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GCDMP

REVIEW ARTICLE

Training

Clinical data management employees must receive the training necessary to complete their project-related responsibilities effectively and successfully. This chapter reviews the various factors to consider when adopting a training program for CDM employees. Approaches to the development of master training plans and training plans for individual employees are discussed. Topics which should be covered in data management training are reviewed. Effective strategies for facilitating the learning process are presented, including an overview of the principles of learning and different techniques for introducing course material to trainees. Online training is introduced as a solution to time and logistical constraints, and considerations for choosing and developing online training are reviewed. Trainer qualifications, the training environment, and evaluation and feedback from trainees are included as important factors to consider when adopting and maintaining a training program.

Keywords: Clinical Data Management; Good Clinical Practice; Training Records

Introduction

An effective training program plays a key role in ensuring regulatory compliance, performance effectiveness, and job satisfaction of clinical data management (CDM) employees. There are a number of compelling reasons for developing and implementing effective training programs. Good Clinical Practices (GCP) and other regulatory guidance documents state that all personnel involved in clinical trials must be qualified and properly trained to perform their respective tasks.[1,2,3] Changes in the technical, business, and regulatory environments are occurring more rapidly than ever. As a result, the demands placed on CDM personnel and the scrutinies under which they must perform are increasing. Trainers must be sensitive to these demands and ensure that they optimize the value of the training experience for participants. This chapter discusses the design, development, and delivery of effective training programs for clinical data managers. Core topics for inclusion in CDM training are also discussed.

Scope

This chapter addresses issues relevant to CDM training. It includes a brief overview of classroom training, as well as computer-based and web-enabled training issues and techniques.

Minimum Standards

- Document learning objectives for each component of the curriculum.
- Review and update curriculum and individual course offerings regularly, including applicable SOPs, to ensure that content remains current
- and relevant.
- Train all CDM staff members to perform the job functions that are currently required for their assigned roles.
- Ensure that training documentation is maintained and includes, at minimum for each course, the name of the course offering, the course objectives, the name of the course instructor, the date of the course offering, and the names of attendees. Ensure that this documentation also includes training that occurs outside the organization.

Best Practices

- Document a role-specific training curriculum for each position within the CDM organization.
- Ensure that a master training plan, which is regularly reviewed and revised, documents and prioritizes training needs of the CDM function.
- Perform job-needs analyses and audience analyses to guide development of the training plan.
- Develop and document customized development plans for each employee according to the employee's career objectives and personal development needs.
- Evaluate each training curriculum to determine if the class is best suited for instructor-based training, online user training, or a combination of the two.
- Make training support available for all online user training.
- Evaluate the effectiveness of training.
- Use a variety of methods to enhance learning during training.
- Ensure that content is consistently represented across all training materials and consistently conveyed by instructors, coaches, mentors, peers and others who assist the learner to master targeted concepts and skills.
- Verify that instructors remain qualified by obtaining and maintaining current knowledge of the topics that they teach.

- Ensure that technical training occurs in a separate training environment that simulates the actual CDM work environment.
- Document the organizational responsibility for training in Standard Operating Procedures (SOPs).
- Ensure that managers actively allocate time for employee training and development. The amount of time that should be allocated depends on the needs of the employees and the organizations.

Master Training Plan

Training should be considered at both a macro level (i.e., overall training needs) and micro level (i.e., specific training needs). Appropriate training topics, such as computer systems usage, (SOPs) and working practices, should be included in a master training plan. The master training plan should be reviewed and approved by all key individuals involved in its development and use.

Training plan design should include an audience- and job-needs analysis. The Society of Clinical Data Management (SCDM) task list and capabilities matrix (both available from SCDM) provide a good starting point for this analysis. This analysis should be customized to the organization's assignment of roles and responsibilities. When designing the proposed level of instruction, consider entry-behavior skills, knowledge, and abilities (SKAs). To determine the entry behavior, test a small sample of the target audience to establish if the starting points of the training program and threshold knowledge are accurately represented. The analysis should also consider various training-delivery mechanisms to accommodate differences between the learning styles, learning stages, sex, and ethnicity of the members of the audience.

