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Training on the Use of Technology to Collect Patient-Reported Outcome Data Electronically in Clinical Trials: Best Practice Recommendations from the ePRO Consortium

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Abstract

Electronic capture of patient-reported outcome (PRO) data has many advantages over paper-based data collection. Regulatory agencies have consistently supported the use of electronic PRO (ePRO) data capture and recommended participant and site staff training on the correct use of electronic data capture systems. The objective of this paper is to outline best practice recommendations for training end users, including site staff and study participants, on the use of ePRO technology in clinical trials to enable consistent, accurate, and complete data collection. Site personnel should be trained on study-specific as well as technology-specific topics and be given instructions on whom to contact to obtain technical support. Optimal training takes place over time using multiple modalities, including hands-on, face-to-face training at an investigator meeting or directly in the clinical site; remote training via webinar or teleconference; interactive on-demand self-paced-training via e-learning modalities; and supplemented by proxy training performed by study clinical research associates. Like site personnel training, study participants should be provided with individual, hands-on training by site staff at the initiation of the trial and in conjunction with interactive electronic training modules that can be accessed on-demand throughout the duration of the trial. The recommendations put forth in this paper provide a structured framework for the training that site personnel and study participants need to optimize the advantages trials can gain from using ePRO data collection systems.

Keywords

electronic patient-reported outcome (ePRO), ePRO technology system, study participant training, site staff training, best practices

Introduction and Purpose

With the advancement of technology and the prevalence of personal electronic devices (eg, smartphones and tablets) among the general public, the use of electronic systems to collect patient-reported outcome (PRO) data is preferred by study participants over paper-based method[1-5] and recommended by regulatory agencies, including FDA and EMA.[6-8] The advantages of electronic data capture technology, such as on smartphones, tablets, interactive voice response (IVR), or web-based systems, over traditional paper-and-pencil methods are well documented and include reducing missing data, providing time-stamped records, minimizing site and participant burden, and avoiding data entry errors.[9] Additionally, participant compliance with electronic assessments has been shown to exceed 90%,[10] whereas a previous study documented actual compliance on paper diaries to range from 11% to 20%.[11] However, many of the advantages clinical trial sponsors can gain from using electronic clinical outcomes assessments (eCOAs), including those completed by the patient (electronic patient-reported outcome [ePRO] measures), by the clinician (electronic clinician-reported outcome [eClinRO] measures), and the observer/caregiver (electronic observer-reported outcome [eObsRO] measures), depend on the end users' ability

