

Lessons Learned In Collecting Participant Reported Outcome Data Via Web-Based Data Systems

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National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN)

- Multi-site, multi-protocol network to study interventions for the treatment of substance use disorders
- The Emmes Corporation has a contract to serve as the Data and Statistics Center (DSC) and Clinical Coordinating Center (CCC) for the network
- DSC – Data management and statistical support in 10 active protocols in various stages



Electronic Patient Reported Outcomes (ePro)

- Developed for participant daily diaries or self-administered questionnaires
- Participants use assigned usernames and passwords to access the systems via the internet and complete assessments on study computers or other portable devices

NIDA CTN Participant Login

User name*

Password*

Login

ePro Benefits

- Can be used to:
 - Identify adverse events
 - Track adherence to study procedures
 - Mask study staff from responses to questions
- Compared to paper source documents
 - System can render and parent questions based on other answers (e.g., gender)
 - On-screen edit checks

NIDA CTN-0059: The TAPS Tool

- Develop and validate a tool to screen and assess primary care patients for tobacco, alcohol, prescription drug, and illicit substance use and problems related to their use
- Participants were randomized to complete The TAPS tool on the iPad directly (alone) then via interview or via interview followed by the iPad
- 2,057 participants total



Health Survey

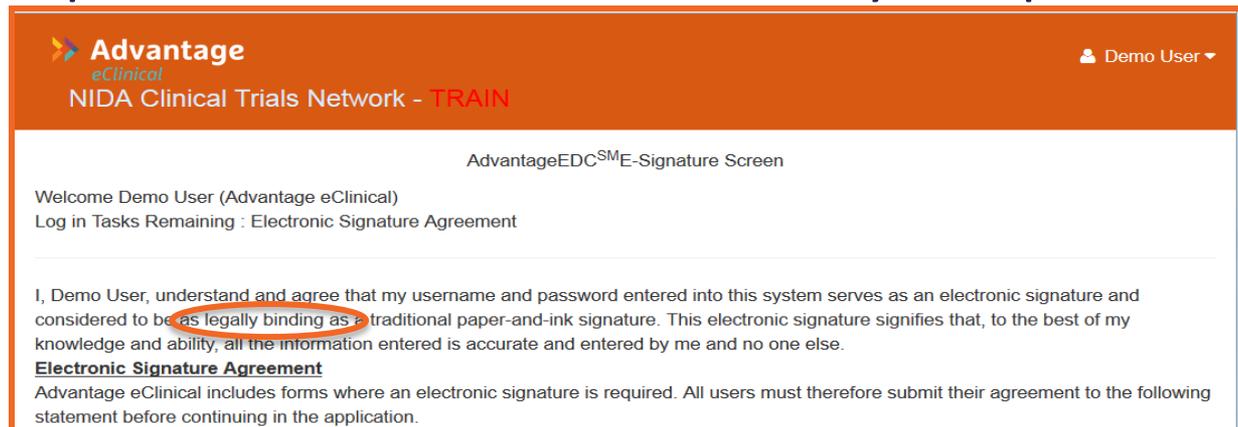
 Click to listen

2. In the PAST YEAR, how often have you had 5 or more drinks in one day?

Daily or almost daily	Weekly	Monthly	Less than monthly	Never
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Implementation - Regulatory Considerations

- Passwords and resetting
 - Automatically generate password based on DEM info (e.g., DOB, Gender+Age)
 - Resetting password without participant e-mail collection
- eSignature phrasing
- Documenting in protocol when direct data entry is expected



The screenshot shows the Advantage eClinical interface for the NIDA Clinical Trials Network - TRAIN. The header includes the Advantage eClinical logo and the user name 'Demo User'. The main content area is titled 'AdvantageEDCSME-Signature Screen' and contains the following text:

Welcome Demo User (Advantage eClinical)
Log in Tasks Remaining : Electronic Signature Agreement

I, Demo User, understand and agree that my username and password entered into this system serves as an electronic signature and considered to be as legally binding as a traditional paper-and-ink signature. This electronic signature signifies that, to the best of my knowledge and ability, all the information entered is accurate and entered by me and no one else.

