

## **Learning Design - at the Course Level**

Clinical Research Associates (CRAs) are responsible for ensuring the progression of clinical research studies to which they are assigned and to make sure the clinical research is conducted properly and in accordance with regulations, and produce valid data (FDA, 1996; Woodin & Schneider, 2003). A task analysis (Morrison, Ross, & Kemp, 2007) reveals that a successful CRA must learn scientific and regulatory knowledge in order to perform their job properly, learn to be precise and detail-oriented, and learn to maintain a diplomatic demeanor and cooperative attitude while discussing errors and issues with site staff. In addition, CRAs need working knowledge of the computer systems they may use for their work at their company, Contract Research Organization X (CRO-X) and of the procedures they must follow in producing work reports. Lastly, a CRA travels frequently to do their job, and this presents challenges that will be addressed in the training course.

### ***Theoretical Background***

The training CRAs require to perform their job well spreads across all three domains of instructional objectives and learning theory: psychomotor, behavioral, and cognitive (Morrison et al., 2007). Instructional objectives offer a means of designing appropriate instruction, provide a framework for devising ways to evaluate student learning, and guide the learner by allowing them to identify the skills and knowledge they must master (2007). For training on general administrative tasks and the use of computer systems for utilizing data and preparing reports, the psychomotor domain may be addressed, with only minor emphasis on cognitive domain. The CRA may simply follow listed steps until those steps are learned.

Working at sites requires review and assessment of large amounts of information, and due to its time-sensitive nature, is particularly cognitively demanding. Learning the scientific and regulatory knowledge that is needed to perform the primary portions of a CRA's work, requires cognitive domain for objectives and learning theory to be addressed. Cognitive domain receives the most attention in instructional programs and includes information or knowledge, naming, solving, predicting, and other intellectual aspects of learning (Morrison et al., 2007). This is fitting as the main aspects of a CRA's job are often abstract and complex, and therefore relate to the cognitive domain.

Affective domain, described by Morrison et al. (2007) as concerning attitudes, appreciations, values, and emotions such as enjoying and respecting is also important to address when designing instruction to meet CRA training needs. CRAs travel to each site once every 8-10 weeks and work with site personnel that are not part of the company that employs the CRA. They are required to work with different personalities at multiple sites, and successful completion of the work requires building rapport and garnering collaboration with sites. It is common for a CRA to meet with two or three coordinators or principal investigator in a given week, that have different personalities and styles of working (Woodin & Schneider, 2003). Attitudes and values like attention to detail or patience and respect, and general honesty and integrity must be given focus and attention in a CRA training program.

Morrison et al. (2007) stress that learning theory provides the foundation for the instructional design process, by explaining how learning takes place to achieve certain kinds of outcomes. They also note that behavioral, social, and cognitive learning theories can potentially operate in complementary, mutually supportive fashion in a given course

(2007). Because a CRA's work when conducting site visits is not one of exact steps to follow, but is rather fluid in nature, cognitive theory is most compatible. At the same time, some aspect of a CRA's work, including preparation for site visits, accessing data systems, or the more routine aspects of report writing and correspondence are compatible with behavioral theory because those tasks are routine, less complex, and generally follow pre-determined steps. Most CRA tasks fall somewhere between completely routine and totally complex. Social theory also presents another important avenue for showcasing what a CRA should do when performing their job. Video showing how to greet a coordinator when first arriving at a site, how to bring up sometimes difficult issues and ask for resolution, or how to hold a visit wrap-up meeting with a site's principal investigator can be very beneficial training for a new CRA.

### ***Subject Matter Content Representation***

The content of the course may be presented by two main methods: text and video, with instant messaging and email providing communication support structures. Several forms of video may be used. Video may be made in-house utilizing senior CRA and other personnel to represent realistic vignettes of CRA and site staff interactions. The purpose of these videos is to realistically demonstrate scenarios that a CRA may encounter while conducting site visits and how to effectively interact with site staff. Video may also be used to provide lectures about relevant regulations and good clinical practices, required attention to detail and knowledge of pitfalls to avoid when monitoring clinical research, and the relevance and importance of the role of the CRA to CRO-X, clients, and the clinical research enterprise.

Video lectures may also provide information on travel, safety, maintenance of work/life balance, and eating healthy when travelling. CRAs spend a majority of their work time on the road, and so these aspects are integral to a complete training program. Lastly, video may be utilized to provide instruction for utilizing computer systems to gather data prior to a visit, complete reports after a visit, inputting and saving data to the main clinical trial management system, or writing correspondence using standard templates and processes. Hence, video will be utilized to meet cognitive, affective, and psychomotor training objectives.