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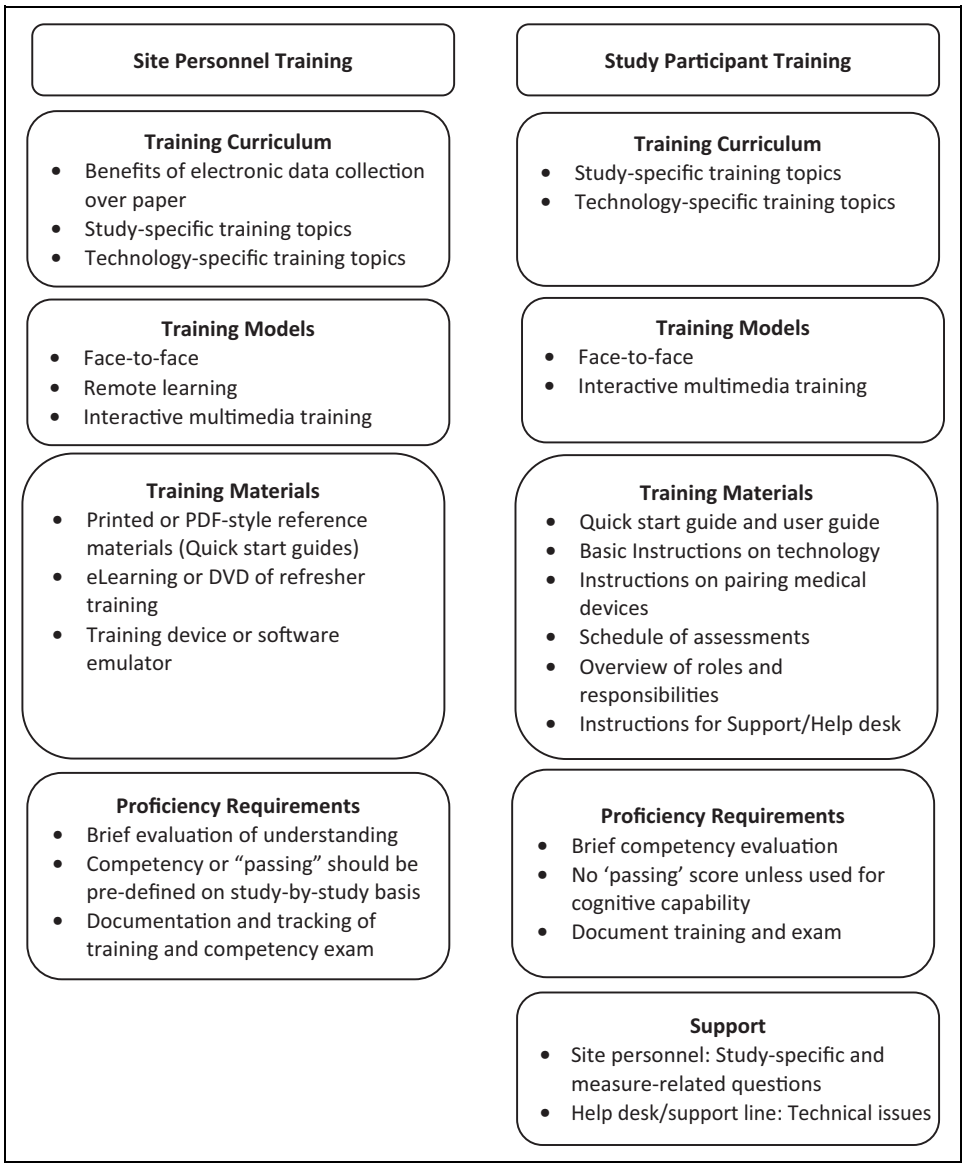

Figure 1. Outline of best practice recommendations for training on ePRO devices and technology systems.

to utilize the electronic systems in a manner compliant with the trial protocol.

Key regulatory guidelines for capturing consistent ePRO data recommend training on the correct use of the electronic data capture system.[6,8] These guidelines include adequate training of site staff and study participants on the ePRO system or device in order to capture ePRO data in an accurate and timely manner.[9,12-14] Studies have recognized the importance of training clinicians, staff, and study participants on the use of ePRO systems and devices in clinical trials and clinical practice and have recommended effective approaches to training.[14,15] Moreover, the use of ePRO technology is easy to learn by both site staff and study participants[16] and can be implemented with trainees with varying levels of computer literacy or comfort with technology.[15] The objective of this paper is to outline best practice recommendations for training end users, including site staff and study participants, on ePRO devices and technology systems in clinical trials to promote consistent and sufficient training prior to initiating trial data collection (Figure 1). These best practice recommendations were developed by consensus among the member firms within the Critical Path Institute's ePRO Consortium.

Investigative Site Personnel Training

Sponsors of clinical trials are expected to ensure that an adequate training plan is in place for all research staff participating in the conduct of a study.[7,13] Integral to successful implementation of ePRO data collection in any clinical trial is the engaged and cooperative participation of the site personnel, who can help guide study participants on how to use electronic study technology to record their PRO data. To ensure

Table 1. Site Personnel Training Models.

