

# Clinical Researcher

## November 2018

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PEER REVIEWED

## **Develop a Comprehensive Learning Needs Assessment for Your Research Staff**

Tracy Graham, RN, BSN, CCRC

Targeted continuing education for research staff is an important component of any research program. Continuing education that is meaningful to research staff promotes professional development and improves the quality of research. The foundation of a successful continuing education plan is a comprehensive learning needs assessment. This article will summarize key strategies for conducting a learning needs assessment that will help you efficiently identify the specific needs of your staff.

### **Setting the Foundation**

The development and implementation of relevant continuing education for research personnel is, and should be, a vital, beneficial component of any research program. Continuing education can equip research staff with the tools necessary to handle increasingly complex and rigorous research protocols by fostering effective protocol selection, implementation, study management, and recruitment and retention strategies.

Continuing education can also assist busy research staff to quickly identify and integrate updates, changes, and revisions to federal, state, institutional, and sponsor regulations, requirements, and policies. In an increasingly competitive climate, where only the most compliant and effective sites are offered study participation, effective continuing education that addresses quality and compliance issues, identified through internal and external audits, inspections, and monitoring, can heighten the desirability of a research site to sponsors.

Finally, continuing education plays a crucial role in the professional development of research staff. However, the creation and conduct of relevant continuing education takes an extraordinary amount of time and resources, regardless of whether you are from a large healthcare center with hundreds of researchers at multiple satellite sites, an academic institution, or a small clinic or physician office. A comprehensive learning needs assessment helps focus time and effort on pertinent topics, which ultimately is a time-saver for both administrators and research staff.

Figuring out how and where to identify topics for continuing education does not have to be a daunting task. With a little investigation and planning, one can isolate the most meaningful and relevant topics.

The foundation of any education plan should be a comprehensive assessment of learning needs. The key to developing such an assessment is to identify, select, and then evaluate the sources that house information on the strengths and weaknesses of staff and the research program as a whole. Tapping into these key sources will assist in identifying reoccurring themes and topics in need of being addressed through education and training.

## **Sources for Identifying Learning Needs**

### *Internal Audits*

One source to examine when looking for potential learning needs is the output of your site's Quality Assurance (QA) and/or Research Compliance program; most large research centers have one or both. Even small clinics or an independent physician office may have current or past QA projects to examine. Ideally, tracking findings from these internal audits will help you to gain insight into the strengths and weaknesses of your research program. Review any audit findings to identify problematic areas, such as drug accountability or informed consent, to help pinpoint specific learning and skill development needs.

### *Lessons Learned*

Looking at the mistakes made by other sites and study staff can be an excellent source of relevant educational topics for your staff. One valuable resource to review is publicly available

U.S. Food and Drug Administration (FDA) Warning Letters. By looking at letters from the past 12 to 18 months, valuable insights can be formed about areas that the FDA has focused on and the problems found at other sites.

During your review, identify the top five most common citations issued by the FDA. These citations can serve as external sources in the learning needs assessment, and can later be compared to the problem areas identified from internal sources. If there is overlap, you have strong evidence to include these areas in the continuing education plan for the upcoming year.

### *Direct Observation*

Direct observation of staff is another effective source for identifying learning needs. Select a random sample of research coordinators and schedule dates to observe them conducting informed consent discussions and study visits. Observe other study-delegated tasks such as drug or device accountability, including receipt, dispensation, and reconciliation. Although this method takes time and, in the case of larger healthcare centers or academic institutions, may involve travel, observation of actual practice can provide great insight on problem areas to target with education and training.

### *Job Descriptions/Competencies*

Review the job descriptions and competencies for your research staff. Identify competencies that have not been the focus of QA activity either recently or in the past. Look for new responsibilities or competencies that have been added. Staff may be unfamiliar with these added responsibilities or the processes involved in achieving them. Finally, when evaluating job descriptions as a potential source for learning needs, always validate with leadership and staff that the listed competencies reflect current expectations and practice.

### *Monitoring Letters*

A random sample of interim monitoring visit letters from sponsor monitoring visits can offer a window on the conduct of research at your site, and serve as an excellent source to identify learning needs. Be sure your sample includes monitoring of industry trials, federally funded

trials, and investigator-initiated research. In addition, ensure the random sample includes research from all service lines or disease categories covered at your site; collect data on common errors, problems that required a corrective and preventive action (CAPA) plan, and items requiring follow-up.