Establish clear learning objectives. This step is critical as learning objectives form the basis for what is to be taught, the performance level, and the conditions under which the task is to be performed. To ensure that the stated objectives are valid and achievable, include a peer review or beta-test of training materials.

Once learning objectives have been established, the training method should be evaluated. Whether the course is most suitable as an instructor-based class or an online course should be determined. A cost analysis of the preferred training method should also be performed to the feasibility of online training. If an internal online training program is being considered, this cost analysis should include a review of the company's infrastructure and resources for maintenance of an internal training website. After implementation, the master training plan and materials should be assessed and updated based on feedback, changes to the audience, and job requirements.

Data Management Training Topics

This section covers topics that affect the daily work environment of data managers. This list is not intended to be exhaustive of training topics. Rather, it should serve as a reference guide for the development of a master training plan and individual development plans.

Standard Operating Procedures and Departmental Policies

Data management departments are required to have SOPs that describe their processes and operations. All data management employees are required to understand and follow these SOPs. Frequently, required training on an SOP consists of having the employee sign a statement that he or she has read and understood the SOP. However, this practice, used in isolation, often falls short of meeting its intended purpose and should be avoided. An example of a more effective approach is to have the trainer go over each required SOP with employees and explain how it affects their daily work flow. Such training sessions often encourage questions that reveal inconsistencies in the implementation of the SOP. Follow-up activities, such as study audits, may also reveal such inconsistencies. Issues identified during follow-up may be addressed by revising the SOP, if applicable, or by intervening to change the working practices of employees. As SOPs are revised, training must also be updated.

Computer Software and Technical Skills

For data entry, cleaning, and analysis, data managers use various software applications, including clinical database management systems, case report form (CRF) imaging software, edit-specification development software, discrepancy management software, and others. To use these software packages, employees require training. Depending on time and budgetary restrictions, this training may be performed by the software vendor, a third party training vendor, or an in-house trainer.

Regulations and Industry Standards

Data management is required to work within the constraints of Food and Drug Administration (FDA) codes and regulations. Additionally, industry standards give employees guidance in their common work practices. Information regarding standards such as GCP, ICH Guidelines, FDA regulations, FDA guidance documents, and the GCDMP can be found in various publications, educational seminars, or web sites. Trainers should make such references available to all employees.

Professional Growth

Individual development plans should include topics that focus on the employee's growth outside of the technical skills required. Skills—such as leadership training, effective team skills, time management, conflict resolution, project management, presentation skills, listening skills, cultural diversity, and medical terminology—allow employees to cultivate their professional skills, helping them to be more productive in a group setting. Often, the human resources department can provide outside resources for conducting such classes. Online courses also offer various training opportunities in this area.

Interdepartmental Processes

To be fully effective, CDM employees must also understand the processes that occur before and after the data is handled in data management (such as site

monitoring, safety monitoring, statistical analysis, and FDA submissions).

One effective approach is to observe other departmental processes firsthand during cross training. Another effective approach is to invite personnel from other business units or departments to attend data management meetings as guest speakers.

Training Techniques and Environment

This section describes different training techniques that may be used to optimize participant learning satisfaction. The importance of controlling the environment to enhance the learning process is also discussed. Additional information regarding these methods may be obtained through the reference citations at the end of this chapter.

Principles of Learning

The principles and techniques described in this section are based on the Interaction Associates, Inc. workshop.[4] To establish an environment that is focused on the learner's needs, a trainer should balance the three principles of *service, respect, and authenticity*. These three principles facilitate the development of a sense of trust between the trainer and participants. The trainer demonstrates service to the participants by being prepared when questions arise, even during breaks. Service may also be exemplified by arriving prepared with innovative methods for teaching the topic. Mutual respect between the trainer and trainees must be established immediately.

Creating a set of ground rules and expectations can facilitate an atmosphere of respect. Acknowledging and validating participant concerns and different learning styles also earn respect from the participants. Finally, being honest and genuine creates a presence of authenticity within the group.

