

# The Use of Ancillary Data Capture Systems in Clinical Trials



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# Background



- Use of technology is increasing in clinical trials
- A variety of systems may be used to collect clinical trial data
- Presentation draws on experiences and lessons learned using a variety of systems in a large multi-center, multi-study clinical trials network

# NIDA CTN



- Clinical Trials Network (CTN) of the National Institute on Drug Abuse (NIDA)
- Multi-site, multi-protocol network designed to study pharmacological and behavioral interventions for the treatment of substance use disorders in community treatment programs
- The EMMES Corporation has a contract to serve as the Data and Statistics Center (DSC) for the network

# What Are Ancillary Data Capture Systems?



- Software systems utilized to capture data beyond that typically collected via case report forms (CRFs) in an electronic data capture (EDC) system
- May be used to
  - Administer study intervention (e.g., TES System)
  - Monitor study intervention (e.g., STRIDE Website)
  - Perform study assessments (e.g., CIDI Assessment)
- Data entered by site personnel or directly by the study participant

# Types of Ancillary Systems used by NIDA CTN



- **Therapeutic Education System (TES)**
  - Interactive, self-directed web-based psychosocial intervention
  - Contains modules on cognitive relapse prevention skills, prevention of sexually transmitted infections, and skills to improve psychosocial functioning
  - Contains a contingency management component whereby participant is eligible for prizes based on completion of modules and provision of drug-free urines
  - Participant interacted directly with the interface either in the clinic or at home
  - Site personnel monitored compliance with the system through administrative rights
  - TES was the behavioral intervention compared to treatment as usual (TAU) in the CTN-0044 study

# Therapeutic Education System (TES)



Participants are provided with a menu of modules to complete



[Home](#) [Logout](#)

TES

You may complete any of the following modules:

- ▶ [What is a Functional Analysis?](#)

Click on a module name above to proceed or view a [MAP](#) of your entire program.

▶ = Current Module   ■ = Incomplete   ■ = Completed   ■ = Not Yet Available



[Home](#) [Logout](#)

TES

Core Modules

Training Module

- ▶ [What is a Functional Analysis?](#)
- Conducting a Functional Analysis
- Self-Management Planning
- Introduction to Problem Solving
- Effective Problem Solving
- Drug Refusal Skills Training
- Seemingly Irrelevant Decisions
- Coping with Thoughts About Using
- Awareness of Negative Thinking
- Managing Negative Thinking
- Managing Thoughts About Using
- Managing Negative Moods and Depression
- Decision-making Skills
- Increasing Self-confidence in Decision-making

# Therapeutic Education System (TES)



Site staff track completion of modules and enter results of urine drug screens

**Progress Report** Print | Close

**Three, Test [Test3]**

Date	Code*	% Accuracy	Module
8/30/07 8:54:31 AM	S.M		Training Module
8/30/07 8:54:37 AM	F.M		Training Module

\* Code Mapping: S=Start, F=Finish, P=Presentation, M=Module, MC=Multiple Choice, FIB=Fill-in-the-Blank

