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

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Society for Clinical Trials
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Tuesday May 16th, 2:30 p.m.

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

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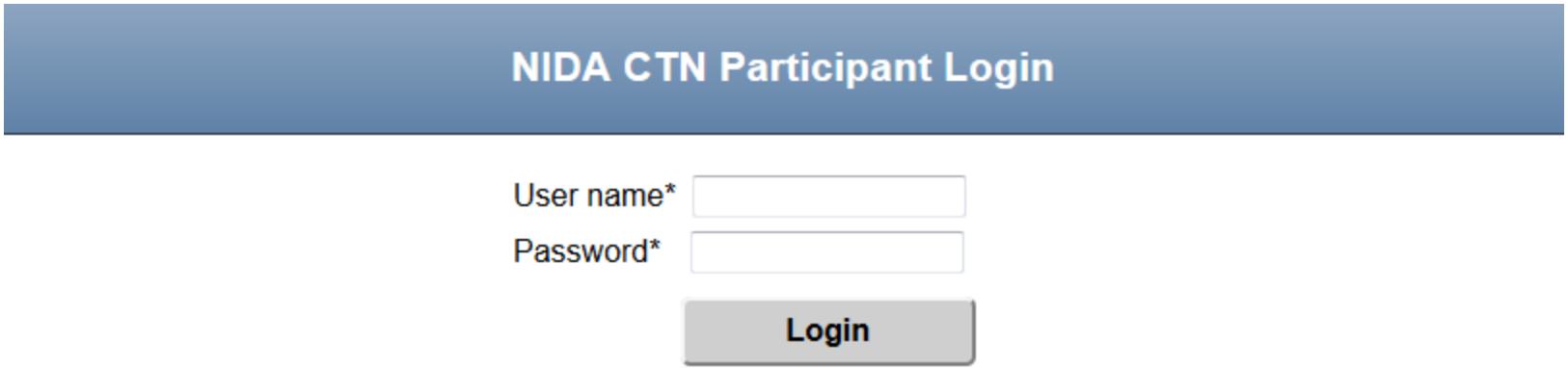
Electronic Patient Reported Outcomes (ePro)

- 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



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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

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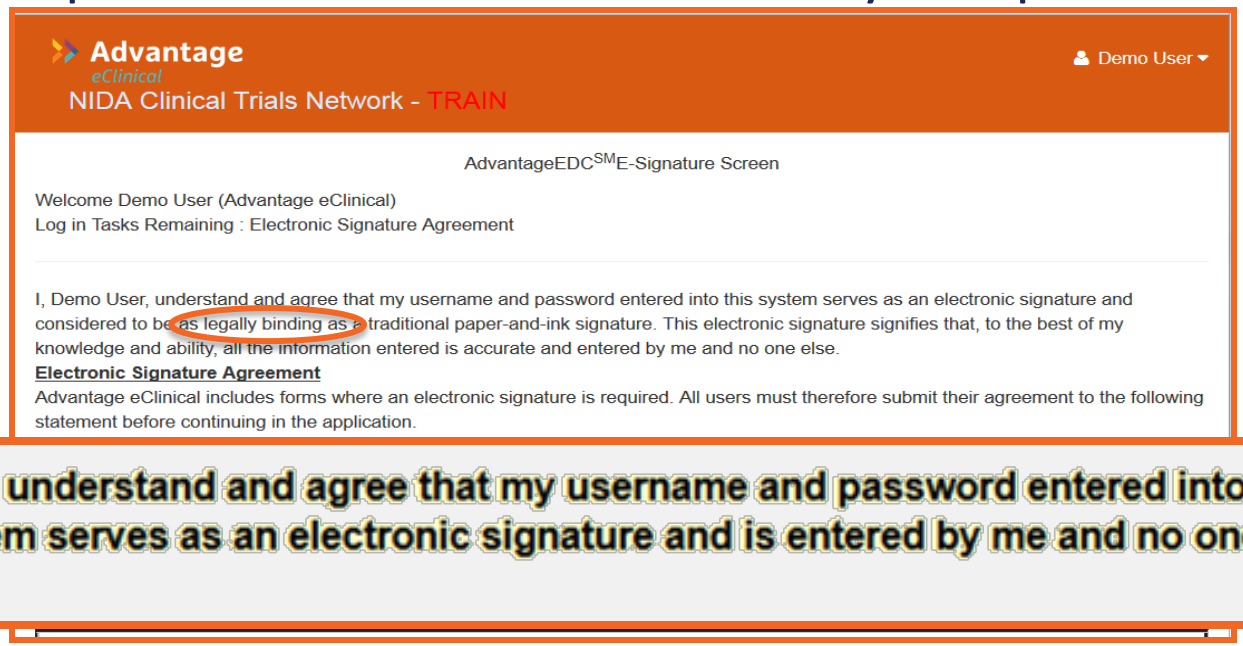
Implementation - Regulatory Considerations