Electronic Signature Agreement
Advantage eClinical includes forms where an electronic signature is required. All users must therefore submit their agreement to the following statement before continuing in the application.

I, 590180, understand and agree that my username and password entered into this system serves as an electronic signature and is entered by me and no one else.

Implementation Considerations

- Backup plans for system down-time or internet connectivity
 - Paper CRFs
 - Noting audit history discrepancy (participant vs. study coordinator)
 - Noting that source exists when unexpected

3. How was assessment completed?

Entered directly in ePRO
In-person visit, collected on paper source
Telephone visit, collected on paper source

Implementation

Data Quality and Monitoring

- On-screen
 - Missing Values popup
 - Consistency checks on-save
- Backend
 - Determine if missing values will be checked (on-site visit)
 - Dependent on study coordinator ability to view (and write) to forms

The screenshot shows a web application interface for the NIDA Clinical Trials Network - Quality of Life - PhenX. The main form area displays a 'Visit number: 00' and a list of assessment questions, each with a yellow radio button indicating it has not been answered. The questions are:

1. Would you say that in general your health is:
2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?
3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?
4. During the past 30 days, for about how many days did physical or mental health keep you from doing things you usually do, such as self-care, work, or recreation?

A 'Confirm' popup dialog is overlaid on the form, containing the following text:

Confirm

The following questions have not been answered:

Question Date of assessment:

Question 1. Would you say that in general your health is:

Question 2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

Question 3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

Click Cancel to review/modify answers or click OK to continue.

At the bottom of the popup are 'OK' and 'Cancel' buttons. The main form also has 'Menu' and 'Save' buttons at the bottom.

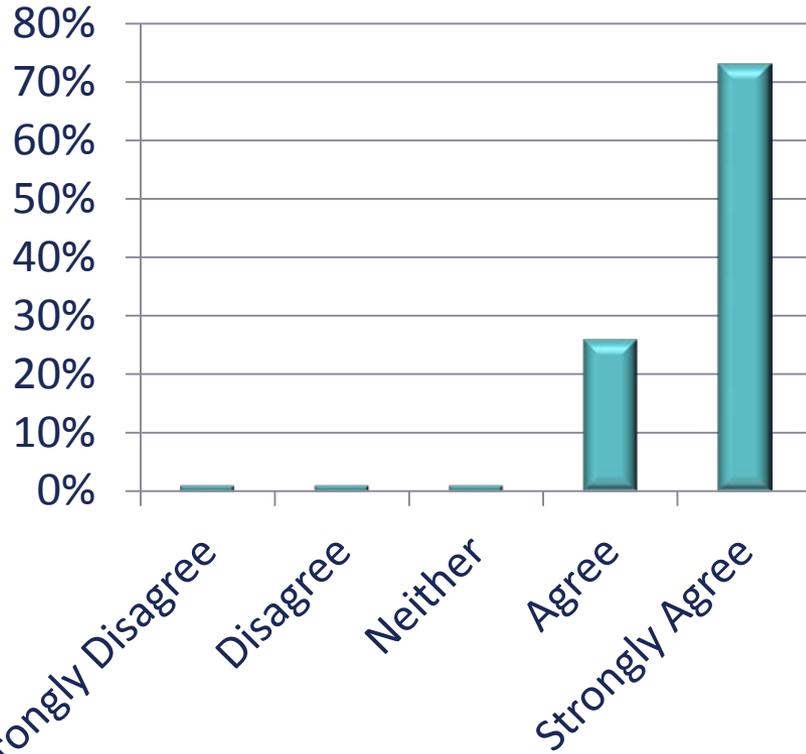
Study Results for the TAPS Tool

- Participant Acceptability Feedback
- Assistance required
- Time to complete the screening instrument