Strategies in Learning

Different strategies may be employed to guide decisions and steer the direction of a training session. Using the learning pathway enables trainees to learn new skills by passing through a logical sequence of steps.[4] The first of the five steps in the learning pathway is for the trainer to provide the *definition*, or meaning, of the skill or task. The second step is for the trainer to *validate* why the skill or task is important. The third step consists of *assimilation* or comprehension by the trainee of how the skill or task works. In the fourth step, the trainee must *integrate* how the skill or task is used in the daily working environment. Subsequently, the trainees reach the fifth step and *transition* or incorporate the task with relation to other skills or tasks that they perform in their job. A trainer can organize the teaching of any concept, skill, or task through the learning pathway.

A trainer also needs to balance the importance of *content, process, and relationship* when presenting a topic.[4] To ensure participant satisfaction, the trainer must provide enough *content* to keep trainees interested while covering the objectives and meeting the participants' expectations. However, if the training session is only made up of content, the learning process will be compromised. The trainer needs to think about the *process* or flow of the training session as well. Therefore, the trainer should include all participants in the session, monitor the pace of delivery, and consider the timeliness of each step. The trainer also needs to establish a trusting *relationship* with participants. Doing so promotes a comfort level for trainees and allows them to feel at ease to ask questions and participate in the class.

Presentation Delivery/Tools and Techniques

Learning is best achieved by receiving information through a variety of methods or techniques. This section describes several methods used to present classroom-training materials. Methods often employed for on-the-job training are newsletters, fact sheets, or quick-tip reference guides. Special attention to mentor-based training should be given to ensure consistent delivery of information. The learner should be encouraged to seek clarification and validate information through multiple means rather than relying on a single source of information.

Lecture is the traditional method of transferring information from trainer to participant. However, research shows that using lecture alone for an extended period of time does not provide the optimum retention level of training materials. Lecture should be used in conjunction with other learning methods such as those described below. Lecture may be integrated with testing— thereby allowing time for self-assessment—or with a discussion of surveys or training materials within the group.

Multi-sensory techniques (e.g., visual, auditory, and kinesthetic) increase the acquisition of training material. Training that impacts as many of the human senses as possible accommodates different learning speeds, styles, and needs. Examples of visually stimulating training are the use of flip charts, colorful presentations, or other visualization techniques. Variation of voice tone during presentations or playing of music can stimulate the auditory senses during training. The kinesthetic sense of touch can be incorporated into training by using exercises with physical movement or objects.

Group discussion and interaction among participants is an effective way to present a common topic. Understanding and comprehension of the topic is enhanced when trainees discuss the topic with each other. Discussion of a topic enables a group to establish a personal connection with the content and provides a common basis for shared ideas. Triggers, such as short readings, role-playing, videos, or open-ended questions, help to stimulate discussions by connecting the participants with each other and the topic.

The "Open, Narrow, Close" technique of *questioning* is one approach that allows the trainer to maintain control of group discussions.[4] This technique is applied as follows. First, open up the content of a discussion with a broad question. Then, focus the discussion on a specific area or subtopic that was mentioned. Follow by closing and transitioning the discussion to the next topic. Questions posed by trainees should be recognized by the trainer as a learning opportunity or "teachable moment." It is imperative for the trainer to understand the question being asked. This understanding can be achieved by

paraphrasing the question, providing parallel comments to the question, or asking for clarification or expansion of certain aspects of the question or comment.

Assignments, simulations, games, or other activities are examples of *active learning* techniques. Research indicates that learning is enhanced by physically performing a related activity. Select the type of activity that best supports learning objectives. Activities might include (but are not limited to) brainstorming, round-table discussions, role-playing, or practicing tasks in a test environment. Using a three-step learning cycle known as a construction spiral[5] is another method to engage trainees in the learning activity. Providing a post-training activity that facilitates the utilization of the new skills in the daily work environment can also be an effective technique.