- 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



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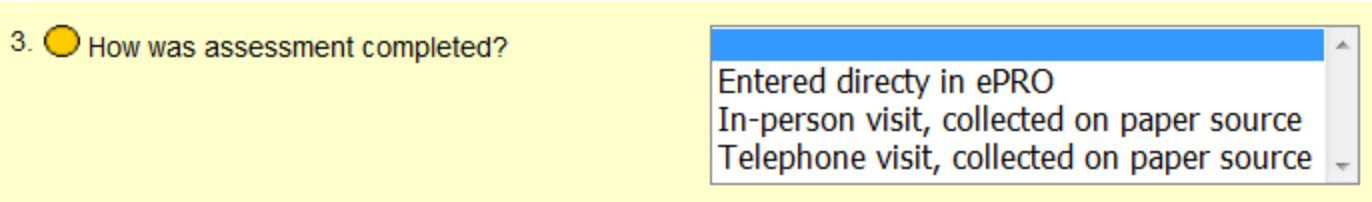
Implementation Considerations

- 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



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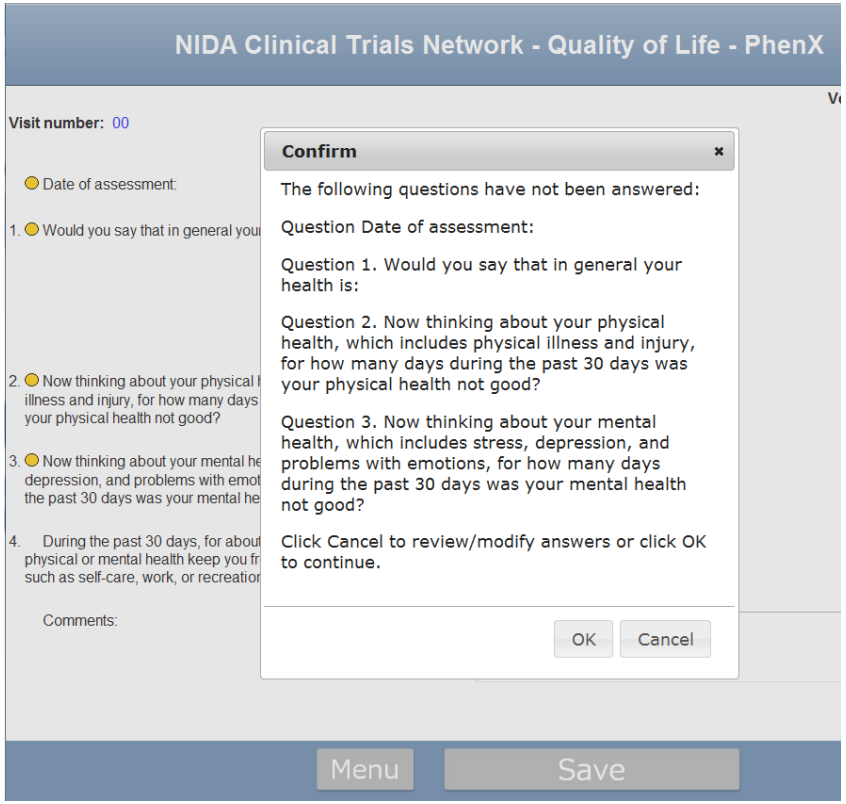
Implementation
Data Quality and Monitoring