Training Models	Advantages	Disadvantages
Face-to-face	• First exposure to system • Identify specific learning issues in real-time	• Cost • Retention of information from investigator meeting to first patient in • Staff turnover • Information presented at one point in time
Remote learning	• Can be recorded • Can be conducted over multiple sessions • Allows for flexibility of schedule	• Difficulty troubleshooting problems remotely • Not knowing if all trainees are engaged
Interactive multimedia training	• Post-training quizzing can be used to determine training effectiveness • Can be conducted over multiple sessions • Allows for flexibility of schedule—available 24/7 • Can refresh on information as needed	• Difficulty troubleshooting problems

Table 2. Site Personnel Training Curriculum.

Study-specific training topics
- Study protocol assessment schedule
  - Assessment workflow
- PRO measure on technology system
  - Software structure and logic of ePRO measures
  - Resolution of error messages
  - Integration of electronic systems (devices, wearables, or systems)
- Participant compliance
  - Guidance to help participants understand importance of completing PRO measures on schedule
  - Regularly monitoring participant compliance

Technology-specific training topics
- Device and electronic system
  - How to turn the device on and off
  - How to charge the device
  - How to access the electronic system
  - How to add participants into the system
  - How to select responses in the system
- Data transmission and troubleshooting
  - How data are transmitted
  - How to resolve problems when data are not able to transmit
- Data and reports
  - How to view and export data
  - How to run reports on ePRO platform
  - How to respond to alerts from ePRO platform
- Support
  - How and whom to contact to obtain technical support

successful use of devices or other data capture technology throughout the trial, site personnel must be familiar with navigating the electronic systems and competent in all procedures required to support ePRO data collection in accordance with the trial protocol. These include the electronic system workflow, preparation of the technology (eg, devices) for use by study participants, training the participants to use the technology to record PRO data per protocol, study workflow and timing of events specific to electronic data capture and systems integration, active data surveillance during the trial (ie, compliance and outcomes monitoring), and occasional data query resolutions.

Site staff training has taken many forms, including hands-on, face-to-face training at an investigator's meeting or the clinical site, remote training via webinar or teleconference, interactive on-demand self-paced-training via e-learning modalities, as well as proxy training by study clinical research associates (CRAs) or trained site staff. Considerations for each method are outlined here and summarized on Table 1. Best practices and key learning principles include spacing training over time, combining graphics with verbal descriptions, administering quizzes, and providing immediate feedback.[17] It is important to consider that optimal training does not typically happen at a single point in time, but rather over time through repetition and the use of more than one delivery medium.

Site Personnel Training Curriculum

Site personnel may have limited computer proficiency, which may result in some reluctance to adopt new technology, particularly in global trials where overall technology access may be lower. Thus, providing site personnel with an introduction to the benefits of electronic data collection over paper may be necessary to promote a site's understanding of how implementation of the new technology reduces site burden, improves data quality, and improves patient compliance with protocol-defined data entry.

Study-specific training topics (Table 2) should include, but are not limited to, software structure and logic that support the administration of the PRO measure, resolution of error messages that may arise from out-of-range, contradictory, or extraneous responses, study protocol assessment schedule, assessment workflow (when to collect, what to collect, how to collect) with "what to do if…" scenarios, and integration of electronic systems (moving between devices, wearables,

and/or systems). It is also important that trial-specific topics include guidance to site staff on helping participants understand the importance and how to complete their PRO measures on schedule, monitoring participant compliance regularly, and what to do if compliance falls below an acceptable threshold.

Technology-specific training topics (Table 2) should include, but are not limited to, turning the device on and off, charging the device, accessing the electronic system, adding participants into the system, selecting responses in the system, data transmission troubleshooting, and repurposing devices for new participants (where appropriate). At the time of training, site personnel should also be given instructions on how to get technical support and whom to contact when they have questions about using the ePRO technology. Site staff should be trained on how to use the ePRO platform to view and export data, run reports, and respond to alerts emanating from the electronic platform.