Examine the data collected from external monitoring letters and identify the top three to five issues found. Again, if the common issues identified from monitoring letters overlap with learning needs identified from other internal and external sources, these areas should be included in the continuing education plan for your staff.

### *Survey Stakeholders*

Research takes the effort of numerous members of the research team, including managers, coordinators, regulatory specialists, research associates, investigators, institutional review board (IRB) staff, and sponsors. A comprehensive learning needs assessment should take into consideration the needs of all your research staff. These research team members are key stakeholders in the education plan created from the learning needs assessment, and will be much more receptive to future education they have personally identified as important to them. Surveying these stakeholders can enhance your understanding of their learning needs from a variety of perspectives.

Those closest to the trenches, so to speak, are often familiar with the most confusing topics, policies, and forms, as well as the most common mistakes and frequently asked questions. Managers, for example, have first-hand knowledge of staff strengths, weakness, and goals, and can provide valuable insight on topics that present the most difficulty for staff. Similarly, the local IRB office staff or IRB members can provide a lens on the trends or problem areas they have observed from recent projects. If your current training program uses preceptors or mentors to train new staff, these team members are another great source to assist in identifying areas that require ongoing education.

When surveying your stakeholders, it is important to ask which policies, procedures, or forms represent frequent sources of questions from research staff. A confusing policy, procedure, or form can be addressed and incorporated into your continuing education plan. Learning how and

why these documents are used and needed will enhance compliance with them and improve the conduct of research at your site.

There are many effective ways to survey stakeholders, including:

- focus group meetings
- web-based surveys
- web-based quizzes

If time permits, schedule a focused meeting with each stakeholder group, as such meetings allow the various stakeholders to speak freely. For example, a meeting with both management and research coordinators may not be as effective as a meeting with research coordinators alone, since staff may feel more hesitant to share weakness in front of management. Similarly, management will be able to speak more freely about their observations without the research staff that reports to them present.

The benefit of in-person meetings is the ability to clarify suggestions and feedback in real time. However, since these meetings take time on the part of all attendees, be sure to provide the agenda for your meeting well in advance. Not only is this respectful to the time of each attendee, it allows all in attendance time to think about research topics or processes that are most problematic, topics they want to learn more about, or education they feel is needed or desired.

If the number of key stakeholders in one focus group is large, the logistics of scheduling a meeting is more difficult. As an alternative, web-based surveys may be used to target large and widespread groups, as they allow stakeholders to provide suggestions and feedback at their convenience. Web-based surveys also allow results to be quickly analyzed and converted to tables, graphs, and charts suitable for presentations.

Meanwhile, although receiving them may seem intimidating to some, surveys targeting staff on a variety of research topics with multiple choice and true/false questions can gather valuable information. Questions about staff experiences with consenting non-English speaking subjects, adverse event/serious adverse event (AE/SAE) reporting, and investigational drug or device accountability are examples of topics to consider. However, developing good questions for such

surveys takes time and practice; be sure to take this time and reference books and articles that will help you design well-constructed questions to ensure the questions measure the outcome you are trying to assess.

Ideally, the survey should be administered via a web-based application, so its results can be easily analyzed. There are many web-based tools (e.g., Survey Monkey) that are free for the creation of smaller surveys or require a minimal fee for larger surveys. A little research on the front end should help you find a tool that is just right for your needs.

To minimize staff discomfort, assure staff that results from these surveys are collected anonymously and that data are analyzed collectively, not individually. Be sure to discuss this plan with leadership, in advance, so that they can endorse the surveys. Emphasize to leaders and staff that, if participation in (and completion of) the surveys is not 100%, the value of the data to the organization will be compromised.

### **Learning Needs Analysis—Putting it All Together**

Take all of the learning needs you have gathered from your internal and external sources and compare them to identify trends and patterns. Note any learning needs or topics that were identified from several sources. For example, if the accurate and prompt identification and reporting of AEs/SAEs was identified as an area of need in your staff survey, in the most recent quality audit, and by mentors and managers, then you have found a definite area of need.

Training on this topic would be appropriate during an upcoming continuing education event.

After careful comparison and analysis, the top three to five topics in need of continuing education and training should emerge. Table 1 is an example of sources used for an annual learning needs assessment and topics that were identified for continuing education. Based on this assessment, mandatory training should be held on AEs/SAEs, unanticipated problems, and violation identification/reporting.

