Using a Variety of Instructional Methodologies in Conducting Clinical Site Training

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Background

Three statistical and clinical coordinating centers at Rho, Inc. are responsible for the overall conduct of large-scale, multicenter, full service consortia each conducting multiple trials. Various instructional modalities are used to conduct initial protocol and ongoing operational trainings for the purpose of addressing the underlying rationale of balancing effective protocol implementation and the need to manage resources to improve efficiencies.

Why Multiple Modalities?

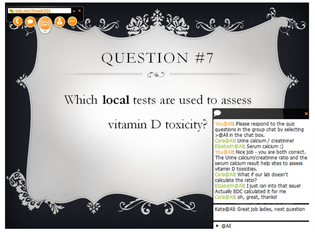
Rho faces challenging limitations in order to provide the required trainings to clinical site staff for proper trial conduct. These challenges include limited time and resources; limited availability from clinical site staff which makes scheduling conference calls, webinars, and in-person meetings challenging; difficulty ensuring clinical site staff understand and retain the trainings provided to complete trial procedures and assessments; and frequent site staff turn-over which mandates the need for repeat or refresher trainings.

In order to maximize the limited resources and manage the practical challenges, Rho is being as innovative as possible in developing, conducting, and evaluating clinical site trainings to meet the trials' needs. Our major innovations are driven by how adults learn, including application of situational learning[1] (practicing protocol-related procedures).

Form a Community of Expertise

While offering individual training opportunities seems like an obvious solution to limited site availability, it is also a significant drain on resources. Conducting trainings with large groups of site staff introduces a set of benefits that is important to weigh against the time it takes to coordinate such an event.

Training in a group setting allows everyone to benefit from multiple perspectives, broadening each individual's understanding of his/her role in the trial and how those roles interact toward the goals of the trial. When site staff are exposed to the same information, it increases the likelihood of the retention, dissemination, and implementation of that information at the site. Protocol trainings conducted via teleconference/webinars allow clinicians, site coordinators, pharmacists, and lab technicians to discuss the protocol together, as an alternative to face-to-face meetings' escalated costs.



Group trainings are effective early in the process, as each site is coming to the table with the same level of exposure to the new trial information. Rho has also been successful in implementing retraining during monthly coordinator teleconferences that often include interactive Q&A sessions. While experienced staff may excel early on, less experienced staff are competitive with their peers and often take the initiative to review trial information in preparation for the next call.

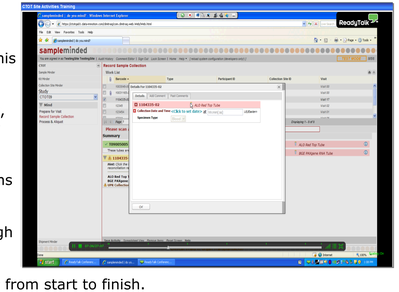
Self-Training

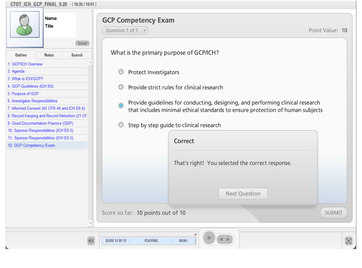
Rho utilizes multiple types of training modules that site staff can complete online at their convenience. Self-training is often accomplished through the use of videos recorded and presented by subject matter experts, recorded in-person trainings, system demos and practice functions, as well as interactive presentations.

When a training need is identified that the Rho staff is not qualified to present, it is our responsibility to identify appropriate sources of training. Protocol chairs develop videos to explain complex clinical procedures that are then posted to the project website for ease of access. Complex disease activity measures are explored during trainings through accredited websites, such as the Lupus Foundation of America™ (www.lupus.org, lupus activity assessments' online trainings).

Self-training modules have proven to be helpful resources when confronted with scheduling challenges, staff turnover and reaching diverse target audiences. They ensure all staff are presented with the same material initially and at regular intervals throughout the trial to avoid learning drift during a long trial. They also provide efficiencies for the subject matter experts who only need to present once. Using multiple types of interactive and visual presentations, we are able to connect with a broader range of learning styles among our vast and diverse target audience.

- **Informative Videos –** Rho records subject matter experts presenting a specific procedure or topic using video resources ranging from mobile device recorders to professional videographers.
- **Demonstrations and Practices** - Many data systems are built with practice functions or e-learnings that are required to be completed prior to gaining access to the live functions. This assures site users gain confidence and competency before performing actions (including entering data, randomizing patients, and tracking specimens) upon enrollment. For example, specimen tracking can be a very complex process and without proper training, can make specimen analysis difficult. Rho trains in two steps. First, the site staff watch a ReadyTalk® recording, a Rho-created audio recording of visually walking a site user through each step of the specimen tracking system. Next, each user is required to complete a practice specimen shipment in a demo system from start to finish.





