White Paper

Learning Management Systems in Clinical Trials

Anzubridge® Clinical

Learning Management Systems in Clinical Trials

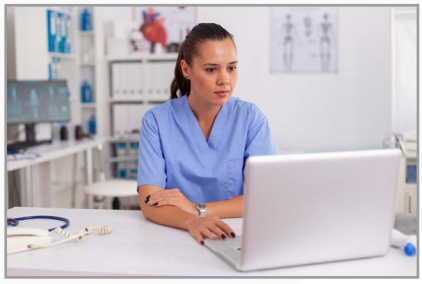
Optimizing Training and Education

Overview of Clinical Study Training

Training is an integral and necessary component of any clinical trial, as it ensures that all personnel involved in the trial understand their roles, responsibilities, and any associated risks. Training can include both theoretical and practical instruction. 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.

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. As such, all clinical trial personnel should be trained prior to their involvement in the trial.

Training Requirements



Site Personnel

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.
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.

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.

Overview of Learning Management Systems for Clinical Studies

FDA and Learning Management Systems

The FDA recognizes the potential of Learning Management Systems (LMSs) to support clinical trial operations. 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.

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.
2. Clinical trial personnel should have a thorough understanding of the EDC software and EDC system features and functionality, including but not limited to:
    - Creating and managing users
    - Creating and managing forms
    - Data entry and data management
    - Data reporting
    - Data validation
    - Database security
    - Auditing
    - Troubleshooting/Support
    - 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.
4. Clinical trial personnel should receive refresher training on EDC software whenever there are significant changes to procedures and processes.
5. Clinical trial personnel should complete training on EDC software prior to using the software for a study.
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.

Benefits of Learning Management Systems

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

Challenges of Learning Management Systems

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. **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. **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. **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.

The Anzubridge®LMS Solution

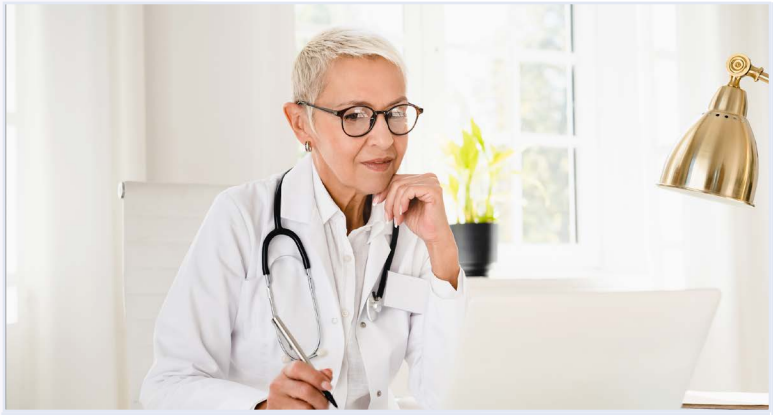
Overview

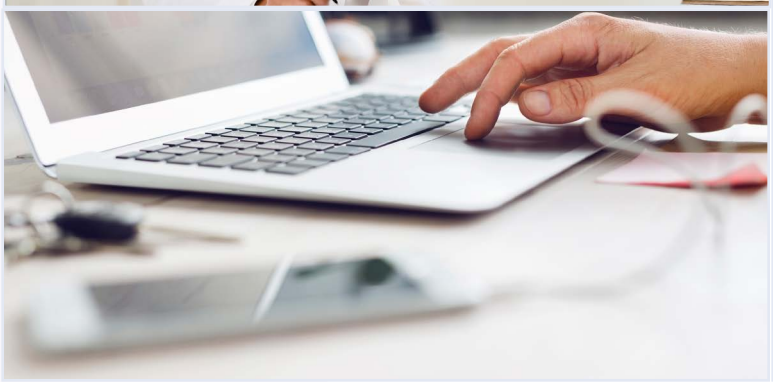
Comprehensive training of site and clinical operations personnel on both the data management software system and the study requirements, is essential for the efficient and timely execution of the study protocol.

