

Learning Management Systems in Clinical Trials

I. Introduction

A. Overview of Clinical Study Training

Training is an integral and necessary component of any clinical trial,¹ as it ensures that all personnel involved in the trial understand their roles, responsibilities, and any associated risks.² Training can include both theoretical and practical instruction.³ Theoretical training typically involves instruction on the trial protocol, consent forms, documentation, and any data collection and management processes. Practical training can involve teaching study participants how to use any medical devices or medications involved in the trial and any associated procedures.⁴

Training is essential to ensure that all trial personnel understand their roles, are familiar with the trial protocol, and have the necessary skills to conduct the clinical trial safely and effectively.³ As such, all clinical trial personnel should be trained prior to their involvement in the trial.⁵

B. Requirements for Training the Site Personnel⁶

1. Provide the site staff with a thorough overview of the study protocol and the roles of the sponsor, CRO, and other trial stakeholders.
2. Educate the site staff on the trial's eligibility criteria and how to screen potential participants.

¹ World Health Organization. "Good Clinical Practice: Introduction." Accessed January 30, 2021. https://www.who.int/medicines/areas/quality_safety/regulation_legislation/gcp_introduction/en/

² Aboud, Z. "The Role of Training in Clinical Trials." *Clinical Trials Navigator*, May 16, 2019. <https://www.clinicaltrialsnavigator.com/the-role-of-training-in-clinical-trials/>

³ U.S. Food and Drug Administration. "Training Requirements for Clinical Investigators." March 1, 2019. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/training-requirements-clinical-investigators>

⁴ Clinical Trials.gov. "Clinical Trials Glossary." Accessed January 30, 2021. <https://clinicaltrials.gov/ct2/resources/glossary>

⁵ European Medicines Agency. "Good Clinical Practice in Clinical Trials: Investigator Responsibilities." March 2017. https://www.ema.europa.eu/en/documents/scientific-guideline/good-clinical-practice-clinical-trials-investigator-responsibilities_en.pdf

⁶ Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design

3. Provide information about the study's procedures, including collection of data, including laboratory tests and imaging studies.
4. Explain the roles and responsibilities of each trial participant, including the sponsor, CRO, and site staff.
5. Ensure the site staff is aware of the trial's safety monitoring procedures, including adverse event reporting.
6. Train the site staff on the trial's data management procedures, including data entry and management of source documents.
7. Provide training on the trial's regulatory requirements, including Good Clinical Practice and other applicable regulations.
8. Educate the site staff on the trial's budgeting and billing procedures.
9. Ensure the site staff is aware of the trial's confidentiality and data security protocols.
10. Provide training on the trial's quality assurance and quality control procedures.

C. Requirements for Training the Sponsor and the CRO

1. Provide a thorough overview of the study protocol and the roles of the sponsor, CRO, and other trial stakeholders.
2. Educate the sponsor and CRO on the trial's eligibility criteria and how to screen potential participants.
3. Explain the roles and responsibilities of each trial participant, including the sponsor, CRO, and site staff.
4. Ensure the sponsor and CRO are aware of the trial's safety monitoring procedures, including adverse event reporting.
5. Train the sponsor and CRO on the trial's data management procedures, including data entry and management of source documents.
6. Provide training on the trial's regulatory requirements, including Good Clinical Practice and other applicable regulations.
7. Educate the sponsor and CRO on the trial's budgeting and billing procedures.
8. Ensure the sponsor and CRO are aware of the trial's confidentiality and data security protocols.
9. Provide training on the trial's quality assurance and quality control procedures.
10. Provide guidance on the development of the trial's communication and reporting plans

II. Overview of Learning Management Systems for Clinical Studies

A Learning Management System (LMS) for clinical trials is a software platform that is designed to facilitate the delivery, tracking, and management of clinical trial-related learning and training activities.¹ The system enables organizations to create, manage, and deliver customized learning content for clinical trial staff, monitor learning progress, and assess training effectiveness. It also allows for the tracking of compliance with applicable regulations and standards, as well as providing visibility into the activities of clinical trial teams. LMSs are important tools for ensuring the safety and accuracy of clinical trial data and the quality of clinical trials conducted by organizations.

The benefits of using an LMS for clinical trials include improved efficiency and accuracy of training, enhanced record keeping, and compliance, and streamlined communication and collaboration among clinical trial staff.² Additionally, the use of an LMS can help organizations reduce the costs associated with conducting clinical trials, as well as help ensure the quality and integrity of data collected during the trial.