Site Personnel Training Models

Face-to-face training

A traditional training method for site personnel, to ensure they are trained to execute all procedures required to support ePRO data collection in accordance with the clinical trial protocol, is face-to-face training. This type of training is typically conducted at the study investigator meeting (IM) or at individual site initiation visits. The key factor in this particular form of training is that it is conducted by subject-matter experts, including those from the ePRO vendor, who are thoroughly familiar with all aspects of the technology and the trial-specific programming being used. Trainers should have an appreciation of the clinical trial environment, as well as the typical work process and environment of the site personnel to tailor the training to the needs of the site personnel.

Although face-to-face training is the traditional method of site personnel training, it can be costly to allot time at the IM for this training and/or to send professional trainers to each clinic site for individual training sessions. Additionally, IMs and site initiation visits are often held months before sites enroll their study participants, which can lead to loss over time of the training information learned. IMs typically include back-to-back vendor presentations, which are not optimal for learning detailed training information. With scheduling conflicts and site staff turnover, it is also not possible for all site staff members to be present for an IM and, for those who do attend, retention of all presented information is challenging. As such, study sponsors often choose alternate site training methods that have lower costs and additional benefits.

Nonetheless, face-to-face training has value in terms of being the first exposure of the site staff to the systems and vendors with whom they will interact and it can be recorded for future use. It is recommended that to enhance ePRO learning at the IM, interactive audience polling/quizzing systems be used to record and track results and identify specific learning issues in real time. These interactive systems can also be used to track trends in responses across global IMs. Other interactive technologies, such as a dedicated audience response system or link on the participant's smartphone/tablet, can similarly help those in attendance to focus on the presentation. Audience interaction is recommended approximately every 5 to 10 minutes[18,19] to keep the participants engaged, aware, and interested in learning. Face-to-face training at the IM may represent the first in a series of recommended trainings, which are spaced over time to optimize learning for site personnel.

Proxy training

In cases when the ePRO vendor-designated trainer is not available to instruct site staff individually, a proxy trainer is sometimes used when the sponsor requires face-to-face training of site personnel. In such a model, for example, the vendor-designated trainers would train proxy trainers, such as CRAs, who will, in turn, conduct face-to-face training of the site staff. The CRA training is typically conducted in a smaller seminar of only CRAs at the study investigator meeting, minimizing the cost of using premium IM time as other site staff are not required to participate in this CRA-only session. The cost of having CRAs conduct the individual training at each investigative site can be minimized if the CRAs execute the training during a study initiation visit where they are already training site personnel on other components of the study protocol. While this model reduces some costs and still provides face-to-face, individualized training for the site personnel, it is recommended as supplemental training and not as the only method or the initial training for site personnel. This method consists of only one training time point and lacks the direct expertise of the vendor-designated trainer and information may be "lost in translation" when the CRA trains site personnel. Thus, this model does not represent a best practice but rather a supplement to training site personnel when training from ePRO vendors or vendor-designated trainers is not feasible.

Remote training (Live Teleconference or Web Conference)

When face-to-face site training is not possible, remote training may be facilitated by a trainer—with the same experience as that described for face-to-face training—via live teleconference or live web conference. It is recommended that each site be provided training ePRO devices or access to technology (eg, IVR system) on which they can practice during the session, following training procedures similar to those recommended for face-to-face training. If applicable, this type of training can be conducted over multiple sessions to minimize site staff fatigue. A live teleconference or live web conference, similar to a live IM, can be recorded to allow site personnel more flexibility to participate according to their own schedules and be readily available for review of training information. In addition, audience polling/quizzing systems can be similarly applied in a remote setting to enhance and embed learnings.

In addition to offering most of the benefits described for face-to-face training, this type of remote training is typically less expensive because multiple sites can be trained at one time.

