

Developing a Site Training and Troubleshooting Plan in the Digital Age



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National Institute on Drug Abuse (NIDA) Clinical Trails 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 - manages AdvantageEDC
- Currently 10 active protocols in various stages
- New protocols often reuse sites but not staff



New Systems



- EDC systems continue to become more complex
 - Direct Data Entry
 - ✦ Requires more on-screen checks
 - ✦ No backup source
 - ✦ All staff must use it (MDs too!)
 - Different browser environments
 - ✦ Security settings, visual and functionality differences, constant upgrades
 - Complex protocol setup
 - New Devices (tablets, laptops)
 - More electronic components (Inventory management, Administrative forms)
 - ePro (Electronic Patient Reported Outcomes)
 - ✦ Trainees (Coordinators) become the trainer



Consequences of Complex Systems



- Widens the gap of experience in users
- Exaggerates issues for those who already had difficulty navigating the system and entering data
- Increases frustration
 - Impacts enrollment
 - Causes more protocol deviations
 - Poorer data quality
- Bigger issue with infrequent system use, few site staff, and frequent turnover



Solutions - Before First Participant



- Hold training close to site activation
- Build additional system functionality to prevent accidental errors
- Identify on-site resource (site's IT) to help with general computer, browser, and Wi-Fi issues
- Remind staff of potential problem areas right before first participant
- Encourage first participant enrollment during normal business hours



Solutions - During conduct of study



- Hold frequent all-site call to discuss common issues
- Update references manuals often with answers to questions or to clarify scenarios
- Ensure availability of **knowledgeable** Coordinating Center staff to quickly respond to system issues or protocol questions
- **Be available** and happy to answer questions
 - Build relationships with staff!
- **Be active** in identifying hidden issues
- Provide additional mini-webinars for areas anyone is struggling with

Solutions - ePro



- Provide guide to easily train study participants who directly enter data in the system
 - Within ePro if possible

Health Survey Tutorial

Welcome!

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

Start

Health Survey Tutorial

Click to listen

Before you begin, would you like to try a couple of practice questions?

Yes No

Pause

← Back

To use this program, you will need to tap your finger on a button on the screen to answer each question.

- Once you tap on an answer, the program automatically goes to the next question.
- You can change your answer by tapping on the 'Back' button at the bottom of the screen.
- You can turn my voice off or on by tapping on the 'Listen' button.
- For some screens, you need to tap the 'Next' button to move forward.

Next

Initial Training



- **Prior Model:** single or multi-day intensive in-person national training
- **Cons:**
 - Expensive
 - Time-consuming especially including travel
 - Long, hard to keep participants' attention
 - Can't just attend role-specific sessions
- **Pros:**
 - Good for opportunity to build relationships
 - Easily gauge involvement and confusion
 - Easy to make interactive



Initial Training



- Shift in training model: National Training Webinars

- Pros:

- Cheaper
- Flexible timeframe
- Easier to fit in schedule
- Allow for more breaks
- Easy to only attend applicable sessions



- Cons:

- Hard to confirm participant engagement
- Hard to gauge understanding
- Hard to develop personal relationships



Webinar Training Tips



- Mix up presenters when possible
- Ask that all participants at a site view the training in a single room
- Make slides “visual”/“text-light” and talk more
- Use a headset, not a speakerphone
- Limit sessions to 60-90 minutes, less for “boring” presentations
 - Create a series of short topic-specific presentations



Webinar Training Tips



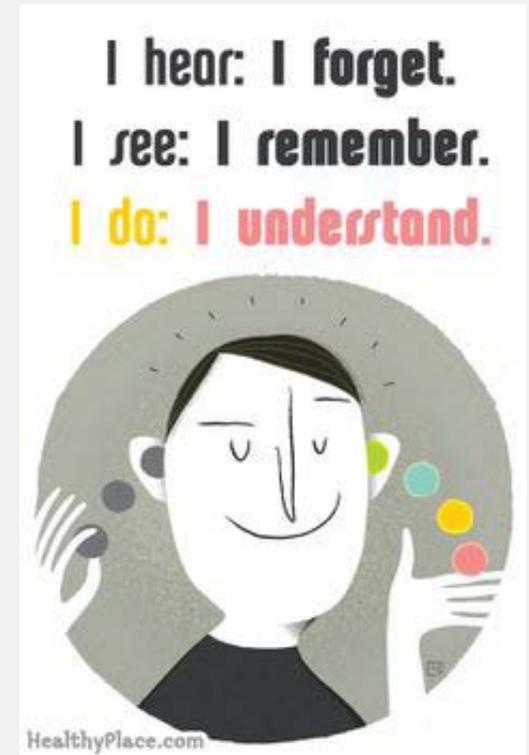
- Include thought-provoking questions/scenarios
 - “Here’s a problem. How do you think we should solve it?” or “Here’s a draft of a solution. What’s wrong with it?”
 - These aren’t polls or multiple-choice questions
- Designs **a series of mini-activities** instead of an information dump