**Table 1: Sources Used for and Topics Determined by Learning Needs Assessment**

Topics Identified for Training in 2017	Source(s) Evaluated in Fall 2016
<ul style="list-style-type: none"> <li>• AE/SAE identification and reporting</li> </ul>	<ul style="list-style-type: none"> <li>• Manager focus group recommends training on AEs/SAEs</li> <li>• Top 5 FDA citation – failure to conduct the investigation according to the investigational plan (AE/SAE reporting)</li> <li>• Top 3 topic identified from staff quiz</li> <li>• Top 3 topic identified from staff survey/focus group</li> </ul>
<ul style="list-style-type: none"> <li>• Unanticipated problem identification and reporting</li> </ul>	<ul style="list-style-type: none"> <li>• Previous finding on external audit of site</li> <li>• Top 3 topic from staff quiz</li> <li>• Top 3 topic identified from staff survey/focus group</li> </ul>
<ul style="list-style-type: none"> <li>• Violation identification and reporting</li> </ul>	<ul style="list-style-type: none"> <li>• Top 5 most common FDA citation</li> <li>• #1 internal compliance audit finding</li> <li>• Top 3 from staff quiz</li> </ul>

**Conclusion**

Meaningful continuing education for research staff promotes the professional and compliant conduct of research. The key to planning relevant continuing education is the completion of a comprehensive learning needs assessment. Using the strategies and sources for conducting a learning needs assessment outlined in this article will maximize the time devoted to this activity.



Beyond the suggestions given here, be sure to incorporate additional strategies and sources of your own. Varying the sources of the learning needs assessment from year to year can expand and validate the organization's introspection, ensuring it continues to capture and address the changing needs of staff.

Time spent on the front end identifying learning needs and evaluating the trends found is the first, and perhaps most important, step in conducting a comprehensive learning needs assessment for developing valuable continuing education for research personnel.

## **Resources**

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U.S. Food and Drug Administration. Inspections, Compliance, Enforcement, and Criminal Investigations—Compliance Actions and Activities—Warning Letters.

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

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PEER REVIEWED

## **The Necessity of Clinical Research Documentation Training Programs and the Value of Learning from Mistakes**

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Source documentation lies at the heart of clinical research workflows for investigative sites. Adequate documentation of protocol-related visits ensures that required information on study conduct and results has been captured for sponsors and other stakeholders.<sup>{ 1 }</sup>

In the clinical research milieu, the focus is on capturing visit information as source data. According to the International Council for Harmonization (ICH),<sup>{ 2 }</sup> source data include all information in original records and certified copies of original records, which may include clinical findings, observations, or other elements in a clinical trial that can be used to recreate or evaluate the trial. These data elements are collected in source documents, which the ICH further describes as original documents, data, and records.<sup>{ 3 }</sup>

Bargaje<sup>{ 4 }</sup> states that source documentation in clinical research:

- Documents the progress of the subject from consenting until the subject completes the study;
- Records the accountability of the investigational product dispensed, consumed, and returned by the subject;
- Serves as the complete record of the subject as the reference for the treating physician at any point in time.

Clinical research documentation is heavily scrutinized to ensure compliance with federal regulations. Because of this, it is imperative that investigative sites have a structured program for training new hires and ensuring annual competency for existing staff. Good documentation practices are essential for site success; instruction in proper documentation techniques for staff helps improve data quality and can lead to fewer queries and audit findings. This can establish a positive reputation for study placement at a site, and perhaps most importantly, increase patient safety.

### Essential Components of Good Documentation

Key attributes for good documentation were first described by the U.S. Food and Drug Administration (FDA) using the acronym ALCOA, which stands for Attributable, Legible, Contemporaneous, Original, and Accurate (see Table 1).<sup>{5}</sup> Additional attributes that documentation should possess are that they be enduring, available, accessible, consistent, credible, and corroborated (see Table 2).<sup>{4}</sup> These traits are essential qualities that clinical research staff should be taught as new hires to incorporate into their practice.

**Table 1: Breaking Down the Parts of ALCOA<sup>{4,5}</sup>**

ALCOA	
Attributable	Who documented the data is clear.
Legible	The document is readable and any signatures on it are identifiable.
Contemporaneous	Documented in the correct time frame along with the flow of events. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay should be defined and justified.
Original	The first record made by the appropriate person.
Accurate	Consistent and real representation of facts.