- 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



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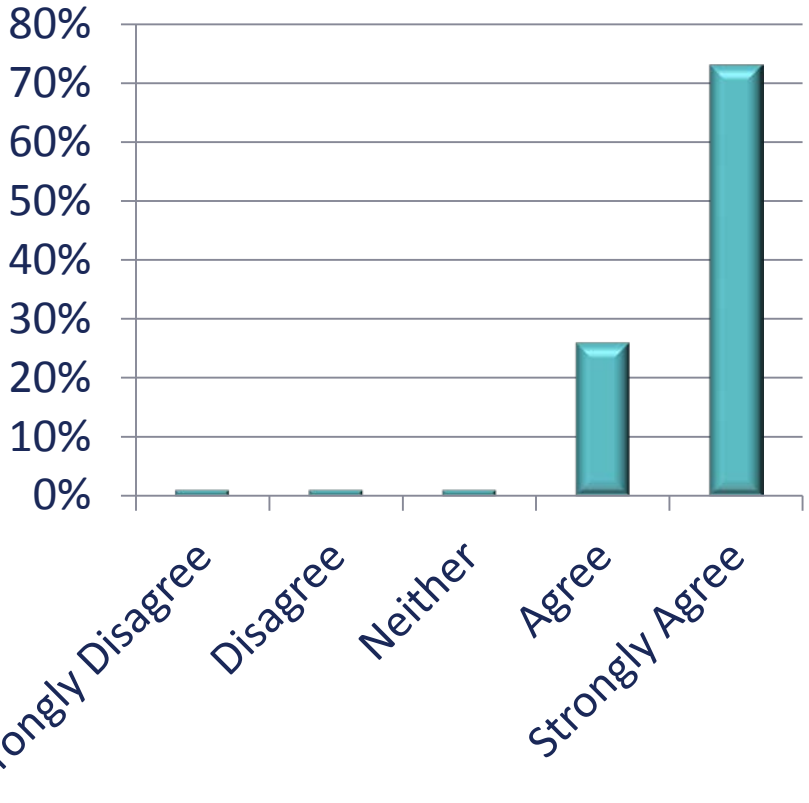
Study Results for the TAPS Tool