Tele-conferences or web conferences can eliminate the use of limited IM time, as well as the cost of training professionals' travel to each site for face-to-face, individual site training. Disadvantages of the remote model relate primarily to the conduct of the training using telecommunication. It may be challenging to troubleshoot problems trainees may have during their interactions with the ePRO technology, know whether every trainee is using the technology as instructed, and know if trainees are truly engaged in the training session. Thus, this method is not recommended for the initial training of site personnel but rather as part of the retraining process. In general, passive forms of training that are largely didactic are not as effective as interactive multimedia-based training.[20]

Interactive multimedia electronic training on device or via web

Interactive web-based or on-device electronic multimedia training is a model that can be utilized alone, or in conjunction with the other models discussed above. In this on-demand model, the training materials are prepared as an online training module accessed using a Learning Management System, a web link, application on the device, or on a DVD provided to the trainees. These materials can include didactic training with graphic and verbal descriptions, software demonstrations, troubleshooting instructions, and interactive knowledge checks to maintain trainees' active engagement throughout the training. In addition, post-training quizzing can be used to determine if the course was effective and remediate users' knowledge. Thresholds can be set to determine when and where to reroute a user who has not demonstrated adequate proficiency on one or more topics. Reporting and tracking of actual and remediated scores can be used to identify trends among trainees, across sites, and across studies/programs.

Interactive web-based/ePRO device-based electronic training has become increasingly common because of several advantages. Like remote training, this type of training can be conducted over multiple sessions to minimize fatigue and allows site personnel more flexibility to participate using an on-demand methodology. Importantly, the training is available 24/7 in the form of modules within each specific training, so trainees can learn at their own pace and site staff can refresh on a particular point as needed. In clinical trials that utilize tablets or handheld devices, the training module can be placed on the ePRO device (available offline) and made available throughout the trial for review of information as needed by the site personnel. This is particularly useful in trials where face-to-face training may not be feasible, because of difficult global logistics, for example. Furthermore, this model can provide tailored training proximal to when it is needed, addressing concerns with recall from the IM and/or turnover of site staff. On-demand electronic training allows refresher training to be conducted at any time.

Site Personnel Training Materials

Printed or PDF-style reference materials such as the site manual can provide a low-cost option for the distribution of training materials (Figure 1). Quick start guides can outline the procedures for site staff to follow at each study visit when the participant's device or technology system is to be used. It is recommended that each device screen or type of screen that site staff would see during each step of a given procedure be presented with detailed instructions for "what to do" at that screen. Such procedures should include, but are not limited to, preparing a device or technology system for a new participant, training the participant to use the device or technology, providing the participant with a replacement device, and procedures for study completion or termination. A risk to having printed manuals is that they may be misplaced or not readily accessible when needed. Ideally, quick start guides should also be available within the electronic system such that all site staff have equal access to these materials 24/7.

Along with the site manual, sites may be provided with an eLearning or DVD copy of refresher training prepared by the vendor for use as a reference throughout the course of the trial. However, DVD copies of training materials can also be misplaced. The maintenance of training materials in a single place is ideal, such as in the study database or on the same device as the relevant ePRO assessments. In addition, sponsors may also choose to provide each site with a training device or software emulator that would be retained at the site to practice study procedures or the software functionality.

Site Training Proficiency Requirements

It is recommended that all site staff who will execute any study procedures on the electronic device or technology over the course of the study be required to participate in the training. In order to ensure that minimal proficiency requirements are met prior to interacting with study participants and caregivers, it is recommended that site staff demonstrate proficiency by completing a brief evaluation of their understanding of the key concepts required to execute the study procedures with the electronic device or technology (Figure 1). Competency or "passing" should be predefined. Although it is not uncommon for a clinical trial sponsor to require a perfect score in an examination, we suggest that the required minimum score be defined on a study-by-study basis, and that a perfect score is not a requirement for satisfying the training requirement. Immediate feedback on the examination results is also recommended to solidify learning and remediate any misunderstandings of the materials in real time.

Documentation and tracking of both the training and the competency examination for all site staff are essential.[13] Training records should be available for investigators and study monitors. Ideally, only site staff who have completed the training and passed the competency examination will train and provision devices and technology to participants who will be using the ePRO system in the study.

Table 3. Study Participant Training Models.