**Table 2: Attributes of Good Clinical Research Documentation{4}**

Documentation Attributes	
Enduring	Long-lasting.
Available and Accessible	Easily available for review by treating physicians and during audits/inspections. The documents should be retrievable within a reasonable time.
Consistent	Unchanging over time.
Credible	Based on real and reliable information.
Corroborated	Evidence should support the data.

### Source Documentation Guidance

The value of source documentation was further noted by the Joint Task Force (JTF) for Clinical Research Competency, which included it as part of the Core Competency Framework within a domain labeled Data Management and Informatics. {6} Within this domain, the JTF addresses the close relationship between clinical research data management and informatics. In treating documentation as a recognized competency for clinical research staff, sites have a responsibility to ensure that a focused training program exists for ensuring team success with its related tasks.

**Table 3: Excerpt of Section 6 of the Core Competency Framework Identified by the Joint Task Force for Clinical Research Competency{6}**

<b>6</b>	<b>Data Management and Informatics:</b> Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database
6.1	Describe the role and importance of statistics and informatics in clinical studies
6.2	Describe the origin, flow, and management of data through a clinical study
6.3	Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting
6.4	Describe, develop, and implement processes for data quality assurance

The use of an electronic means of documentation has become the norm, moving away from paper-based sources. For clinical researchers, if an electronic health record (EHR) is used, considerations may be with both documentation and extraction (data mining) of information

from the system. This has important considerations for the care of research participants, such as study eligibility, continuity of treatment longitudinally, and ongoing subject follow up.

In July 2018, the FDA announced its finalized guidance on “Use of Electronic Health Record Data in Clinical Investigations,”<sup>{7}</sup> giving directions to sponsors, clinical investigators, contract research organizations (CROs), institutional review boards, and other interested parties on the use of electronic health record data in FDA regulated clinical investigations. Some of the key concepts from the guidance are that {7}:

- EHR data improve patient safety, data accuracy, and clinical trial efficiency;
- Study staff can more easily combine, aggregate, and analyze data from multiple sources (orders, notes, etc.);
- EHR systems provide access to real-time and longitudinal healthcare data, and can facilitate post-trial follow up on patients to assess long-term safety and efficacy.

From this FDA guidance, use of electronic systems for clinical trial documentation and management is encouraged. The efficiency that electronic documentation allows can significantly save documentation time for sites, while promoting continuity of care. Once again, site documentation programs should cover considerations with electronic systems and their features specific to clinical research. It also is important that the elements of ALCOA should be present whether the documentation is paper or electronic.

### **Source Errors**

In clinical research training programs that teach research documentation, the ultimate goal is to have sustainability of correct documentation workflows in practice. Unfortunately, the role of human error comes into play. As the old saying goes, to err is human, and well-intentioned people can make very costly mistakes in clinical research. Even with proper training, guidance, and regulations, we know that source documentation errors will still exist.

Experience is always a good teacher, but in the absence of experience, one can learn from the mistakes of others. One approach can be to expose research staff to examples of real-world mistakes made in clinical research and the inevitable consequences. This can be done by sharing

details from auditing or interim monitoring visit reports. Sites can learn from these mistakes and become proactive concerning source documentation errors by finding root causes and patterns, then creating adequate solutions.

### **Site Challenges**

Rapid enrollment periods and short timelines can cause staff to hurry through documentation and not give it the attention it requires. Heavy workloads and low staffing can contribute to errors. During these times, staff may start documentation but not complete it until weeks later, forgetting what should have been documented at the time of the event. Important details may be missed or misunderstood, and staff may not be as thorough as desired, leading to errors in records that are not caught until the time of a routine monitoring visit. The discovery of ineligible research participants in this fashion is a study coordinator's nightmare.

When multiple protocols are being conducted by a site for the same disease state, it is also easy to confuse protocols. Similar studies can create confusion, but so can multiple staff assisting with and documenting data on an individual study. This can also lead to inconsistencies in documentation. Protocols may be amended and staff may be in the habit of documenting under a previous version, or revert back. Lastly, while research staff can be excellent at their jobs, investigator oversight and documentation that reflects it are critical.

### **FDA Warning Letters**

When training staff how to document research visits, also consider providing exposure to what not to do. The best way to do that is to review Warning Letters publicly shared by the FDA. The FDA is quite transparent about findings from its audits. Researchers can subscribe to e-mail updates about FDA Warning Letters on the agency's website. {8}

The posted letters can be reviewed by company, issuing office, subject, response letters, or closeout letters. Further, throughout their website, Warning Letters can easily be shared using Facebook, Twitter, LinkedIn, Pinterest, or sent with e-mail.