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

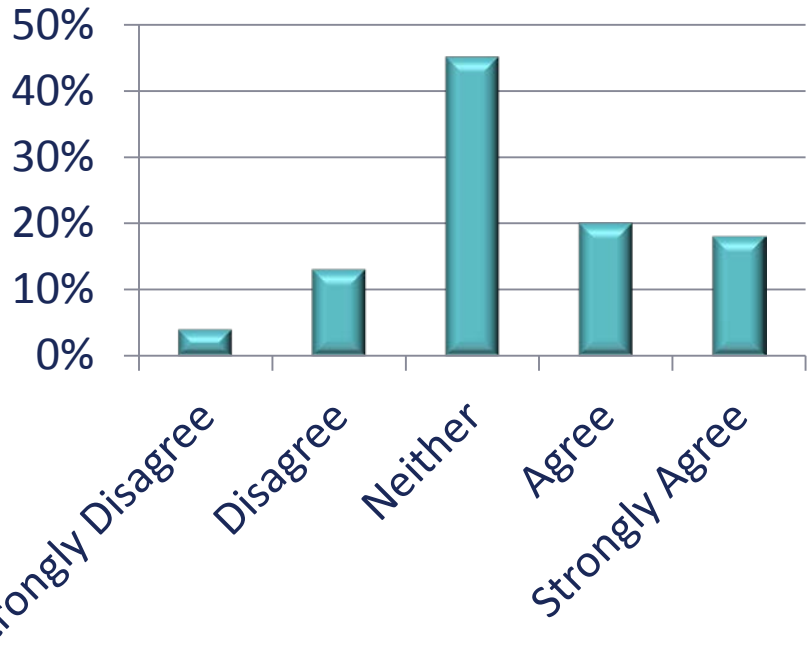
Study Results

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



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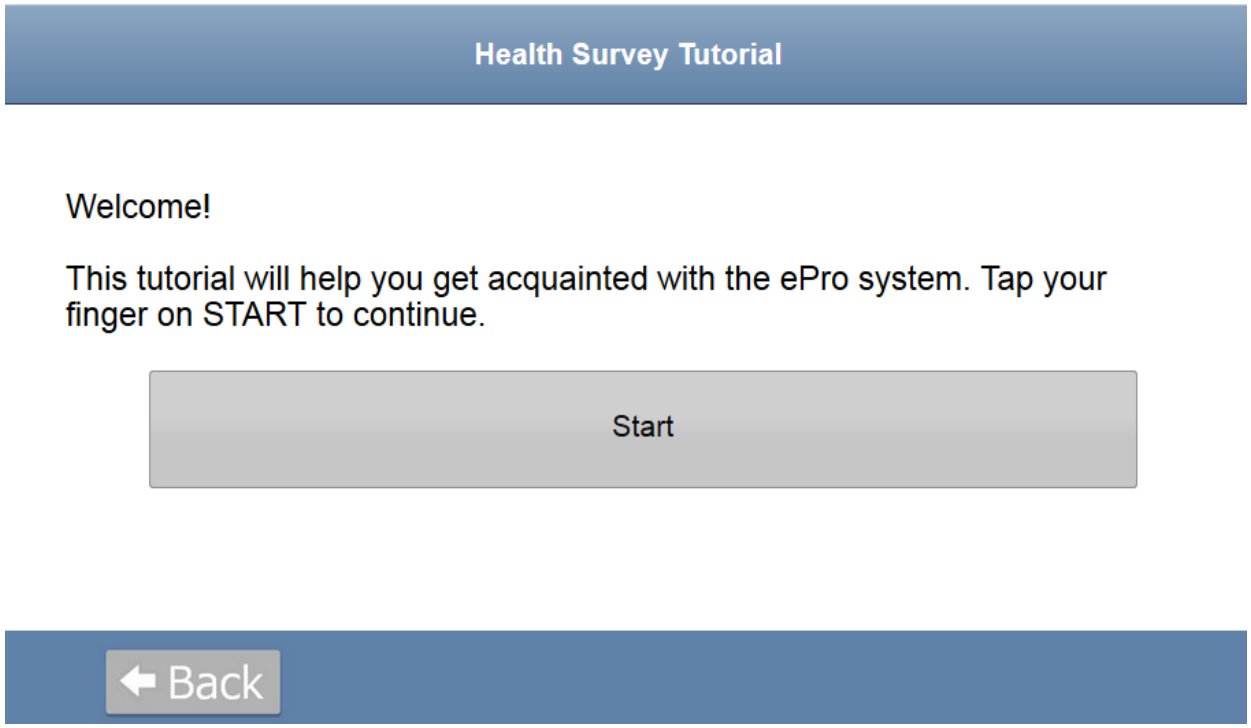
Study Results

Assistance Required

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



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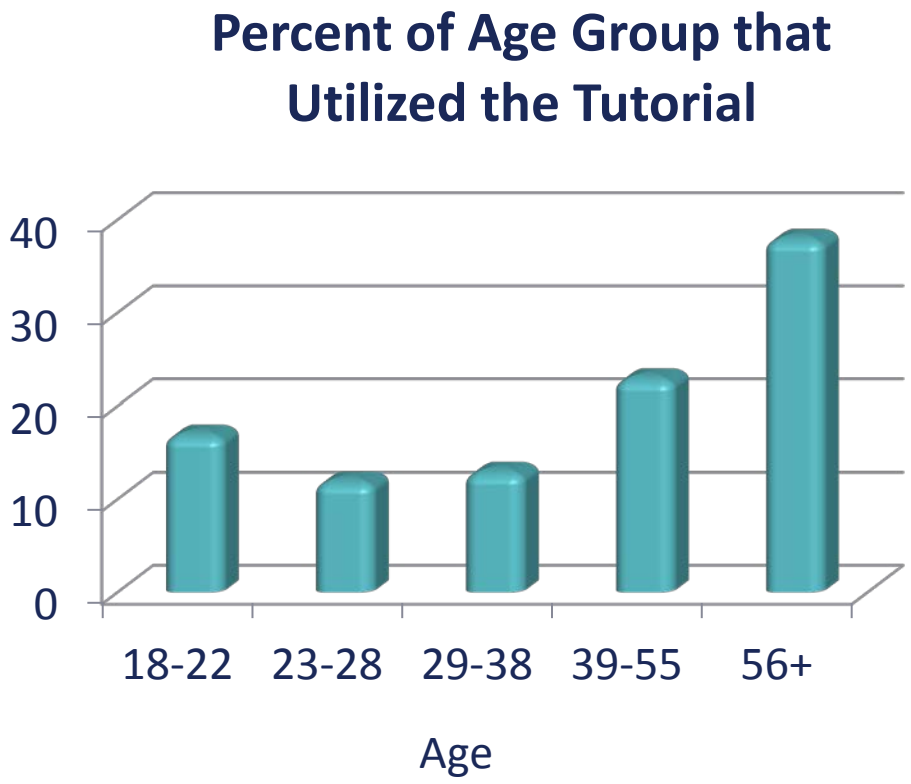