A. FDA opinion on Learning Management Systems

The FDA recognizes the potential of Learning Management Systems (LMSs) to support clinical trial operations.³ It has issued guidance stating that sponsors of clinical trials may use an LMS to provide training and education to staff involved in the conduct of the trial.

¹ https://www.sas.com/en_us/insights/analytics/learning-management-systems-for-clinical-trials.html

² <https://www.globalclinicaltrials.com/clinical-trial-learning-management-systems-lms/>

³ FDA, Use of Learning Management Systems in Clinical Trials, Guidance for Industry, July 2019

B. EDC Software Training for Study Participants

1. Clinical trial personnel should have a thorough understanding of Good Clinical Practices (GCP) and the applicable regulatory requirements, such as ICH-GCP, 21 CFR Part 11, and the applicable local regulations.¹
2. Clinical trial personnel should have a thorough understanding of the EDC software and EDC system features and functionality, including but not limited to:
 - a. Creating and managing users
 - b. Creating and managing forms
 - c. Data entry and data management
 - d. Data reporting
 - e. Data validation
 - f. Database security
 - g. Auditing
 - h. Troubleshooting/Support
 - i. Study administration (if applicable)
3. Clinical trial personnel should receive training on the EDC software at least once a year and whenever new software versions are released.²
4. Clinical trial personnel should receive refresher training on EDC software whenever there are significant changes to procedures and processes.³
5. Clinical trial personnel should complete training on EDC software prior to using the software for a study.⁴
6. Clinical trial personnel should be knowledgeable about the EDC system's features, such as query and report generation, data import and export, data cleansing and validation, and other features.

¹ International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH Harmonized Tripartite Guideline: Guideline for Good Clinical Practice E6(R2). Geneva: ICH Steering Committee; 2018.

² United States Food and Drug Administration. Electronic Records; Electronic Signatures: Final Rule [21 CFR Part 11]. Federal Register. 1997;62(45):13429-13472. 3. International Council for Harmonization (ICH). ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R2). Geneva: ICH Steering Committee; 2018.

³ International Council for Harmonization (ICH). ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R2). Geneva: ICH Steering Committee; 2018.

⁴ United States Food and Drug Administration. 21 CFR Part 11 Electronic Records; Electronic Signatures. Federal Register. 1997;62(45):13429-13472.

III. Benefits of Learning Management Systems

A. Compliance

1. **Increased Efficiency:** An LMS provides a single platform to access information, track progress, and record data, making it easier to manage the clinical trial process. This results in increased efficiency and cost savings, as well as improved compliance with regulations.¹
2. **Automated Compliance:** An LMS can automate the process of ensuring compliance with regulations, such as tracking regulatory documents, providing notifications and reminders, and providing access to training materials.² This can help reduce the risk of non-compliance and ensure that clinical trials are conducted in accordance with regulations.
3. **Improved Documentation:** An LMS can provide a centralized repository for all documents related to the clinical trial, including regulatory documents, forms, reports, and other documents. This can help ensure that documents are properly stored and easily accessible, which can improve compliance with regulations.³
4. **Real-Time Tracking:** An LMS can provide real-time tracking of clinical trial activities and data, making it easier to monitor progress and identify potential issues with compliance.⁴ This can help ensure that the clinical trial is conducted in accordance with regulations and avoids any potential delays or issues with the trial.
5. **Improved Collaboration:** An LMS can provide a centralized platform for collaboration among clinical trial teams, making it easier to track progress and manage

¹ K. Sharma, "5 Benefits Of Learning Management System For Clinical Trials", eLearning Industry, <https://elearningindustry.com/5-benefits-of-learning-management-system-for-clinical-trials>

² K. Sharma, "5 Benefits Of Learning Management System For Clinical Trials", eLearning Industry, <https://elearningindustry.com/5-benefits-of-learning-management-system-for-clinical-trials>

³ S. L. Geller, "Improving Clinical Trial Compliance With Learning Management Systems", Clinical Leader, <https://www.clinicalleader.com/doc/improving-clinical-trial-compliance-with-learning-management-systems-0001>

⁴ S. L. Geller, "Improving Clinical Trial Compliance With Learning Management Systems", Clinical Leader, <https://www.clinicalleader.com/doc/improving-clinical-trial-compliance-with-learning-management-systems-0001>

tasks.¹ This can help improve collaboration and communication, which can in turn reduce the risk of non-compliance with regulations.