**Figure 1: FDA Warning Letters Online{8}**



## Documentation Findings

The most common inspection findings related to source documentation are that it is not reliable, not adequate, or not accurate.{4} Staff should be trained to recognize that, when findings are made by the FDA, they are reported in relation to specific expectations stated in the *Code of Federal Regulations* (CFR). When the FDA gives a site a citation, it does so with examples of how the site is in violation of the expectations.

Using Warning Letters as examples can be useful to show new hires the consequences of failing to follow regulations on proper documentation as dictated in the CFR. Reviewing violation examples and considering ways that site workflows can prevent such violations can be useful for new hire training and ongoing staff competency review (see Table 4).

**Table 4: FDA Citations Using the *Code of Federal Regulations* and Examples**

FDA Citation	Violation Examples	Prevention Strategies
<p>21 CFR 312.60: Failure to ensure that the investigation was conducted according to the investigational plan.</p>	<ol style="list-style-type: none"> <li>1. Enrolling ineligible subjects not meeting study entry criteria.</li> <li>2. Missing study procedures indicated in the protocol, such as chest X-rays or electrocardiograms.</li> <li>3. Disqualifications during study run-in period, yet patient enrolled.</li> </ol>	<ol style="list-style-type: none"> <li>1. Have a colleague double-check study entry criteria before a patient is enrolled.</li> <li>2. If using an EMR, capitalize on tools to help you find information quickly.</li> <li>3. Cross reference protocol with Schedule of Events to make sure procedure milestones are met.</li> </ol>
<p>21 CFR 312.62(a): Failure to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.</p>	<ol style="list-style-type: none"> <li>1. Drug dispensed does not match the amount taken by the research participant.</li> <li>2. The amount of drug returned does not match what should have been returned.</li> </ol>	<ol style="list-style-type: none"> <li>1. Count and document drug return with the subject present, not after the person has left.</li> <li>2. Count medication before dispensing.</li> <li>3. Discrepancies should be explained in source or note to file.</li> </ol>
<p>21 CFR 312.62(b): Failure to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.</p>	<ol style="list-style-type: none"> <li>1. Absence of accurate histories documented.</li> <li>2. Failure to complete forms required.</li> </ol>	<ol style="list-style-type: none"> <li>1. Keep medical history section updated.</li> <li>2. Use source documents that have been verified by sponsor or CRO.</li> </ol>
<p>21 CFR 312.62 (c ): Failure to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the application is not approved for such indication, until two years after the investigation is discontinued.</p>	<ol style="list-style-type: none"> <li>1. Not maintaining records related to drug disposition, including dates, quantities, and usage.</li> <li>2. Not retaining consent forms and case report forms.</li> </ol>	<ol style="list-style-type: none"> <li>1. Keep a drug dispensation log with study drug accountability.</li> <li>2. Check with sponsor prior to shredding documents.</li> <li>3. If possible, scan informed consents into the electronic medical record.</li> </ol>



## **Proactive Approach**

A study of FDA violations can lead to focusing on the prevention of documentation errors. Learning from the mistakes of others can be a powerful tool in training. The most impactful, proactive approach is staff education. Each member of the study team should undergo training on the study and that training should be documented. Principal investigators should delegate responsibilities to staff adequately trained on the protocol and the tenets of Good Clinical Practice. Particular training should be provided on ALCOA and other good documentation practice requirements. {5}

Use of an eligibility checklist can help prevent wrongful enrollment. A checklist can be created if a sponsor does not provide one. When utilized, having a second person review the checklist for completion and tie the results to successful enrollments is key. Rushing and distraction can both easily contribute to errors related to subject eligibility, so remember to take time to focus on each and every individual who is being enrolled.

Staff workload also needs to be considered by management. If the enrollment period is extremely fast or if staff are responsible for too many studies, errors are likely to occur. Sites should determine if it is feasible to take on additional studies. Keeping realistic workloads can go a long way in error prevention for both staff and investigators.

Sponsors and CROs, meanwhile, need to determine if investigators are committed to full participation throughout the duration of studies. {5} While study staff may be doing the bulk of documentation, that does not preclude the investigator from responsibilities detailed in the Form FDA 1572.