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Study Results

Assistance Required

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  - 5-10% of participants actually used

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Study Results

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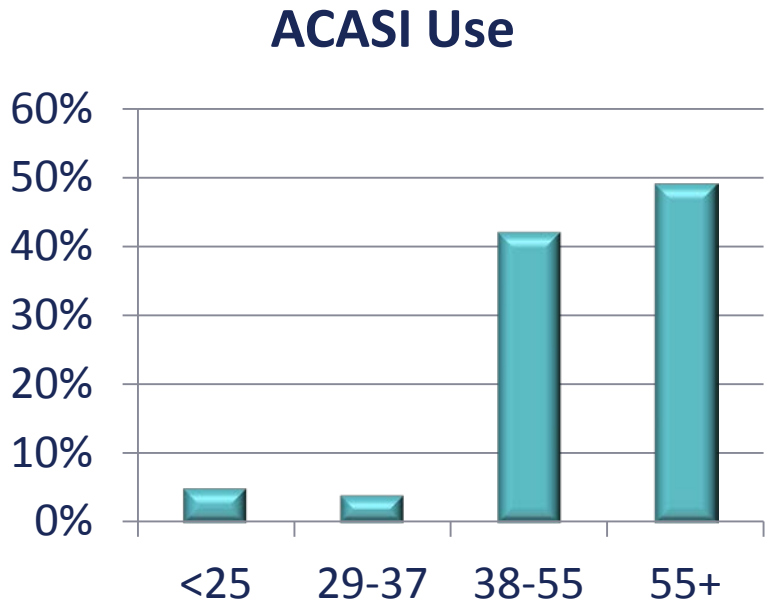
  - 5-10% of participants actually used
  - “Participant had slight blindness, voice recording was very helpful in completing iPad task”



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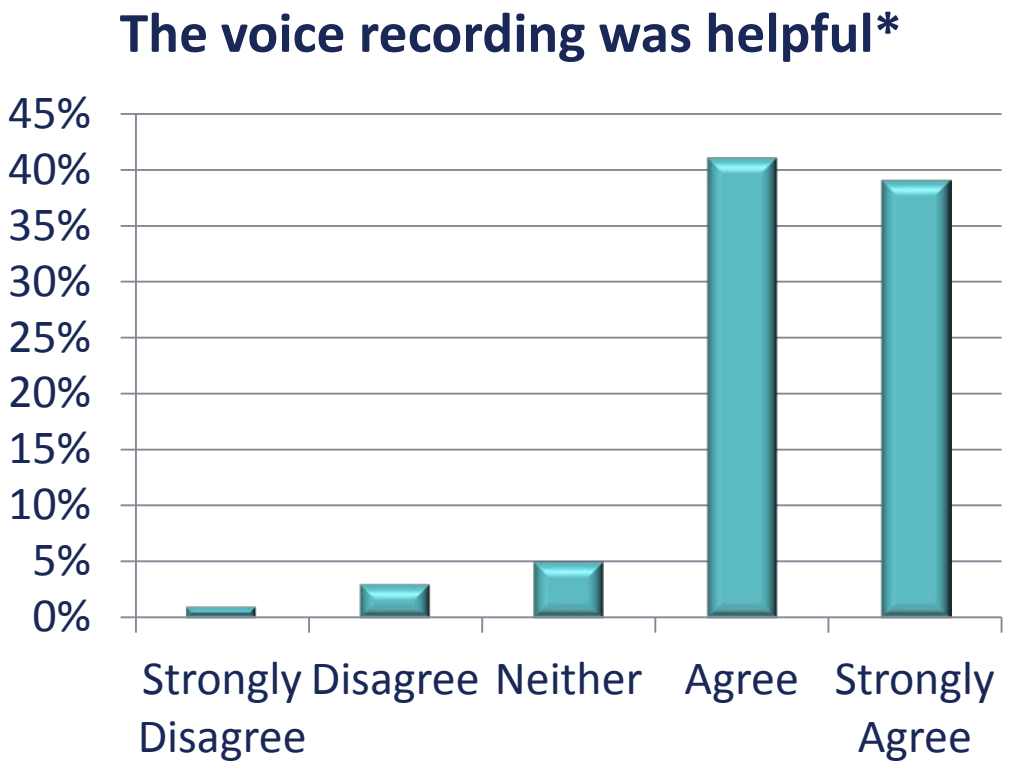