Training



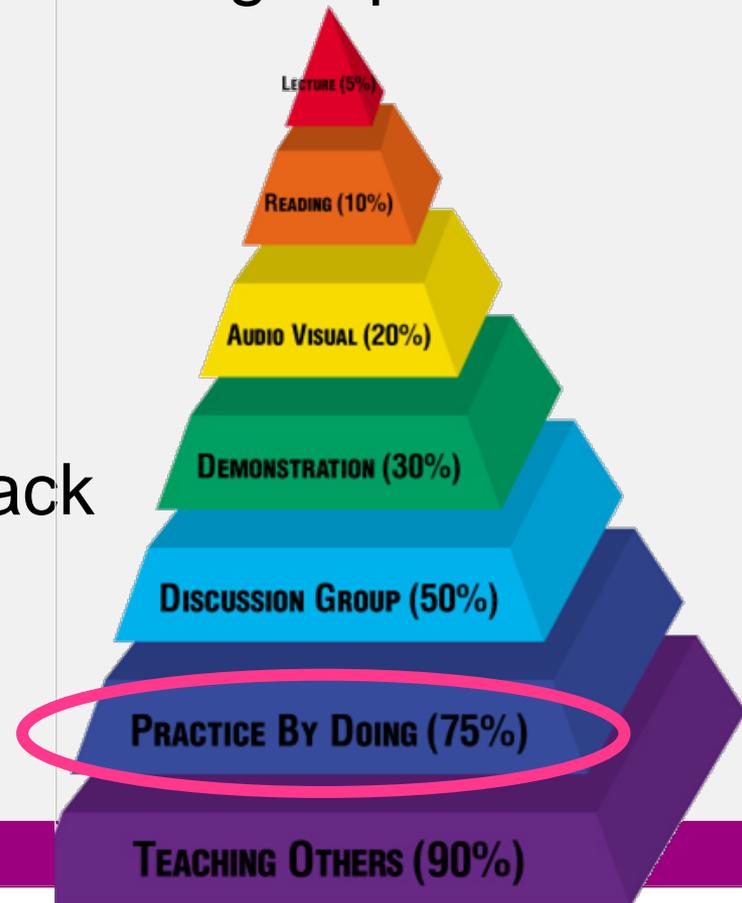
- **Active learning** engages the whole person, not just the intellectual mind.
- When people try to do things and fail or succeed, emotions are triggered, and these have a significant effect on how we remember
- Ensure there are plenty of practical activities alongside theory for participants to integrate the learning



Additional Training Tools



- Create **role-specific** practicum with **real scenarios**
- Participants demonstrate understanding of protocol **and** system training
 - Enrollment
 - Indicate missing data
 - Submit AEs and Protocol Deviations
 - Primary outcome
- Verify and provide useful feedback
- Document training completion



Conclusions



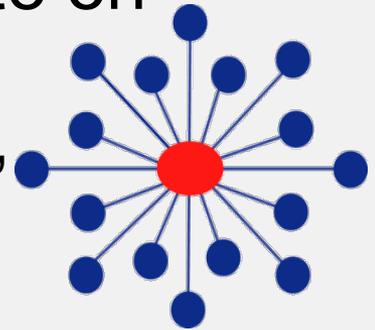
- As we move to all electronic management of trials, training and **verification of understanding** becomes vital
- Provide on-going training throughout the conduct of a trial
- Identify issues at one site, train all
- Develop relationships so staff feel comfortable asking questions



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Abstract



As Electronic Data Capture (EDC) systems become more advanced, it is even more vital to ensure training is adequate for the wide range of experience in users. Data entry systems have become more complex with numerous enhancements to meet the needs of maintaining a high level of data quality in trials that use direct data entry on a variety of devices and user modes. With the removal of paper source documents to serve as a backup, the availability of Coordinating Center staff to quickly respond to system issues becomes vital. Adding these system enhancements can cause site staff more difficulty in navigating the EDC system and entering data, which may increase frustration and impact enrollment and cause more protocol deviations and poorer data quality. Also, with the addition of electronic patient reported outcomes (ePRO) to EDC systems, considerations should also be made to train study participants who directly enter data in the system.

In recent studies conducted by the Clinical Trials Network of the National Institute on Drug Abuse, The EMMES Corporation, which serves as the Data and Statistical Center (DSC) for the network, has created training and troubleshooting plans to address these new issues. The particular components of these plans will be discussed and will include identifying the various demonstrations or add-on training sessions, developing these sessions to be informative and directly applicable to the trainee, creating a hands-on training or practica, and having adequate Coordinating Center staff available to troubleshoot one-on-one and an off-hours helpdesk.