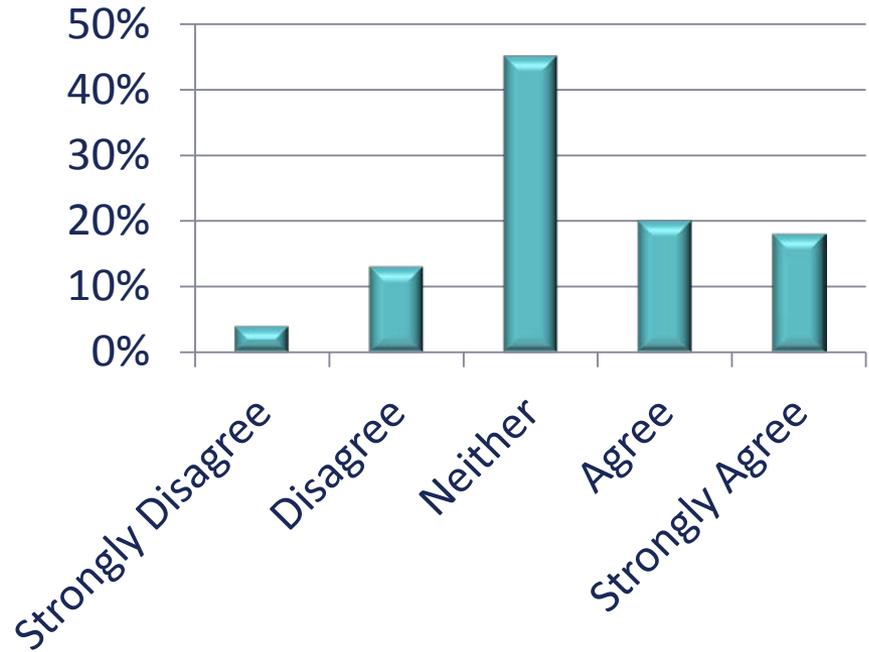
Study Results

Participant Acceptability Feedback

The iPad touch screen was easy to use



I would prefer answering these questions on an iPad instead of having a person ask me



Study Results

Assistance Required

- Training of study participants – Tutorial screens
 - 25% of total population utilized

Health Survey Tutorial

Welcome!

This tutorial will help you get acquainted with the ePro system. Tap your finger on START to continue.

Start

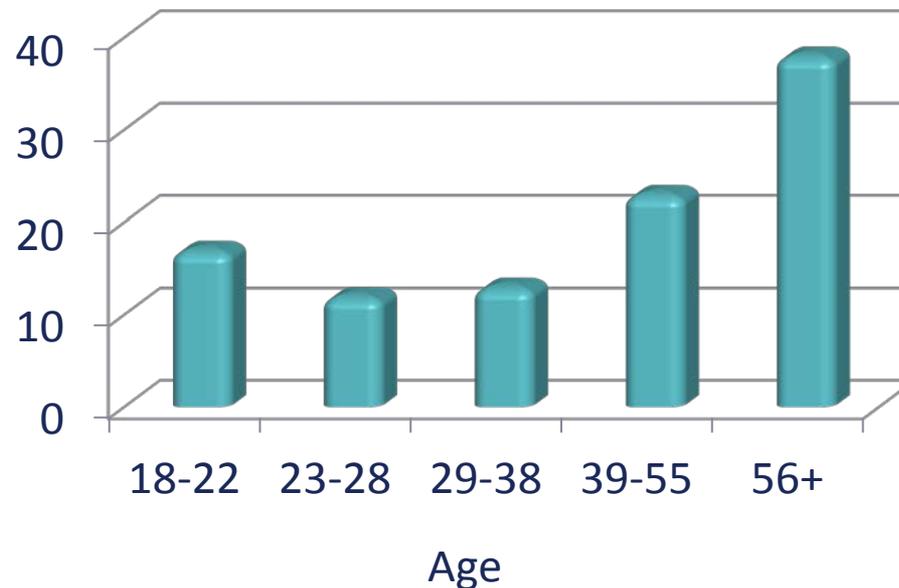
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Study Results

Assistance Required

- Training of study participants – Tutorial screens
 - 25% of total population utilized