*Of those that answered

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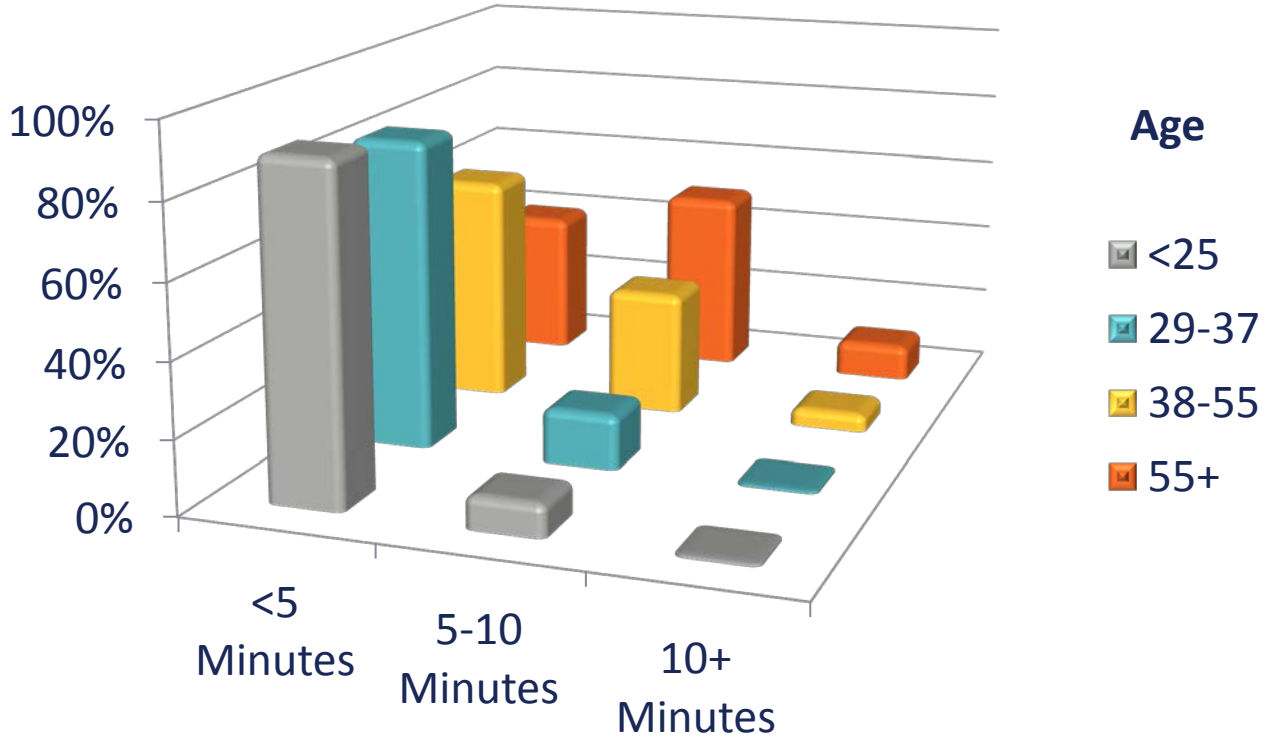
Study Results