**Enter Results: test**

Mo. Day Year Hour Min.  
3 / 3 / 2010 14 : 48 Eastern Standard Time

Today's Scheduled Target Behaviors

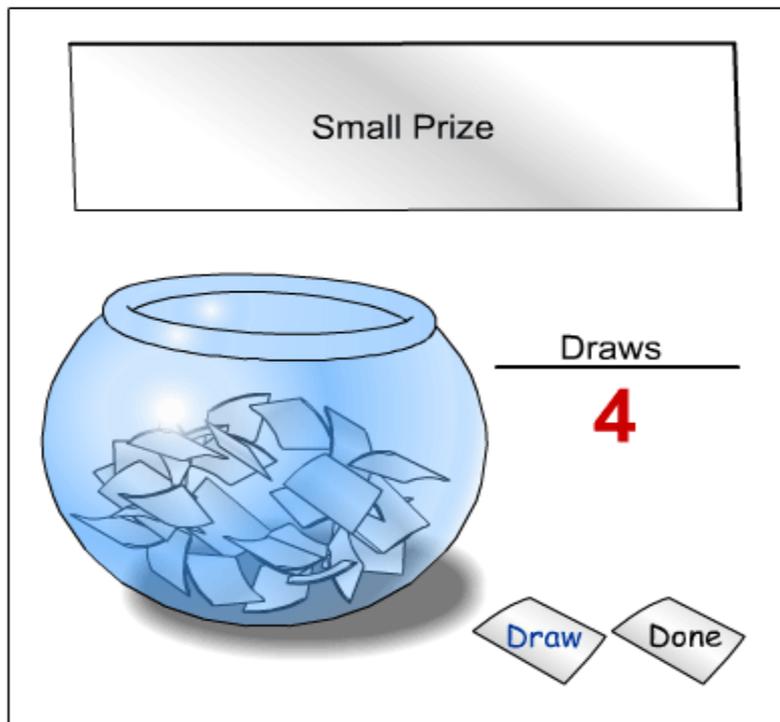
Primary substance abstinent?  Yes  
 No  
 Excused  
 No Show

All substances abstinent?  Yes  
 No  
 Excused  
 No Show

# Therapeutic Education System (TES)



Participants earn draws and prizes for completion of modules and drug-free urines and site personnel track redemption of draws and provision of prizes



## Account History

### Primary

<input type="checkbox"/> Date	Description	Amount	Redeemed On
2/22/2010 10:34 [EST]	Voucher Deposit: All Neg	2.00	
2/22/2010 10:34 [EST]	Voucher Deposit: Primary	1.00	
2/25/2010 10:33 [EST]	Voucher Deposit: Primary	0.00	
2/25/2010 10:33 [EST]	Voucher Deposit: All Neg	0.00	
2/25/2010 10:35 [EST]	Voucher Deposit: Primary	0.00	
2/25/2010 10:35 [EST]	Voucher Deposit: All Neg	0.00	
2/28/2010 1:57 [EST]	Voucher Deposit: All Neg	0.00	
2/28/2010 1:57 [EST]	Voucher Deposit: Primary	1.00	
3/01/2010 10:13 [EST]	Voucher Deposit: Primary	1.00	
3/01/2010 10:13 [EST]	Voucher Deposit: All Neg	0.00	
3/01/2010 10:26 [EST]	Voucher Deposit: Primary	1.00	
3/01/2010 10:26 [EST]	Voucher Deposit: All Neg	0.00	
3/01/2010 10:39 [EST]	One Draw for: Small Prize	-1.00	3/01/2010 10:40 [EST]
<input type="checkbox"/> 3/01/2010 12:27 [EST]	One Draw for: Small Prize	-1.00	
3/01/2010 2:00 [EST]	One Draw for: Small Prize	-1.00	3/01/2010 2:01 [EST]

BALANCE 3.00

Redemption Note (optional)

Redeem

# Types of Ancillary Systems used by NIDA CTN



- **STRIDE Website**
  - Web-based system designed to schedule and record details (date, duration, type, etc.) about exercise and health interventions
  - Study participants can access the system from the clinic or at home to schedule intervention sessions and to document completion of intervention sessions, as well as any barriers to completing scheduled intervention sessions
  - Site personnel can use the system to monitor completion of intervention sessions and to help participants schedule or document completion of intervention sessions
  - Used on the CTN-0037 study to capture information about the two study interventions: Vigorous Intensity High Dose (VIHD) Exercise and Health Education

# STRIDE Website



Participants use the website to plan an intervention session and receive a worksheet to document their prescribed session

Home  
Contact

## YOUR EXERCISE PLAN

999999

Thursday, April 29, 2010

### Exercise Level and Time

Start Time

12 00 AM

Treadmill

Average Speed 1.5

Exercise Time: 0 mins.

Average Grade .01

Calories to burn this session

112.5

Plan

Click to delete session plan

Delete

REMEMBER TO PRINT YOUR SESSION LOG

Printer-friendly version

### Exercise Log

999999

Use this form as your personal training log

It is recommended that you fill in the results of your exercise, such as actual time and heart rate, upon completion

Sign in and update your personal record to keep your information up to date.