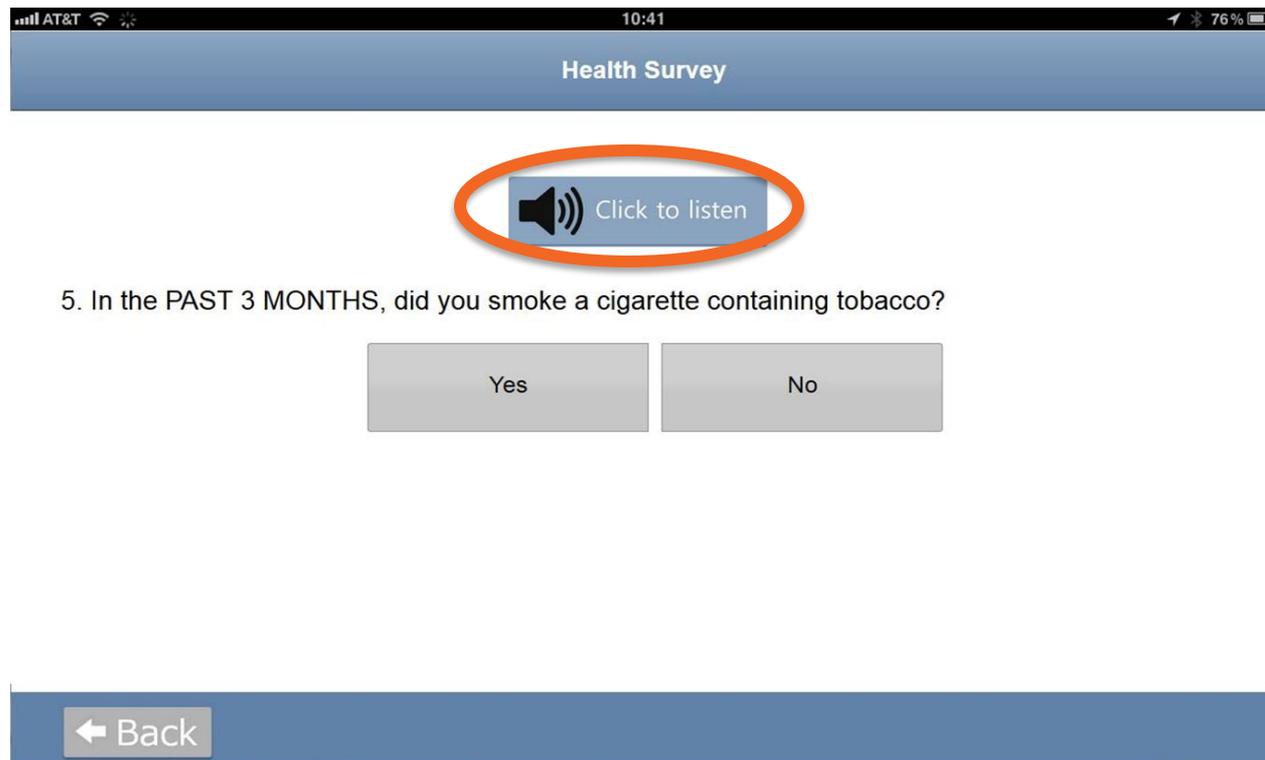
Percent of Age Group that Utilized the Tutorial



Study Results

Assistance Required

- Use of ACASI (Audio/text to voice) component
 - 5-10% of participants actually used

