# 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?

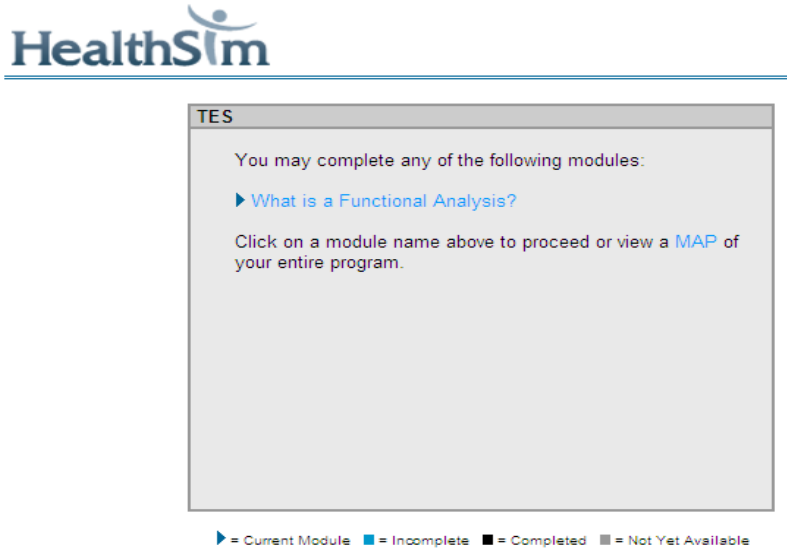
- Software systems utilized to capture data beyond that typically collected via case report forms (CRFs) in an electronic data capture (EDC) system
- May be used to
  - Administer study intervention (e.g., TES System)
  - Monitor study intervention (e.g., STRIDE Website)
  - Perform study assessments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

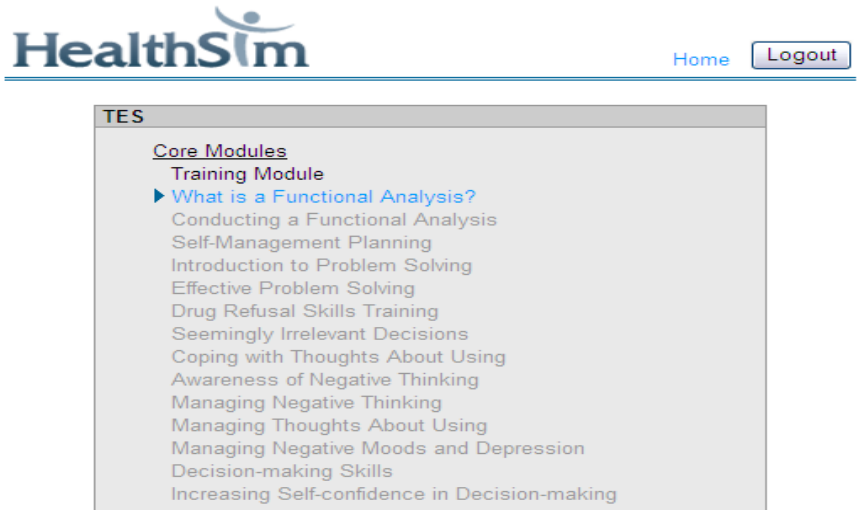
# Types of Ancillary Systems used by NIDA CTN

- 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)

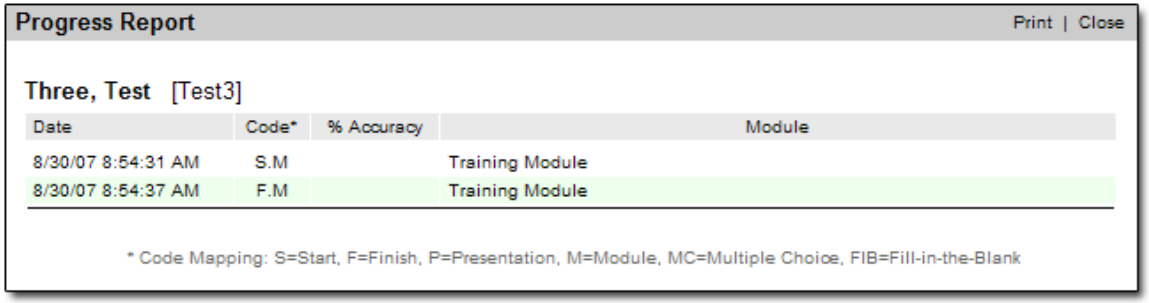
Participants are provided with a menu of modules to complete