Calories to burn for this session

112.5

Start Date

Thursday, April 29, 2010

Start Time

5:00 PM

Location of exercise

In the Lab

### Treadmill

Speed 3.1 Estimated Time 18 minutes

Grade 0.03

Heart Rate  bpm

RPE  (6-20)

Distance  miles

Actual Time (min:sec)  :

Pre-Step count

Post-Step count

# STRIDE Website



Participants document completion of intervention session and reports are available to track progress

[Home](#)

[Contact](#)

## UPDATE YOUR RESULTS

Thursday, April 29, 2010

Indicate the time that you completed your session below

Start Time

5:00 PM

End Time

12:00 AM

**Treadmill**

Avg. Speed 3.1

Avg. Grade 0.03

Plan time (mins) 18

Actual time (mins : secs)

Avg. HR

Avg. RPE

Actual EE

Energy Exp. (Polar HR)

Energy Exp. (Treadmill)

Distance (miles)

Pre-Session Step Count

Post-Session Step Count

[Submit](#)

ALL FIELDS MUST BE COMPLETED

[Home](#)

[Contact](#)

## YOUR EXERCISE RESULTS

999999

STRIDE Overall Progress:

[Week 1](#)

Date Scheduled	Date Updated	Location	Prescribed Calories	Actual Calories
4/29/2010	4/29/2010	LAB	112.5	213
		<b>Avg. Speed</b>	<b>Avg. Grade</b>	<b>Time</b>
	Treadmill	3.1	0.03	15m 25s
Date Scheduled	Date Updated	Location	Prescribed Calories	Actual Calories
4/29/2010	4/29/2010	LAB	79	125
		<b>Avg. Speed</b>	<b>Avg. Grade</b>	<b>Time</b>
	Treadmill	2.3	0.06	15m 25s

# STRIDE Website



Participants can document any barriers to completing scheduled intervention sessions

Please identify specific barriers which made it difficult to meet your exercise goals

## Barriers to Exercise

Please check ALL OF THE REASONS that apply to you

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Time               | <input type="checkbox"/> Weather            | <input type="checkbox"/> Stress                      |
| <input type="checkbox"/> Travel             | <input type="checkbox"/> Inconvenience      | <input type="checkbox"/> Injury                      |
| <input type="checkbox"/> Work               | <input type="checkbox"/> Emotional triggers | <input type="checkbox"/> Pain or discomfort          |
| <input type="checkbox"/> Fatigue            | <input type="checkbox"/> Social function    | <input type="checkbox"/> Health problems             |
| <input type="checkbox"/> Lack of motivation | <input type="checkbox"/> Lack of support    | <input type="checkbox"/> I did not find it difficult |
| <input type="checkbox"/> Holidays           | <input type="checkbox"/> Family demands     | <input type="checkbox"/> Other                       |

If other, please be specific

Submit

# Types of Ancillary Systems used by NIDA CTN



- **Composite International Diagnostic Interview (CIDI)**
  - A structured diagnostic interview that evaluates the presence of Axis 1 disorders as defined in the Diagnostic and Statistical Manual – IV (DSM-IV)
  - A web-based version of the CIDI was used on the CTN-0037 study to administer the instrument and to determine if the participant met the substance use disorder diagnosis required per the protocol
  - Due to instrument length and complex skip patterns, we chose to use an already developed/validated system rather than to program it into the study EDC system

# CIDI



Upon enrollment of participant in the EDC system, the participant ID is programmatically “pushed” to the CIDI system to allow for easy registration of the participant in the CIDI system

Available Transfers:				
Participant ID	Initials	Sex	DOB	
370143	ABC	A	2/1/1900	<a href="#">Register »</a>
370167	ABC	A	2/1/1900	<a href="#">Register »</a>
370172	ABC	A	2/1/1900	<a href="#">Register »</a>
370173	ABC	A	2/1/1900	<a href="#">Register »</a>
370189	ABC	A	2/1/1900	<a href="#">Register »</a>