If a site does not already have one, its leaders should consider the importance of having a standard operating procedure (SOP) on source documentation. The SOP should provide an overview of the essentials of documentation, while not being so rigid that the site staff cannot comply with it. New staff should be trained in this SOP, which should be evaluated annually. Existing staff should review any updates and document the review.

Having an internal quality assurance (QA) program can also lead to enhanced site data and documentation quality. These programs should be run by a point person who can perform internal QA audits to make sure that staff are in compliance with the protocol. Ideally, this should begin to occur around the time of first randomization in a new study.

Once new hires are out of an orientation period, consider including them on an internal QA committee. They can be given a QA checklist to review source documentation from experienced peers who can help them know the essential requirements for review. By learning from their team, they can contribute to site quality, and in turn, improve their own documentation.

## **Conclusion**

Staff who are true novices to clinical research will need an experienced preceptor to show them proper documentation techniques within the limits of the protocol and federal regulation. Value lies in having site staff learn from the mistakes of others as a means of preventing similar mistakes. As time becomes the teacher and staff become confident and skilled in their documentation, it is important to also consider ongoing refresher training and annual competencies.

Documentation could be thought of as creating a story of patient activity over the duration of the protocol. Site staff should look at their documentation and ask if it will make sense four years from now when someone inspects the records. Training with the rationale for how the regulations shape how one documents the data that are documented, along with FDA Warning Letters to learn from the mistakes of others, can solidify proper technique and further ensure site success.

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## NOVEMBER 2018 CLINICAL RESEARCHER

### HOME STUDY

#### *Meshing the Gears of Education and Training*

### Develop a Comprehensive Learning Needs Assessment for Your Research Staff

#### LEARNING OBJECTIVE

After reading this article, participants will be able to articulate the importance of continuing education in clinical research and apply recommendations for conducting a learning needs assessment at their organization.

#### DISCLOSURE

Tracy Graham, RN, BSN, CCRC: *Nothing to disclose*

- 1. What is the main impact continuing education should have on research staff?**
  - a) Exposes shortcomings in how sponsors want research programs to be conducted at study sites.
  - b) Helps staff to focus time and effort on cutting costs and increasing profits from clinical trials.
  - c) Provides a set of nonconfrontational behaviors that can be applied when monitors are onsite.
  - d) Promotes professional development and improves the quality of research.
  
- 2. Continuing education can equip research staff with tools. What is a goal of using these tools that is mentioned in the article?**
  - a) To develop and implement one-time-only research programs.
  - b) To conduct detailed learning needs assessments for external vendors.
  - c) To better handle increasingly complex and rigorous research protocols.
  - d) To ensure that patients are compliant with the protocol when participating in trials.
  
- 3. How does continuing education most directly assist busy research staff?**
  - a) Allows for quick identification and integration of new and updated regulations.
  - b) Allows for choosing only affordable and immediately pertinent courses for assigned projects.
  - c) Provides quick recaps of courses that were completed a long time ago.
  - d) Gives insider knowledge about sponsors when preparing for external audits.
  
- 4. How can audit findings help identify staff learning needs?**
  - a) By mandating the establishment of a Research Compliance Program.
  - b) By highlighting feedback from the Quality Assurance department.
  - c) By uncovering problematic areas of study conduct by staff.
  - d) By identifying unaddressed themes and topics on the minds of patients.

**5. FDA Warning Letters are a valuable resource. What should you be most aware of during your review of the agency's Warning Letters website?**

- a) The riskiness of the therapeutic areas that the FDA appears to focus on most.
- b) The costs associated with the quality and compliance issues identified during inspections.
- c) The disparities in penalties enforced on large healthcare centers and academic institutions versus small, independent firms.
- d) The identification of the top five most common citations issued by the FDA.

**6. How does direct observation contribute to assessing training needs?**

- a) Provides insight on problem areas to target with education and training.
- b) Proves that clinical research does not require external monitoring.
- c) Pinpoints only the specific learning and skill development needs of principal investigators.
- d) Enables assessment of tasks in real time using new technology mandated by sponsors.

**7. A sample of monitoring letters is a good source for identifying learning needs. What should the sample include?**

- a) Monitoring reports on industry trials, federally funded trials, and investigator-initiated research.
- b) In-depth details on why certain therapeutic areas were challenging for site staff.
- c) Proprietary information on how findings from these internal and external audits affect investments in the targeted firms.
- d) Analyses of the time taken for sites to respond to monitors' queries.