# Therapeutic Education System (TES)

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

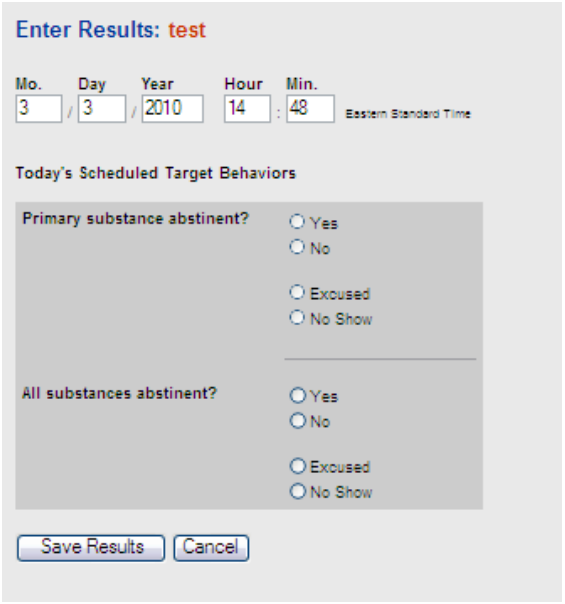


**Progress Report** Print | Close

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

**Today's Scheduled Target Behaviors**

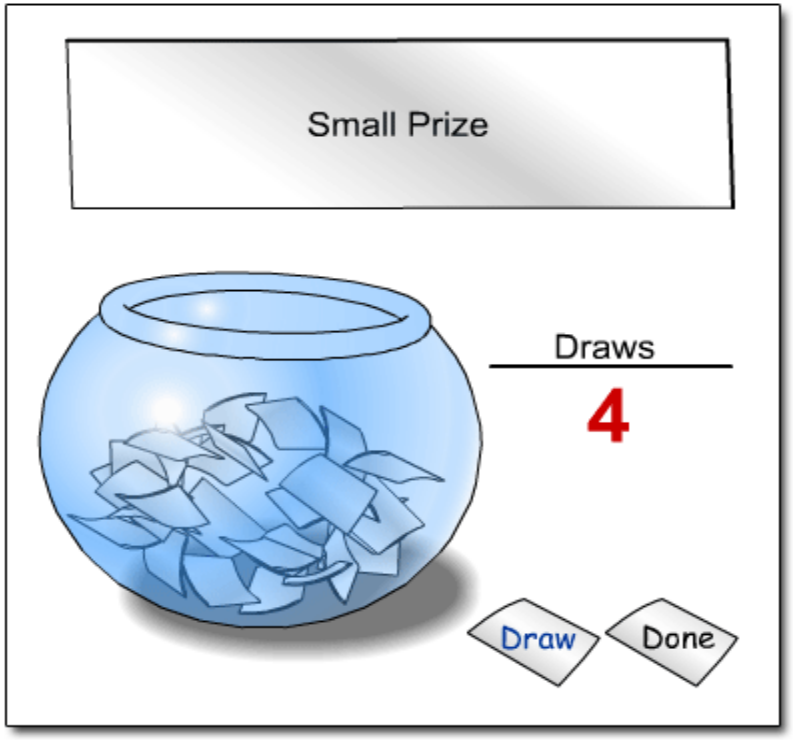
Primary substance abstinent?
- Yes
- No
- Excused
- No Show

All substances abstinent?
- Yes
- No
- Excused
- No Show

Save Results | Cancel

# 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**

| 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] |
| 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)