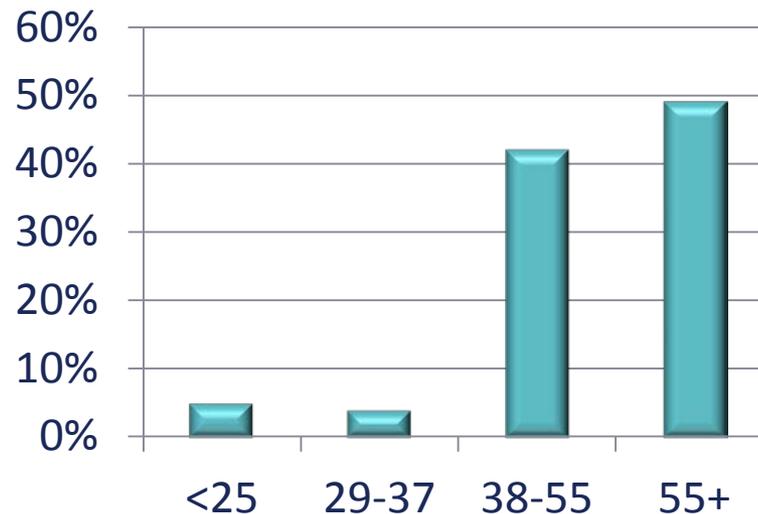


Study Results

Assistance Required

- Use of ACASI (Audio/text to voice) component
 - 5-10% of participants actually used
 - “Participant had slight blindness, voice recording was very helpful in completing iPad task”

ACASI Use

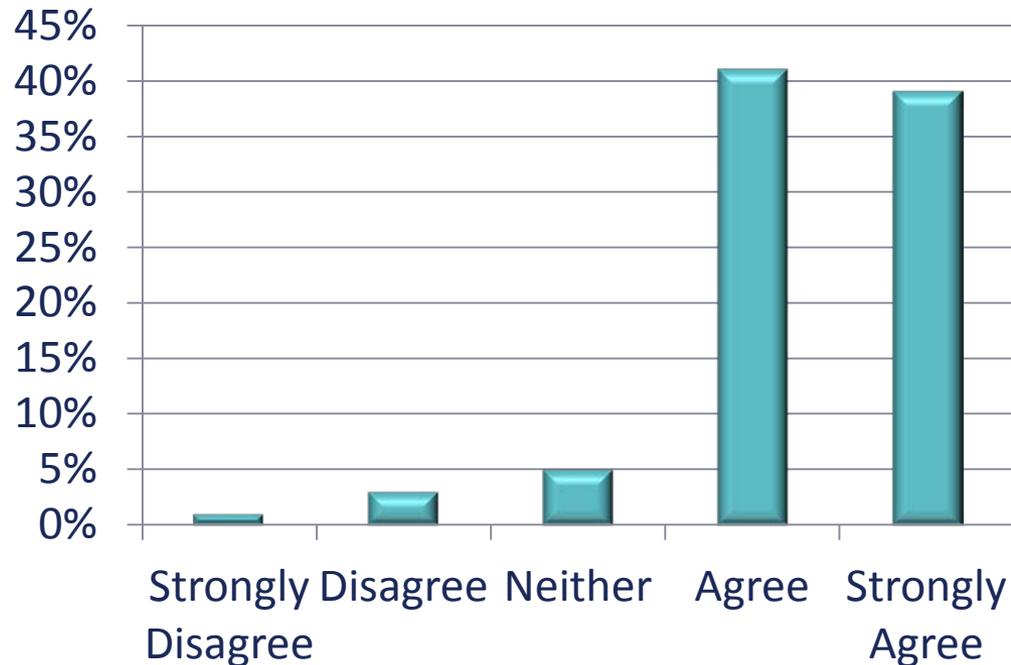


Study Results

Assistance Required

- Use of ACASI (Audio/text to voice) component
 - 5-10% of participants actually used