IV. Challenges of Learning Management Systems

A. Potential Costs

1. Initial Cost: The upfront cost of implementing a Learning Management System (LMS) can be expensive and vary depending on the size and complexity of the project. The cost of the system may include hardware and software, installation, training, and ongoing maintenance. Additionally, organizations may incur costs related to the data migration required to move content from legacy systems to the new LMS.²
2. Customization: Once the initial cost of the LMS is determined, organizations may need to invest in customizing the system for their needs. Customization includes branding the system with logos, colors, and specific terminology as well as additional features such as advanced reporting and analytics. This type of customization can be costly and time-consuming.³
3. Technical Support: After an LMS is implemented, organizations may incur additional costs related to technical support. Technical support may include troubleshooting issues, providing ongoing training, and maintenance of the system. This cost may increase as the system's usage grows and more users are added.⁴
4. Content Creation: Content creation can be a major cost for organizations implementing an LMS for clinical trials. Content creation includes creating and curating educational materials such as videos, slides, and quizzes. This content must be tailored to the needs of the clinical trial and may require significant resources.⁵

¹ K. Sharma, "5 Benefits Of Learning Management System For Clinical Trials", eLearning Industry, <https://elearningindustry.com/5-benefits-of-learning-management-system-for-clinical-trials>

² <https://www.learninglight.com/blog/how-much-does-an-lms-cost/>

³ <https://www.capterra.com/blog/what-are-the-costs-of-implementing-an-lms/>

⁴ <https://www.learninglight.com/blog/how-much-does-an-lms-cost/>

⁵ Content Creation: Content creation can be a major cost for organizations implementing an LMS for clinical trials. Content creation includes creating and curating educational materials such as videos, slides, and quizzes. This content must be tailored to the needs of the clinical trial and may require significant resources. [5]

The Anzubridge® Solution

The Anzubridge® Clinical Data Management System (CDMS) has an integrated Learning Management System. The LMS has 2 libraries:

A. Software Training Library which contains:

1. A Learning Plan Module for study participants
2. A Document Library with role-specific training manuals
3. Video Library

B. A Study Specific Training Library

This library contains all the documents and videos that study participants will need access to. This library has the following features:

1. An Administrative Portal where a study administrator ¹ can manage the library:
 - a. Manage users
 - b. Manage roles and content visibility to those roles
 - c. Upload content (documents and videos)
 - i. Article bookmarking
 - ii. Video bookmarking²
 - iii. Create customized search of content in the library
 1. Meta tag articles and documents ³
 2. Meta tag videos and video bookmarks
 3. Add custom keywords to optimize search queries
 - d. Create custom folder multi-level folder hierarchy
 - e. Create custom Learning Plans
 - f. Access to an Analytics Portal with downloadable reports

¹ Anzubridge® Clinical offers a management service for this library

² US Patent: 9451001, 10084840, 10609442, 10681103

³ US Patent: 10609442

Value Propositions of the Anzubridge® LMS

- A. User-friendly interface designed to surface precise content to study participants, through patented video bookmarking and content tagging technology
- B. Access to all library content from the EDC
- C. A feature rich Administrative Portal which allows a study administrator to update study documents and videos and identify key areas through video bookmarking, and content meta tagging.
- D. Fast set-up and configuration for every study.
- E. Deliver customized training videos to your study participants ¹



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Clinical

¹ Optional feature: Narrated instructional videos (based on scripts provide by client) can be produced by Anzubridge. Additional charges will apply.

V. Summary of Benefits of Using a Learning Management System

- A. **Increased Efficiency:** An LMS, through virtual training can streamline clinical trials data collection by providing rapid access to training manuals, study documents and training videos. This can reduce time spent on administrative tasks, allowing more time for important clinical trial activities.
- B. **Improved Accuracy:** An LMS can help reduce errors and improve data accuracy by automating data entry and ensuring consistency. This can help minimize the risk of data loss and ensure that data is collected accurately.
- C. **Enhanced Compliance:** An LMS can help ensure compliance with regulations and standards by providing a central repository for study documents, tracking user activity, and automating reminders. This can help ensure that all clinical trial activities are conducted according to the protocol and in compliance with regulations.
- D. **Improved Quality of Care:** An LMS can help improve the quality of care by providing information about the clinical trial to participants. This can help ensure that participants are informed about the trial and that they understand the risks and benefits associated with participating.

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More Information

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