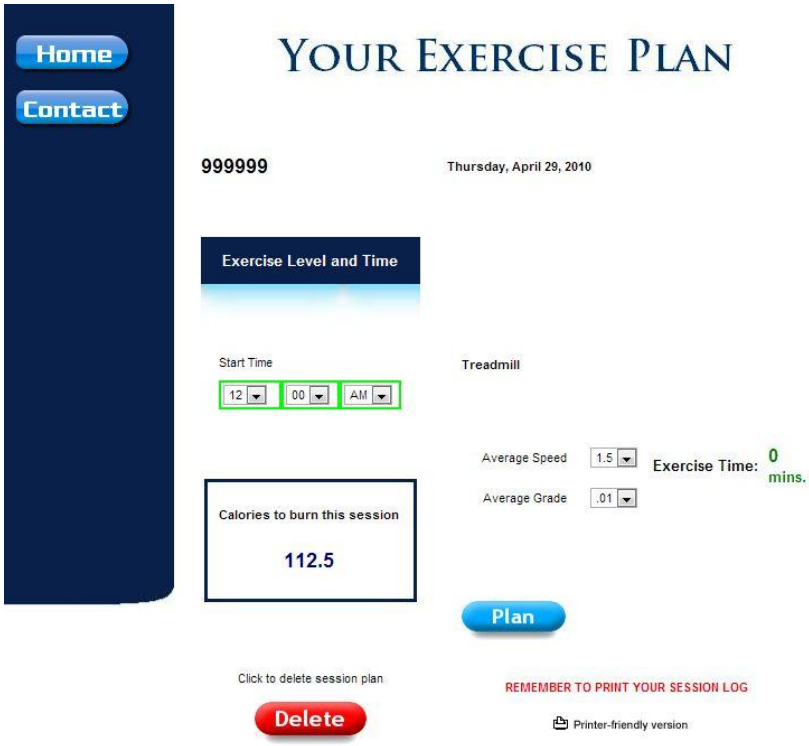
Redeem

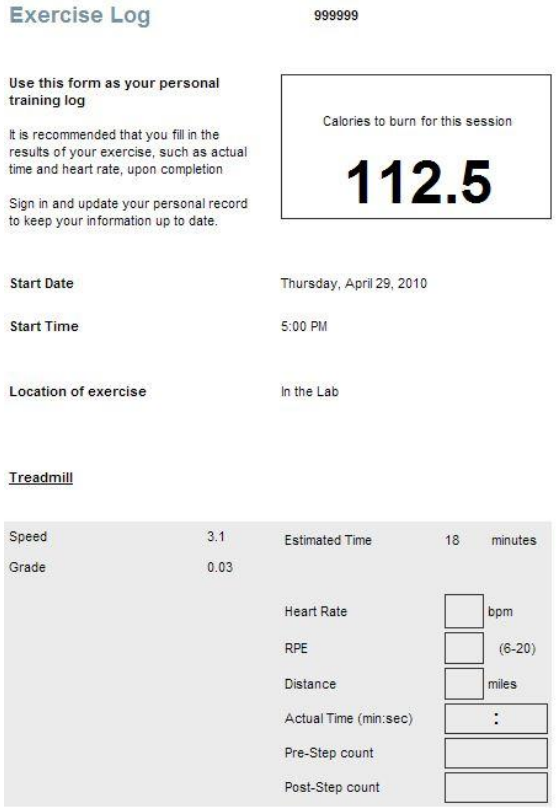
# Types of Ancillary Systems used by NIDA CTN