Training Models	Advantages	Disadvantages
Individual training with site personnel	• Answer participant questions in real time	• Retention of information over duration of study • Variability of training provided by different site staff
Interactive multimedia training	• Learn at own pace • Can be placed on ePRO device/system for easy access • Available for review throughout the trial • Consistent training for all participants • Quiz questions or knowledge checks can be used to determine training effectiveness	• Difficulty troubleshooting problems

Study Participant Training

In addition to general regulatory requirements regarding training for investigators and study staff, FDA guidance on the use of PRO measures includes specific recommendations for clinical trial quality control, including "training and instructions to patients for self-administered PRO instruments."[7] This requirement is generally understood to extend to the use of a smartphone, tablet, IVR, or web-based system where PRO data are being collected electronically.

Reducing participant burden in completing PRO measures is critical to promoting compliance with protocol-driven data entry requirements.[7] Participants are generally not familiar with the expectations (flow and function) associated with entering PRO data on electronic systems or devices in a clinical trial. Participant training is recommended to ensure that study participants understand how to use the technology, when they need to interact with the technology, and the importance of their compliance in accurately reporting their study data on a regular basis.[12]

The two most common modalities of participant training include individual hands-on training with site personnel and interactive electronic training on the ePRO device (offline, available 24/7) or via e-learning modalities on the web (Table 3). The modality in which the interactive electronic training is deployed varies with ePRO vendors and the logistics of the study. Considerations for each method, key training topics, and best practices are reviewed below.

Table 4. Participant Training Curriculum.

Study-specific training topics
- Study assessment schedule
  - When to complete ePRO measures
- ePRO measure on technology system
  - How to use the screens and menus of ePRO measure
  - Practice examples of response scales
    - Visual analog scale
    - Numeric rating scale
    - Verbal rating scale
  - Resolution of error messages from: out-of-range, contradictory, and extraneous responses
  - Technology element
    - Number spinners
    - Scrolling
    - Review screens
- Participant role and responsibilities in the trial
  - Compliance to trial expectations
  - Accuracy in completing PRO measures

Technology-specific training topics
- Device and electronic system
  - How to turn the device on and off
  - How to access the electronic system
  - How to charge the device
- Data transmission and troubleshooting
  - How data are transmitted
  - How to resolve problems when data are not able to transmit
- Security issues
  - How to log in
  - Importance of protecting passwords
  - Assurance that data provided will be secure and confidential
- Support
  - How and whom to contact to obtain technical support

Participant Training Curriculum

Regardless of training method, participants should be trained on and feel comfortable utilizing the ePRO system to complete the PRO measures. Study-specific training topics (Table 4) should include, but are not limited to, instructions to navigate through the screens or menus of the ePRO format of the PRO measure, completion of the PRO measure, use of rating scales on the device or technology system (eg, visual analog scale or numeric rating scale), resolution of error messages that may arise from out-of-range, contradictory, or extraneous responses, as well as the study assessment schedule. It is also important that participants be instructed on trial-specific technology elements such as number spinners, scrolling, and review screens. In addition, the training module should emphasize the role and responsibility of the participant in the trial as well as the importance of compliance to trial expectations and accuracy in completing the PRO measures. Technology-specific training topics (Table 4) should include, but are not limited to, turning the device on and off, charging the device, accessing the technology, and data transmission and troubleshooting. The importance of setting a personal password or

personal identification number (PIN) and technology system security should be explained to participants, emphasizing not to share passwords nor allow others to enter data for them. Participants, in turn, should be assured that their data will be secure and kept confidential. Participants should be provided instructions on how and whom to contact for technical support when using the device or technology.

A practice mode of the PRO measure should be provided to allow participants to familiarize themselves with items similar in format and structure to those in the measure itself, including the technology elements and rating scales. The practice measure should include representative screens or menus of the flow and types of tasks or items that participants will complete.