# CIDI



Upon completion of the assessment, the user is provided with a report that contains the participant's diagnosis, which is used to assess study eligibility

Diagnostic Report - Substance Use Diagnosis Report (SUDS Report) - 370167						
Substance Abuse Report (CIDI Sections J and L)						
Substance	Screened	Abuse	Abuse Recency	Dependence	Dependence Recency, Full Criteria	Dependence Recency, Any Criteria
Alcohol	Yes	Yes	Within last 2 weeks	Yes	Within last 2 weeks	Within last 2 weeks
Marijuana	No	N/A	N/A	N/A	N/A	N/A
Stimulants	Yes	Yes	Within last 2 weeks	Yes	Within last 2 weeks	Within last 2 weeks
Sedatives	Yes	Yes	Within last 2 weeks	Yes	Within last 2 weeks	Within last 2 weeks
Opioids	Yes	Yes	Within last 2 weeks	Yes	Within last 2 weeks	Within last 2 weeks
Cocaine	Yes	Yes	Within last 2 weeks	Yes	Within last 2 weeks	Within last 2 weeks
PCP	No	N/A	N/A	N/A	N/A	N/A
Psychodelics	No	N/A	N/A	N/A	N/A	N/A
Inhalants	No	N/A	N/A	N/A	N/A	N/A
Other	No	N/A	N/A	N/A	N/A	N/A

(\* indicates that a comment was entered for that answer; mouse over the answer to view the comment.)

# Communication Plan



- A communication plan should be developed soon after identifying the system to be used on the study
- The plan should include:
  - Expectations for software developer support
  - Delegation of responsibilities
  - Workflow for identifying and reporting issues
  - Timeframe for resolving issues
  - Process for integrating software updates
- Helps to ensure that all parties (sponsor, software vendor/developer, and data center) understand and agree upon responsibilities

# Maturity and Scope of System



- Systems will vary in complexity and sophistication
- Systems range from being simple and home-grown to complex and well-validated
- Know what type of system you are getting
  - If the system is home-grown, will you be responsible for any testing and validation?
  - If the system is more mature, how much customization can be done to meet the needs of your project?

# Technical Needs of the System



- Determine the technical needs of the system
  - Where will the system be hosted?
  - What are the hardware and software requirements for hosting the system?
  - What are the hardware and software requirements for using the system?
- Identifying these needs early allows time to procure hardware and software for the hosting group and users prior to study implementation

# Data Structure



- Request the system diagram and data dictionary
- Verify that the data being captured by the system are sufficient and identifiable if intended for analysis
- Identify if protected health information (PHI) is being collected
  - If PHI is collected, develop security measures, such as encryption and restricted access, of the data
  - Ensure that appropriate parties(i.e., the participant, the IRB) are aware that PHI is being collected

# Integration with EDC



- Determine how to link ancillary system data with EDC system data
  - The ancillary system diagram and data dictionary can facilitate this process
- Determine whether or not the system can communicate with the EDC system
  - Can a participant who is registered in the EDC system be automatically registered in the ancillary system?
  - Can data from the ancillary system populate fields in the EDC system?

# Training



- Identify who is responsible for training the users on the ancillary system
- Set-up a training platform/environment
- Develop a training exercise/practicum
- Develop a user's guide for the system
- Conduct training using a variety of methods (i.e., face-to-face, webcast, etc.)

# Monitoring Data Integrity



- Determine if data entered in the system will be reviewed by study monitors
  - In some of the systems we've used, the ability to create a user with read-only rights does not exist, making it challenging for monitors to review data
- Determine if it is possible to generate queries on data entered in the system
  - We have been able to generate queries for data entered in one of the systems, but it required some manipulation of the data structure in order to import it into our query software

# Conclusion



- The use of non-EDC ancillary data systems in clinical trials is feasible
- Appropriate planning, communication, and research is needed to ensure the successful set-up and implementation of such a system

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# Questions?