The voice recording was helpful*

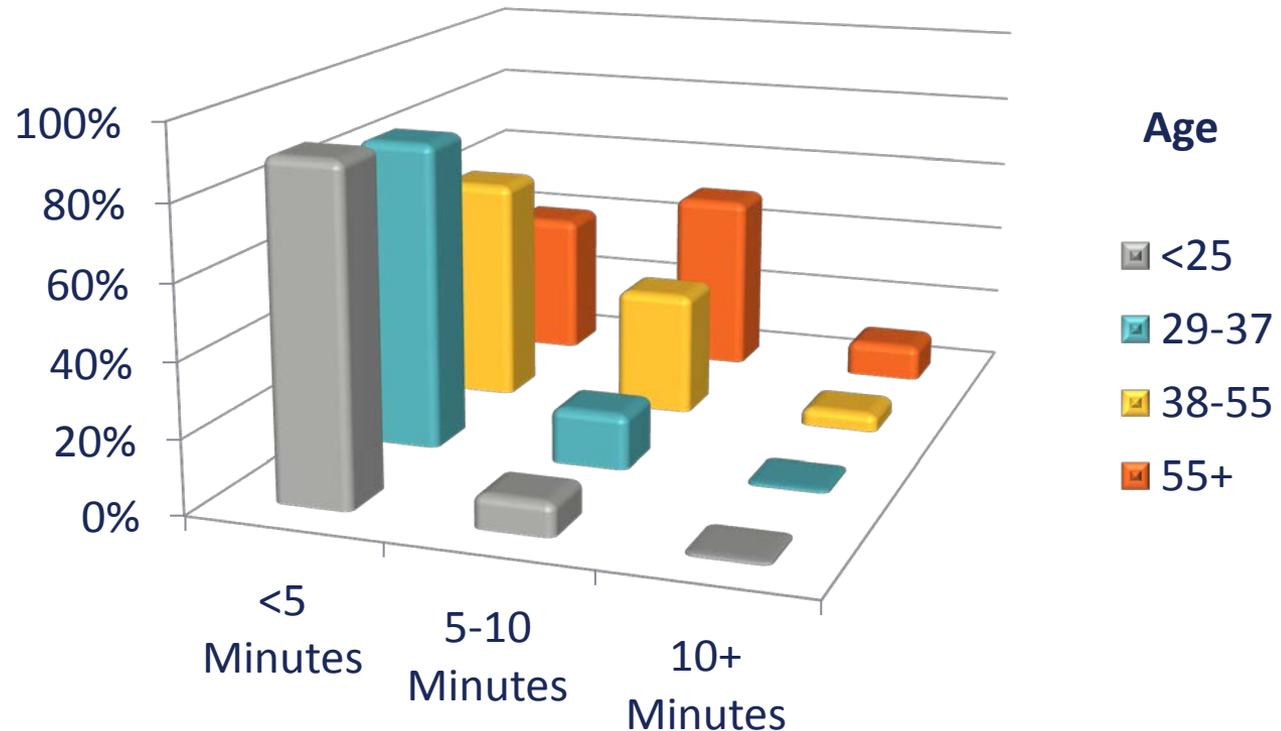


*Of those that answered

Study Results

Time to Complete iPad Screening Instrument

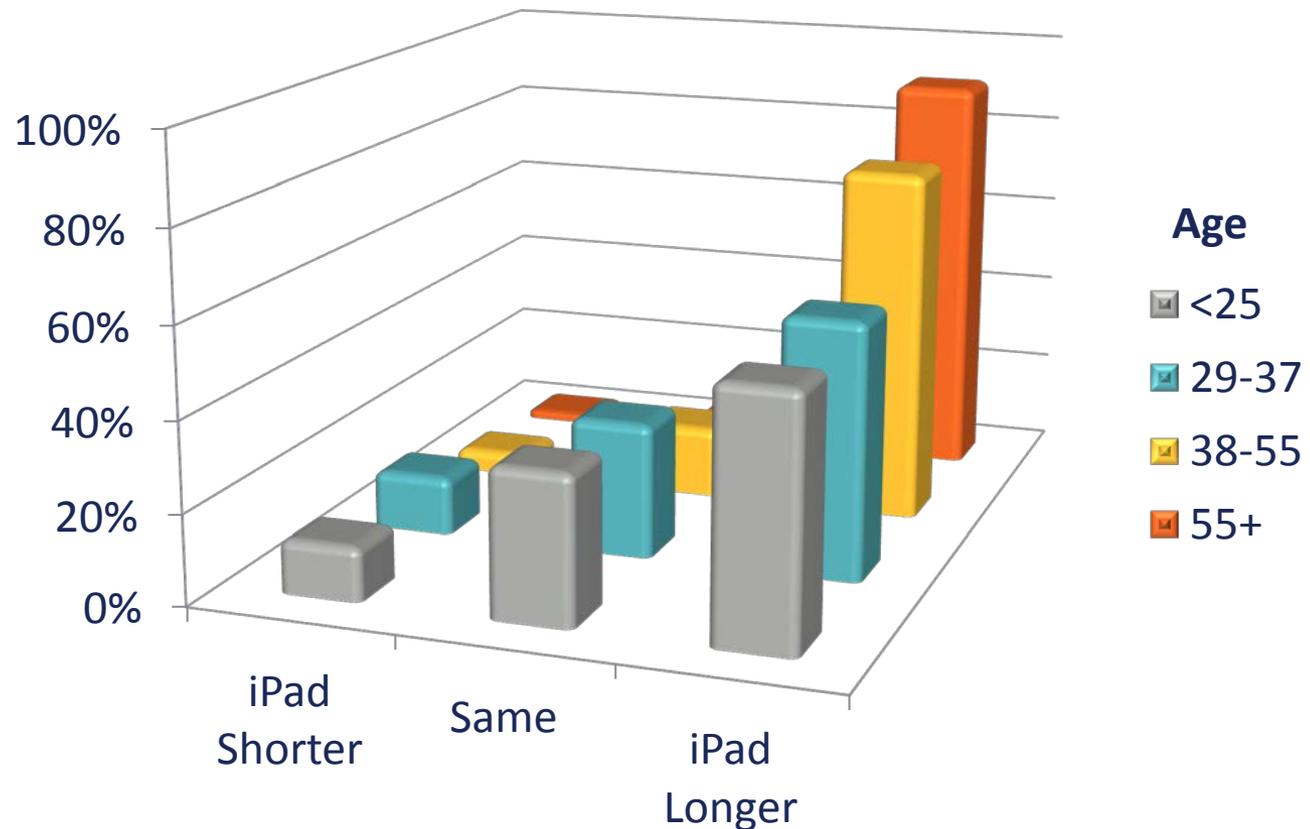
- 13 Questions related to substance use
- 19% of users encountered technical difficulties or requested help using the iPad



Study Results

Time to Complete iPad Screening Instrument

- Comparing iPad to Study Coordinator administration



Summary

- Using an ePro system has a number of benefits, but many considerations need to be thought through to address complexities, such as participant population demographics and familiarity with technology.

Acknowledgements

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Abstract

In clinical trials, it has become increasingly common to collect research data directly from study participants without intervention by the study coordinator. Electronic participant reported outcome (ePro) systems are typically developed for participant daily diaries or self-administered questionnaires. Participants can use assigned usernames and passwords to access the systems via the internet and are able to complete assessments on study computers or other portable devices. Data collection from study participants via an ePRO system can be used to identify adverse events, track adherence to study procedures, and to mask study staff to responses to questions. The latter is particularly beneficial for sensitive questions or responses to questions that might be influenced by social desirability. Assessments can be customized based on the participant's characteristics (e.g., gender-specific questions can be tailored within ePRO using the information from the participants' responses to demographic items).

Studies conducted by the National Institute on Drug Abuse (NIDA)-sponsored National Drug Abuse Treatment Clinical Trials Network (CTN) use questionnaires to collect data on participant characteristics and outcome measures. The Emmes Corporation, which serves as the Data and Statistical Center for the CTN, developed an ePro system within its web-based data collection system to collect research data directly from participants. In designing an ePRO platform, there are various aspects of the system that need to be assessed and validated before launching, including regulatory requirements, training of study participants, backup plans for system down-time or internet connectivity, and data quality and monitoring. These aspects of ePRO system design will be discussed in the context of a recently completed CTN study which had the primary goal of validating an electronic screening instrument for tobacco, alcohol, and other substance use. Data on participant acceptability feedback, including assistance required and time to complete the screening instrument, from this study will be presented.