Several therapeutic areas have a specific FDA or EMA guidance specifying relevant training topics. For example, the 2016 EMA guidance on oncology studies states,

- Comprehensive education and training of research staff, including investigators and the whole clinical research team, to ensure they understand the importance of PRO assessment and will be able to motivate their patients to complete the PRO instruments.
- Education and training of patients before completion of the questionnaire, including that there is no incorrect answer and explaining the purpose of the assessment.[21]

Meanwhile, the 2015 EMA asthma guideline recommends that "patients should be adequately trained in respiratory function testing, inhaler technique, compliance and the use of patient diaries."[22] Finally, the 2016 FDA guidance on ulcerative colitis states that "patients should be trained on the completion of the event log or diary. The instructions for completion of the stool frequency and rectal bleeding assessments should be incorporated into the event log or diary for ready reference by the patient. Sponsors are encouraged to propose an electronic data collection method (e.g., IVR, electronic diary, or Web-based system) as an alternative to pen and paper data collection. If an electronic data collection method is proposed, sponsors should provide instructions for training in electronic methods."[23]

Participant Training Models

Individual training with site personnel

In this training model, participants are provided individual, hands-on training with site staff at the initiation of the trial. It is essential that the site staff conducting the training are competent using the device or technology system, navigating through the PRO measure, troubleshooting, and understand the study protocol and requirements. Site personnel should also be cognizant of the participant's individual learning pace and ensure that the participant is comfortable with the information presented. As recommended above, participants should be given access to a "practice" mode of the assessment during training and throughout the trial. It is important, however, to distinguish between the practice mode and trial mode to avoid participant confusion and inadvertently completing the practice mode for which data are not saved. Additionally, the length of the training process should be short (maximum duration of 15 minutes) to minimize burden on participants.

An advantage of this training model is that site personnel can answer any question participants may have in real time. Disadvantages, however, are that information presented at the beginning of the trial can be forgotten over time and there can be variability in the training content or duration offered by different site staff. This presents the challenge of ensuring that site staff deliver the important training components in the same order and in a similar duration of time at all sites. Thus, provisions for reviewing information with site staff should be used in conjunction with interactive multimedia electronic training that is available to the participant at all times equally throughout the duration of the study. A training checklist of key elements to be covered during the individual training should also be developed to ensure consistency across and within sites.

Interactive multimedia electronic training on device or via web

In this model, the training materials are typically presented as an online multimedia training module accessed using a Learning Management System or web link, application on the device, or a DVD provided to the trainees. These materials can include device and technology demonstrations with graphic and/or audio instructions, troubleshooting instructions, and interactive knowledge checks throughout the training to ensure participant understanding of the material before proceeding to present additional information. The practice mode of the PRO measure should also be available for participants in a similar manner to that discussed above. The length of the training course in this model should also be short (5-10 minutes) with 2 to 4 knowledge checks as appropriate to reinforce learning and retention.

Advantages of this training method are that participants can learn at their own pace and, importantly, the training module can be placed on the ePRO device (offline) or system and be readily available throughout the trial for review as needed. It is recommended that the initial training session be conducted at the first site visit so participants can engage the site staff with questions. An ideal solution is to fully educate and train site staff and study participants utilizing multiple modes of learning, implemented at multiple points in time.

Participant Training Materials

It is important that participants are provided with reference materials for use during the training as well as the trial (Figure 1). Recent FDA guidance on ulcerative colitis[23] recommends that such training be housed in the same environment as the PRO assessment for ready access at all times by the participant throughout the course of the trial. In some cases, it may be of added value to include a colorful, user-friendly quick start guide that can be electronic or printed as a hard copy. Information in the quick start guide should include basic instructions on device and technology use, such as how to turn the device on

and off, charge the device, access the technology, advance to the next screen or menu, make response selections, and troubleshooting.

If relevant, instructions for pairing medical devices (eg, glucometers, peak expiratory flow meters) and activity trackers/monitors should be included. Additionally, participants should be provided an overview of the schedule of assessments (eg, event-based assessment available at all times, morning or evening assessments available during predefined windows, and alarm schedule). Participant roles and responsibilities, clinical trial expectations, accuracy in reporting, and compliance should also be included in training materials. Finally, instructions for contacting a help desk or the study site to resolve data transfer–related problems or other issues should be made available in the guide.