- **Interactive Presentation with Comprehension Tests** – Rho also employs an automated model of training using Articulate® software. Articulate® allows Rho to employ more controls that ensure staff are gaining maximum comprehension of the material presented. This is done with slide presentations that include embedded questions in multiple forms, forcing the user to respond correctly before moving on to a new content area. Additional features prevent trainees from skipping ahead prior to a topic being fully covered.

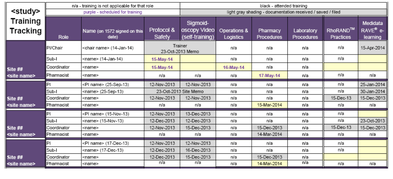
Documentation & Tracking

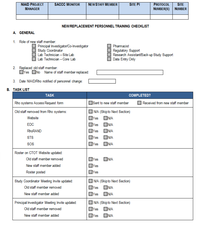
Staff must demonstrate an acceptable level of knowledge and proficiency in the protocol and trial activities prior to beginning the protocol and must also exhibit ongoing proficiency to ensure quality performance over time. Each protocol has its own training requirements, which may include a combination of attending presentations, completing self-trainings, reading protocol-specific documents and SOPs, passing comprehension tests, and demonstrating understanding by performing mock assessments. Some of these assessments are repeated throughout the course of the trial to confirm ongoing proficiency. This encompassing training process places a large demand on Rho to track training and conclude that site staff are qualified to perform trial assessments. Rho posts all training materials on the project website and then documents and tracks completion.

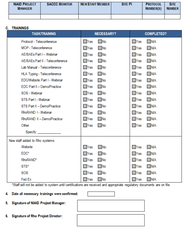
- **Paper Systems**

  Once a specific training is complete, an official certification letter or memo may be sent to the staff member from the certifying party, which is then filed by within the site's trial documentation.

  Training progress is tracked using Microsoft® Excel, which is updated to reflect the completion date and any necessary follow-up. If refresher trainings are required, they are added as additional columns in the tracker and/or are documented in the attendee list within meeting minutes.





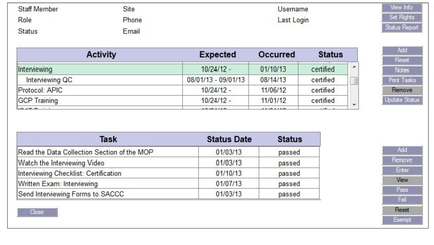


- **Web-based Systems**

  Rho's website hosts a training checklist for each site staff member which may be "checked in" and "checked out" by the appropriate certifying party for each training item. Using this system, Rho is able to monitor training progress real-time by referencing these individualized staff checklists.

- **Data Management Systems (DMS)**

  One of Rho's innovative systems includes a web-based tracking system where Rho adds each first and subsequent refresher training requirements for every site user. The comprehensive tests are graded in real-time by the system, once completed and data-entered. Rho monitors each activity individually and approves the site staff once all tasks are completed. At any given time, reports may be run to show the training and certification progress, dates of completion, and any outstanding tasks.



Training Program Evaluation

Rho's ultimate goal is to produce high quality data that lead to high quality analysis outcomes. Training presented prior to site activation is just the first step.

Throughout the trial, Rho actively monitors and evaluates training programs to assess whether they need to be expanded and/or revised.

Sites are the first-line evaluators of the trainings. What questions do they raise? What specific parts of the trial do they find unclear? If one question is asked, it is likely that there is confusion among other sites as well. Those questions are compiled and discussed with all sites on a coordinator or team call. The presentation of one question and answer about a particular topic will likely spark further conversation, with sites helping each other in their mutual understanding.

Ongoing review of trial data can identify trends or problems with the implementation of the training program. Is a particular assessment or site triggering an above-average number of queries? These trends point to topics or sites that may require additional training.

Monitoring visits are also a treasure trove of helpful information. If the monitor sees trends in the source documents across multiple sites, re-trainings should be presented. If the monitor is able to observe participant assessments, he/she is able to give the site real-time feedback on their processes and is able to give Rho feedback

Conclusion

Effective training is not just a pre-activation presentation. It is an evolving process over the course of the trial that uses a variety of methods and theories to not only teach but also continually reinforce concepts with the ultimate goal of collecting quality data to answer the trial's questions.

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Giving flight to research

[1]Lave. J & Wenger, E. (1991). Situated Learning. Legitimate peripheral participation, Cambridge: University of Cambridge Press.

Autoimmune Disease Clinical Trials

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