**8. How many focal issues for training should be identified from data across various sources?**

- a) The top 10 issues.
- b) The top three to five issues.
- c) Only what sponsors say is the most important issue.
- d) Only the issue with the greatest impact on the cost of running a trial.

**9. Which team members are a good source to assist in identifying areas that require ongoing education?**

- a) Preceptors or mentors who train new staff
- b) Representatives from vendor organizations
- c) Social media managers
- d) External institutional review board/ethics committee staff

**10. What is the key to planning continuing education?**

- a) Ensuring training courses are short and affordable.
- b) Reviewing staff productivity metrics on a quarterly basis.
- c) Reviewing staff interest levels in attending offsite training versus onsite.
- d) Completing a comprehensive learning needs assessment.

# The Necessity of Clinical Research Documentation Training Programs and the Value of Learning from Mistakes

## LEARNING OBJECTIVE

After reading this article, participants will be able to articulate the nature and regulation of source documentation in clinical research, outline the essential components of good documentation, and use examples of FDA Warning Letters for training purposes.

## DISCLOSURE

Paula Smalles, DNP, RN, CCRP, CCRC: *Nothing to disclose*

### 11. Which of the following is true about source data?

- a) The data include all information necessary for recreating or evaluating a trial in original records and certified copies of original records.
- b) The data include only information contained in regulatory binders.
- c) The data constitute the complete record of the subject as the reference for the treating physician at any point in time.
- d) The data should be de-emphasized in clinical research.

### 12. Clinical research documentation is heavily scrutinized because:

- a) The paperwork minimization requirements of healthcare organizations are strict.
- b) Compliance with federal regulations must be ensured.
- c) The public demands it.
- d) Media reports of research misconduct focus on it.

### 13. The acronym ALCOA was first described by:

- a) The National Institutes of Health
- b) The European Medicines Agency
- c) The U.S. Food and Drug Administration (FDA)
- d) The International Council for Harmonization

### 14. Good Clinical Research Documentation attributes include:

- a) Enduring, consistent, credible, corroborated, accessible
- b) Original, accurate, contemporaneous, legible, attributable
- c) Consistent, cost-effective, corroborated, contemporaneous
- d) Legible, signed, dated, verified

- 15. The Joint Task Force (JTF) for Clinical Research Competency addresses research documentation in what section of its framework?**
- a) Scientific Concepts and Research Design
  - b) Ethical and Participant Safety Considerations
  - c) Clinical Trial Operations
  - d) Data Management and Informatics
- 16. In July of 2018, the FDA announced its finalized guidance on “Use of Electronic Health Record [EHR] Data in Clinical Investigations.” Which statement was NOT included in this document?**
- a) EHR data improve patient safety, data accuracy, and clinical trial efficiency.
  - b) EHRs provide access to real-time and longitudinal healthcare data and can facilitate post-trial follow-up on patients to assess long-term safety and efficacy.
  - c) EHRs help study staff can more easily combine, aggregate, and analyze data from multiple sources (orders, notes, etc.).
  - d) EHRs create an increased workload for study sites that may contribute to human error.
- 17. Clinical research training programs that teach research documentation strive for sustainability of correct documentation workflows in practice. Despite this, what is likely to occur?**
- a) Source documentation errors will still exist.
  - b) Routine monitoring visits will increase in frequency.
  - c) The cognitive burden from numerous responsibilities will overwhelm staff.
  - d) Staff turnover related to lack of training will only get worse.
- 18. Common FDA citations include:**
- a) Failure to ensure that the investigation was conducted as inexpensively as possible.
  - b) Failure to maintain records of how patients learned about their trial results.
  - c) Failure to ensure there are no deviations from expected study conduct.
  - d) Failure to maintain records on principal investigators’ earnings from speaking engagements.
- 19. Ways to prevent documentation errors include all of the following EXCEPT:**
- a) Principal investigators should delegate responsibilities to staff adequately trained in the protocol and Good Clinical Practice (GCP).
  - b) Only reviewing monitor reports that seem most serious.
  - c) Use of eligibility checklists.
  - d) Factoring in considerations about staff workload.
- 20. Having an internal quality assurance program can lead to which of the following?**
- a) Enhanced site data and documentation quality
  - b) Increased staff workload and burnout
  - c) Staff insecurity from an awareness of their errors
  - d) Noncompliance with GCPs