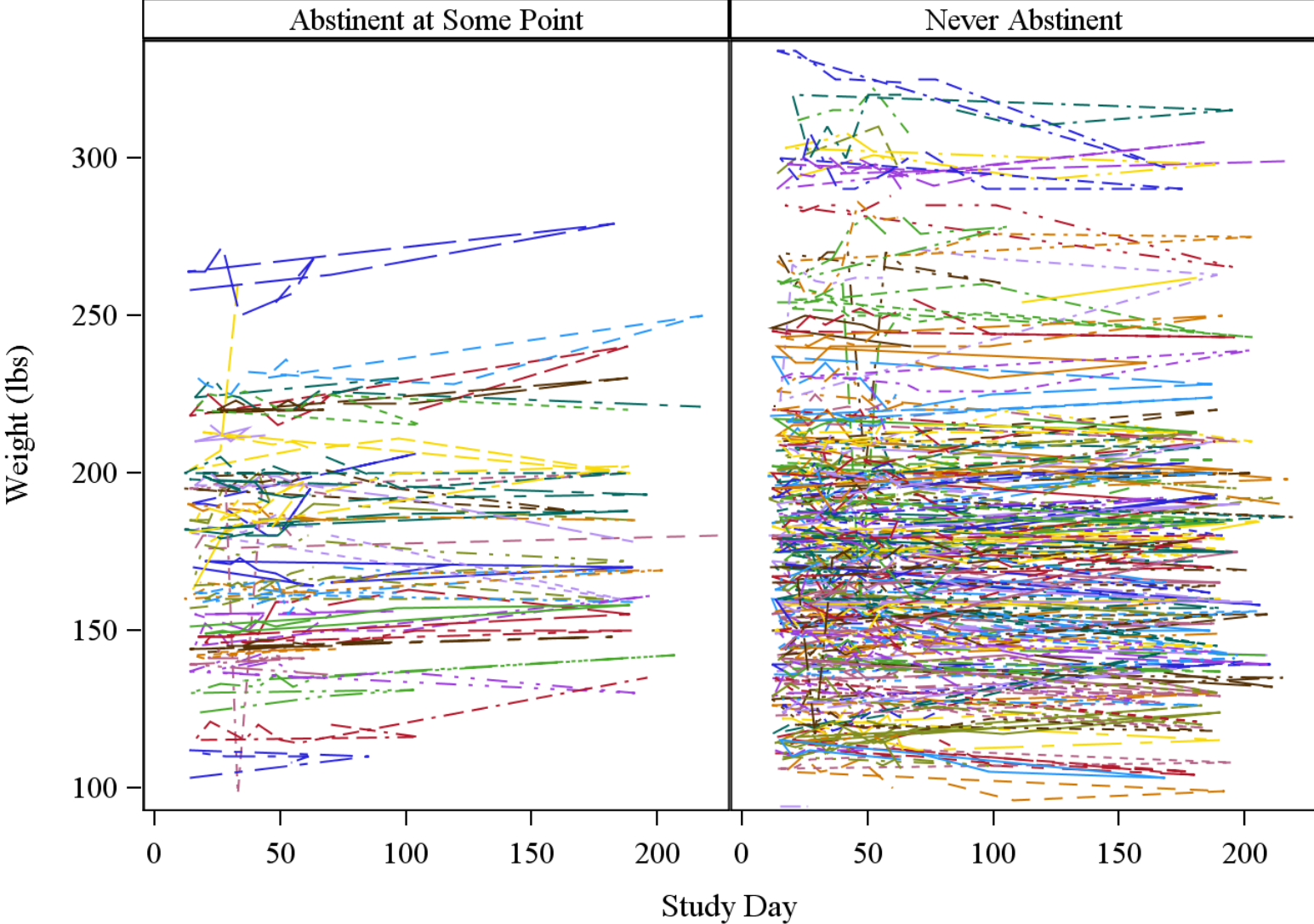
**If you find any of the above information – please inform DSC, IGNORE and DELETE it**



- Pay special attention to CDISC data
  - “Epoch” and “Visit Name” usually have to be combined or use study day
  - “Domain” is defined on each CRF
- These are raw data
  - Data cleaning not perfect – check for inconsistencies and outliers
  - Note how missing data is coded – varies from study to study and form to form
- Be very careful when merging datasets
- When publishing/presenting, make sure to reference primary manuscript



### CTN-0009: Spaghetti Plot of Weight over Time by Level of Nicotine Abstinence



# Statistical Considerations

## Secondary analyses have several pitfalls:

- Type I error (false positives)
- Underpowered
- Must be interpreted with caution
  - Cannot imply causality
  - Analyses are exploratory in nature and hypothesis-generating
- Analyses from Data Share will likely be *post hoc* – must acknowledge



***Despite these pitfalls, secondary analyses are powerful tools and, as long as they are reported in a transparent manner, will contribute significantly to the literature***

# CTN Web Seminar: Secondary Analyses

## Secondary Analyses Clinical Trials

- Presenters: George Bigelow, Abigail G. Matthews, Daniel Feaster
- Learning objectives:
  - Review statistical issues with analyzing and reporting secondary analyses
  - Explore importance of pre-specification
  - Discuss reporting and interpreting secondary analyses, including PC perspective

<http://ctndisseminationslibrary.org/display/1039.htm>



# CDISC Resources

- Official website:

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

- Standards:

<https://www.cdisc.org/standards/foundational/sdtm>

- SAS import:

<http://support.sas.com/documentation/cdl/en/cdisc/60755/HTML/default/viewer.htm#titlepage.htm>



# References

- Matthews, A., Feaster, D., & Bigelow, G. (2013). Secondary analyses for clinical trials in development. *CTN Web Seminar Series*. <http://ctndisseminationslibrary.org/display/1039.htm>
- Shmueli-Blumberg, D., Hu, L., Allen, C., Frasketi, M., Wu, L.T., Vanveldhuisen, P. (2013). The national drug abuse treatment clinical trials network data share project: website design, usage, challenges, and future directions. *Clinical Trials*, 10 (6): 977-986.
- Funding opportunity: Accelerating the Pace of Drug Abuse Research Using Existing Data.  
<http://grants.nih.gov/grants/guide/pa-files/PAR-16-234.html>

# Questions / Comments



*Alternatively, questions can be directed to the presenter(s) by sending an email to [CTNtraining@emmes.com](mailto:CTNtraining@emmes.com).*

# http://ctndisseminationlibrary.org/ctnraining.htm

A recording of this presentation will be available electronically.

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
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- Helping Clinicians Become Proficient in Motivational Interviewing


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- Protocols (Studies) in the CTN
- CTN Nodes & Community Treatment Programs (CTPs)
- CTN International Activities *new!*
- NIDA's CTN web site
- ATTC's Blending Product site
- NIDA Data Share
- CTN Directory (2014)


### New in the Library RSS




Lessons Learned for Follow-up Phone Booster Counseling Calls with Substance Abusing Emergency Department Patients by Donovan, Hatch-Maillette, Phares, et al. *J Subst Abuse Treat* 2014 (in press).



Client and Provider Views on Access to Care for Substance-Using American Indians: Perspectives from a Northern Plains Urban Clinic by Kropp, Lilleskov, Richards, et al. *Am Indian Alsk Native Ment Health Res* 2014;21(2):43-65.



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# Next Topic...

## **Preparation for Drug Management and Accountability in a CTN Clinical Trial**

**October 19, 2016  
1:00 pm ET**



**THANK YOU FOR YOUR  
PARTICIPATION**