- 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

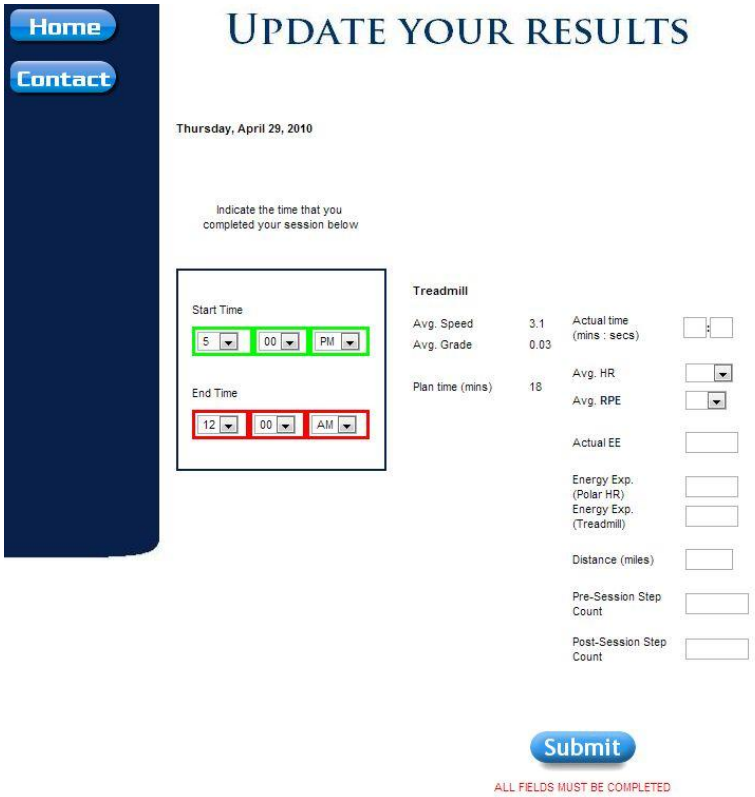
Participants use the website to plan an intervention session and receive a worksheet to document their prescribed session