Time to Complete iPad Screening Instrument

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



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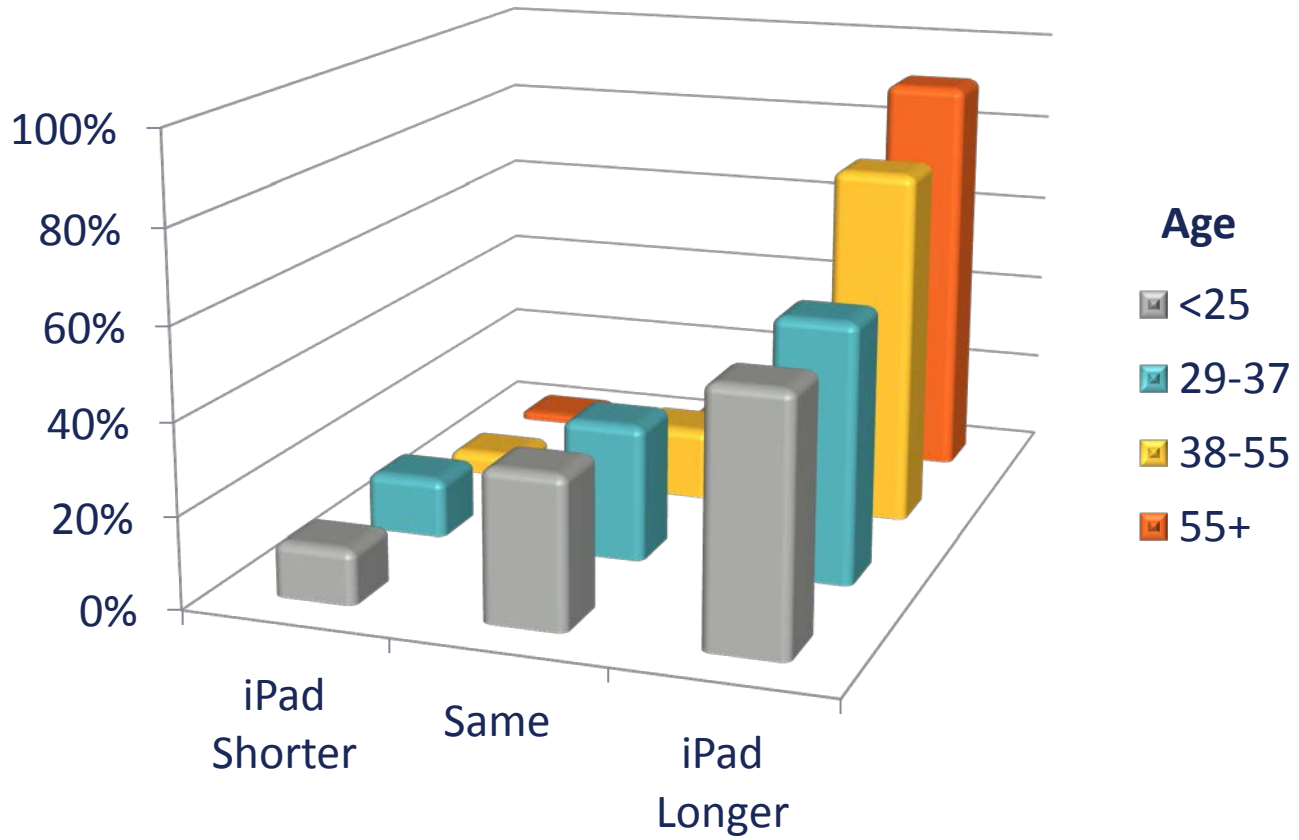
Study Results

Time to Complete iPad Screening Instrument

- Comparing iPad to Study Coordinator administration



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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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- Thank you to the members of the NIDA CTN DSC and TAPS Tool Lead Investigative teams.

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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.