Storytelling allows trainees to relate the topic of discussion to their own daily environment. Stories may relate a similar experience, draw an analogy to the topic being discussed, or give an example of how the topic relates to the participants. However, it is important not to generalize or make assumptions about participants when sharing stories. The trainer/trainee trust-level must be kept intact.

Online Training

Due to time and logistical constraints, it is often necessary to provide online training materials for employees. Online training can consist of outside vendor courses performed via the Internet, as well as internally developed training.

This type of training provides flexibility because the class may be taken at a convenient location, time, and pace. Online training is also beneficial since it avoids travel time and expenses involved in bringing employees to a central location for training.

Online training from *outside vendors* should be evaluated for the organization, accuracy, relevance, content, and cost of course materials. Products from different vendors should be compared to determine the most valuable and relevant course for the employees.

Internal training may be performed online via a department website on the company intranet. Training materials, such as presentations, examples, case studies, quizzes, glossaries, and tip sheets are easily referenced from the web. Links to other reference materials, such as forms, that are used for training may also be posted.

An internal training website should contain a main menu which lists the courses available. An introduction for each subtopic and a summary of the objectives for the course should also be provided. As with instructor-led training, it is important to measure the knowledge obtained from the course to ensure that the objectives are understood. It is also important to use the different training techniques discussed earlier to keep the student interested. Visual graphics with screen shots are particularly helpful with online software applications training. With online training, it is imperative that an instructor or resource center be available for questions from the student. Online courses should be constructed to avoid boredom, which can lead to the student skipping sections or doing the minimum work necessary to advance to the next section. Worksheets, study guides, clear endpoints, and rewards for course completion can assist with these issues. Providing a practice environment for users is also beneficial.

Certain navigational features should be considered when an organization is assessing online training, internal or external. Forward, Back, and Exit buttons should be available at each menu to facilitate the student's movement from screen to screen. A Help button should be provided at each step to assist the student in navigation, as well as course guidance. Bookmark and sound-card options are also beneficial.

Accessibility of online training by students with language barriers or disabilities should also be evaluated. Internet services, such as Bobby Worldwide (http://www.cast.org/bobby/), can be used to test an internal website for issues related to language, vision, or hearing. Once the website is constructed, it can be sent for accessibility testing regarding obstacles such as sound cards for the hearing impaired, pages that are difficult to read or color-dependent for the visually impaired, and other issues.

Trainer Qualifications

A data management trainer should have experience in the topic of presentation, as well as experience in training techniques. The trainer must understand industry standards as well as departmental policies. Training techniques and methods may be found in various publications, some of which are listed in this chapter. Also, many companies offer training courses, which can be found on the Internet.

A trainer must always be prepared to handle strategic or "teachable moments." These situations may include an upset participant, an irrelevant or long- winded statement that guides the participants in an unplanned direction, or a compelling comment. When the need for transition from the current situation to the next step in the training process is recognized, the trainer must choose the best route to reaching that next step. However, the principles of service, respect, and authenticity, as previously discussed, must be maintained during this process so the trainer/trainee trust stays intact.

Training Environment

During training, regulating the physical and mental climate is important. Start by ensuring that pre-work assignments are distributed well in advance of the training event and that expectations are clearly understood. Temperature, room arrangement, lighting, and external noise should be kept at an optimal level during the session. Frequently, climate and tone are set at the beginning of a training session. Beginning with a fun activity, providing food and drinks, or playing music contributes to an optimistic training atmosphere. Closing the training session on a positive note is also important. Summarize the key contents covered during the class. Recognize the efforts of and the goals accomplished by each participant. Encourage participants to establish a plan to implement the topics discussed in their daily working environments.

Evaluation and Feedback Techniques

Implement a 360˚ feedback process regarding all aspects of the training experience. Feedback should include comments about the trainer, the training materials, and the training environment. Testing may be appropriate at this stage. Explain to the trainees how the feedback will be managed. Encourage trainees to contact the trainer after the training session if necessary.

Recommended Standard Operating Procedures

- Data Management Training Program and Documentation.

Competing Interests

The author has no competing interests to declare.

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