A few forms of text may be utilized in this CRA training course. First, are user manuals for CRO-X's computer systems that will outline detailed steps for utilizing IT resources and which may be used as reference by CRAs, with video having been planned as the primary training medium for this area. In addition, check lists will be provided to CRAs to outline various tasks a CRA must do before, during, and after a site visit. Because there are four types of sites visits (site selection, site initiation, interim, and site close-out) different check-lists will be designed to address the challenges of each visit type. These texts will address primarily the behavioral and psychomotor levels of learning.

The other forms of text used in this training program are textbooks and guidance documents previously created by experts in the field of clinical research. The first, "E6 Good Clinical Practice: Consolidated Guidance" is a guidance document developed for industry by the Food and Drug Administration in cooperation with the International Conference on Harmonization (FDA, 1996). It is a training tool that covers the most important aspects of the daily conduct of clinical trials and provides a very good

overview of best practices (FDA, 1996). The second text, “The CRA’s Guide to Monitoring Clinical Research” is a standard textbook specifically written to guide CRAs in their work (Woodin & Schneider, 2003). These two texts will address the cognitive domain of the training.

### ***Student Interaction with Course Content***

Bates and Poole (2003) explain that the most dominant form of learner-machine interaction in education is typing (p.68). CRO-X uses company-wide instant messaging and email systems to facilitate communication among project team members. These systems may be used by students to communicate with their instructor during study of course materials. Students may interact with content by pausing, rewinding, or otherwise going back to parts in video that requires further attention and study. Learners are encouraged to highlight or otherwise annotate texts to meet their learning needs.

### ***Interaction among Students***

Most CRAs are home-based and often do not meet with other CRAs. Although CRAs may meet their immediate team members during study kick-off meetings, CRAs tend to lead solitary work lives. This fact makes interaction between CRAs a necessary and welcome component of training. The goals and objectives of training may be met by providing planned opportunities for group exercises so that learners interact with each other during a portion of their studies. These are also opportunities for socialization and team-building, that may be structured to appropriate extents so as to avoid distractions or outside influences and second-hand information interfering with the integrity, design, and goals of the course.

### *Assessment Strategies*

Bates and Poole (2003) explain that opportunities must be built for explicit interaction within learning materials through the use of exercises, activities, tests, and feedback (p.99). Brief quizzes administered to learners may be sufficient in assessing whether students have been paying attention to the material and have absorbed them. Quizzes may be essay questions combined with multiple choice and fill in the blank so that cognitive skills are assessed in addition to the affective or psychomotor aspects of training. Tasks related to use of computer systems may be assessed by using a mock-up of the real system, and asking learners to perform tasks that resemble what they do in the real world for their work. Because video will be used for training, video may also be used to assess learning (Bates & Poole, 2003, p.200). Videos may be prepared that show some incorrect behaviors or ways of performing certain tasks during a site visit. And then asking students to pick out problems and provide corrections, which in turn may enable the trainees to fully learn the correct ways of working and mistakes to avoid.

Naturally the ultimate measures of the training are how well CRAs perform their work, and integrate into CRO-X's organizational structure to develop their career. Each CRA's manager may follow up during their regularly scheduled phone calls in order to know whether the CRA is having difficulty or requires additional or repeat training. CRAs may be encouraged to ask for additional help or training as needed and know that doing so is an opportunity to perform their job better, and achieve growth within the company. When the managers inform CRAs of opportunities for growth within CRO-X, each CRA may be more open to discussing any deficiencies in training that they feel may impede their career growth or excellence in performance.

## ***Feedback***

Feedback may be given in several forms to learners in this training program. Firstly, the instructor, who is an experienced CRA may give feedback that is rich and meaningful, and not only a grade. The feedback may be a combination of explaining what the learner has answered incorrectly, combined with correct answer and additional advice and guidance. Instructor may be provided as quickly as possible after each assessment task is completed. The instructor may also provide more informal feedback as each student instant messages or email them with questions or asks for guidance. Feedback may also be obtained from surveys that site staff complete and send to each CRA's managers. Such feedback will be discussed during routine phone calls between manager and CRA, as a component of training as well as career development. This integrated feedback approach indicates that the training has practical relevance to each CRA trainee.

## References

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