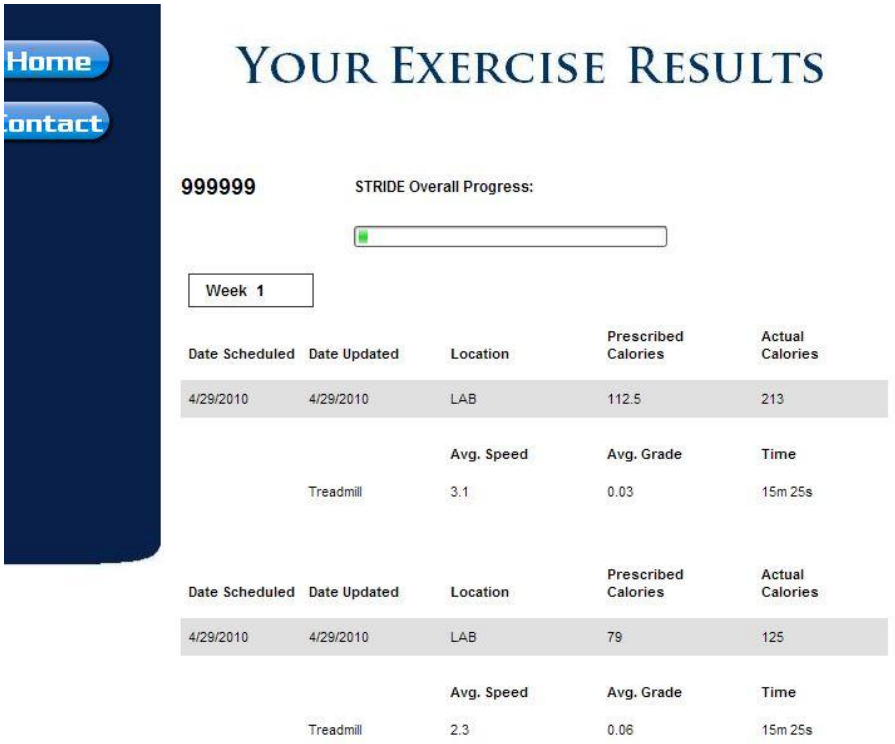


# STRIDE Website

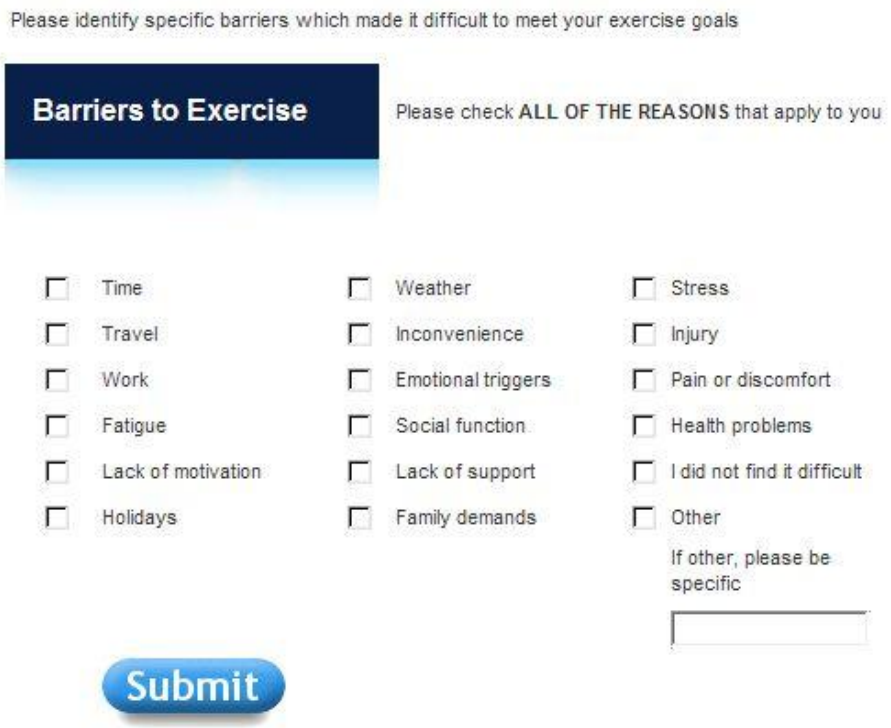
Participants document completion of intervention session and reports are available to track progress



# STRIDE Website

Participants can document any barriers to completing scheduled intervention sessions

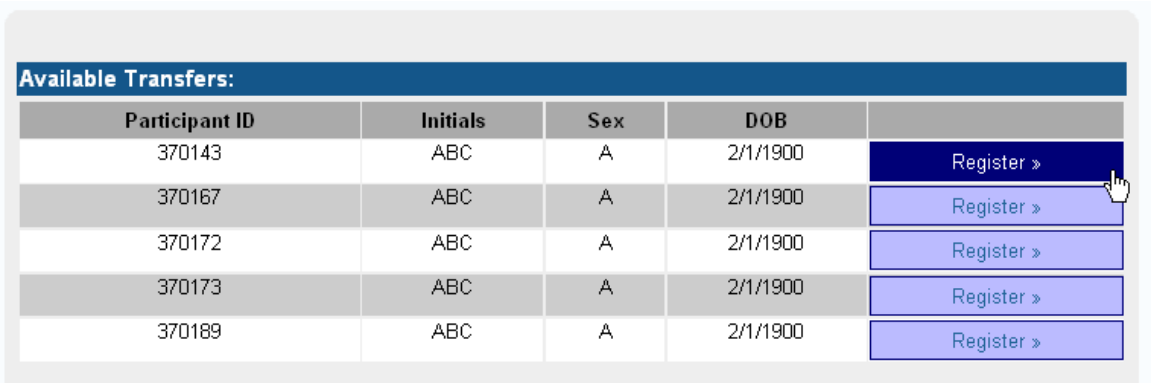


# Types of Ancillary Systems used by NIDA CTN

- 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 | Register » |
| 370167 | ABC | A | 2/1/1900 | Register » |
| 370172 | ABC | A | 2/1/1900 | Register » |
| 370173 | ABC | A | 2/1/1900 | Register » |
| 370189 | ABC | A | 2/1/1900 | Register » |

# 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 |
| Psychadelics | 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.)

« Cancel  Print

# 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

# Acknowledgements


- This project 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. HHSN271200900034C

- Thank you to Dr. Paul Van Veldhuisen, NIDA CTN DSC Principal Investigator, and other members of the NIDA CTN DSC team.

# Questions?