Participant Proficiency Requirements

It is recommended that all study participants be required to complete training and answer a brief competency examination (Figure 1). However, unlike for site personnel, a "passing" score should not be required, unless the examination is presented to determine cognitive capability for reliable self-completion of the ePRO measure, such as may occur in a pediatric setting or due to disease compromise of cognitive function. The examination should serve as a learning tool by providing immediate feedback and explanations for incorrect responses. Completion of both the training and the competency examination should be documented and training records available for investigators and study monitors.[13]

In cases where the training and examination are coupled on the same device or technology system as the PRO measure, a gating system can be implemented to only allow participants access to the PRO measure after the completion of the training and examination. Again, a passing score should not be a prerequisite, but rather a remediated passing score would be sufficient. For example, if a participant selects an incorrect answer, the next screen would explain the correct answer and have the participant acknowledge what is a correct answer. The record of actual and real-time remediated scoring can be used to assess data trends and identify areas where additional training may be needed.

In the case of pediatric or cognitively impaired populations, on-device ePRO training and quizzes can be used to determine whether a given participant has a sufficient level of cognitive functioning to understand the requirements of the trial and how to complete the PRO measure or if an alternative procedure such as interviewer administration or an observer-reported measure is needed. When this determination is conducted on device, these decision trees occur seamlessly in real time during the brief training element and comprehension quiz.

Support

As part of the training, participants should be made aware that support for trial-related questions and problems is available. Participants should refer first to site personnel for support. Study sites should also be responsible for study-specific and measure-related questions. A help desk/support line for technical issues available 24/7 in the participant's local language is typically provided by the ePRO vendor, but in cases where one is not, sponsors should make provisions with a call center to support participants in the study. Tracking help desk/support issues throughout a trial can provide important information on areas that need to be addressed more thoroughly in training for both site staff and participants to minimize those issues over the duration of the trial.

Conclusions

Electronic capture of PRO data has many advantages over paper-based data collection, and regulatory agencies encourage the use of electronic data capture as well as participant and site staff training. However, guidelines for training for both sites and participants in clinical trials on ePRO data collection are rarely provided in clinical trial protocols.[24] Moreover, training guidelines for the navigation of ePRO devices are limited. This paper puts forth recommendations for key topics to be included in the training, the recommended methods of training, and best practices for training on ePRO devices and technology.

As training of site personnel is critical to the success of implementing ePRO data collection in a study, we recommend that only site staff who have completed training and passed competency examinations provide training and provision devices and technology to study participants. Site personnel should be trained on study-specific as well as technology-specific training topics and be given instructions on whom to contact to obtain technical support. Optimal training takes place over time using multiple modalities, including hands-on, face-to-face training at an IM or directly in the clinical site, remote training via webinar or teleconference, interactive on-demand self-paced training via e-learning modalities and supplemented by proxy training with CRAs.

As with site personnel training, study participants should be provided with individual, hands-on training by site staff at the initiation of the trial and in conjunction with interactive electronic training modules that can be accessed on-demand throughout the duration of the trial. As part of the training, participants should be given reference materials in the form of a user-friendly quick start guide or electronic training module (device or web) for basic instructions on device and technology use, an overview of when assessments are available, and how to get support for trial-related questions and problems. The recommendations put forth in this paper standardize the training that site personnel and study participants need to optimize the advantages trials can gain from using ePRO data collection systems.

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Declaration of Conflicting Interests

Jenny Ly is an employee of ERT. Mabel Crescioni has no conflicts of interest. Sonya Eremenco has no conflicts of interest. Serge Bodart has no conflicts of interest. Mario Donoso has no conflicts of interest. Adam Butler is an employee and stockholder in Bracket Global. Susan M. Dallabrida is an employee of ERT.

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