Time management is an important requirement of any medical practice. Any study participant must have instant, targeted access to relevant information to streamline study execution. For site participants or operations personnel, this critical information consists of 2 components:

- Use of the software.
- Study specific information. Each study has training and education requirements that are specific to the study protocol.

This information must be organized in a hierarchical structure with granular metadata attached to content that allows the user to logically navigate, access, and surface information on demand.





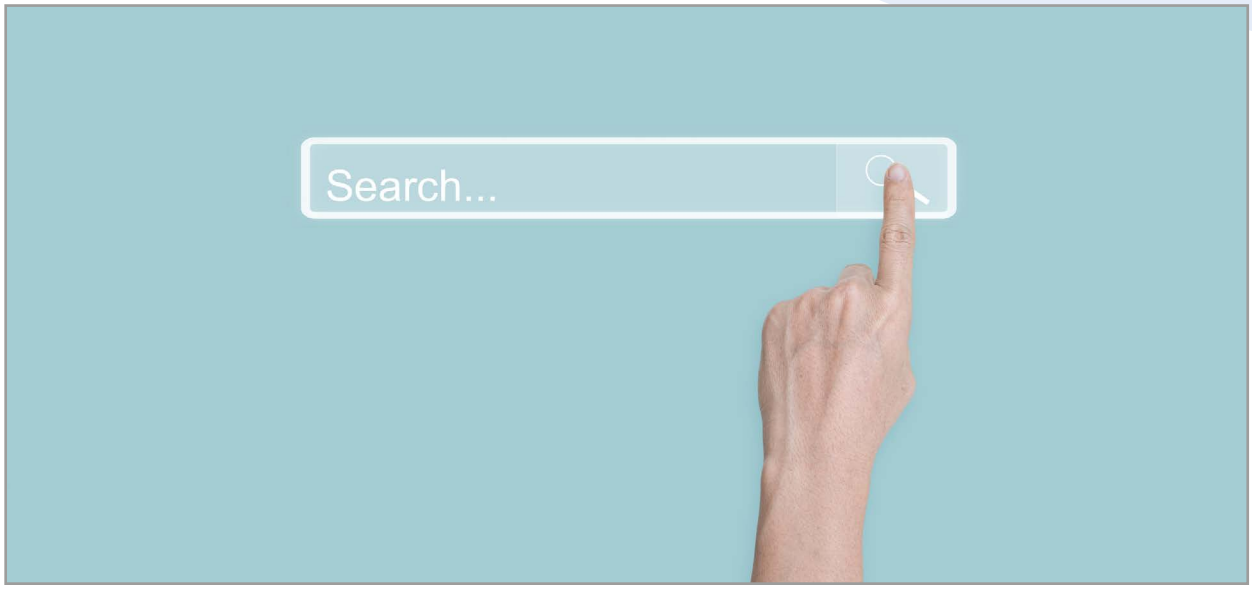
The Anzubridge®LMS Solution

There are many trials/studies that would benefit from media capture and review added to their study protocol. The Anzubridge® CDMS offers this feature. Training of study participants, including reviewers, is an essential component in understanding operational requirements and software features and workflows.

Strategies for Surfacing Relevant Content for CDMS Users

This concept is based on the process of locating and accessing relevant information in a digital library. These strategies include:

1. **Cataloging and organization:** Categorizing and organizing content in a logical and easily searchable manner can help users locate relevant information more quickly and efficiently.
2. **Indexing and cross-referencing:** Creating indexes or cross-referencing materials within a collection can help users discover related content and expand their search beyond their initial query.
3. **Displaying content prominently:** Positioning popular or high-priority items in prominent locations can help users easily locate and access them.
4. **Intuitive filtering:** Providing users with a user-friendly interface to filter library content.



Strategies for Search Optimization Using a Tagging Infrastructure

Tagging of content refers to the process of adding descriptive metadata to content in a content library, in order to improve the discoverability and accessibility of the content to users. Metadata provides additional information about the content that can be used to search and sort it within the library. Tagging can be particularly important for content libraries that are housed in a single location(server), as it can help users locate specific items more easily.

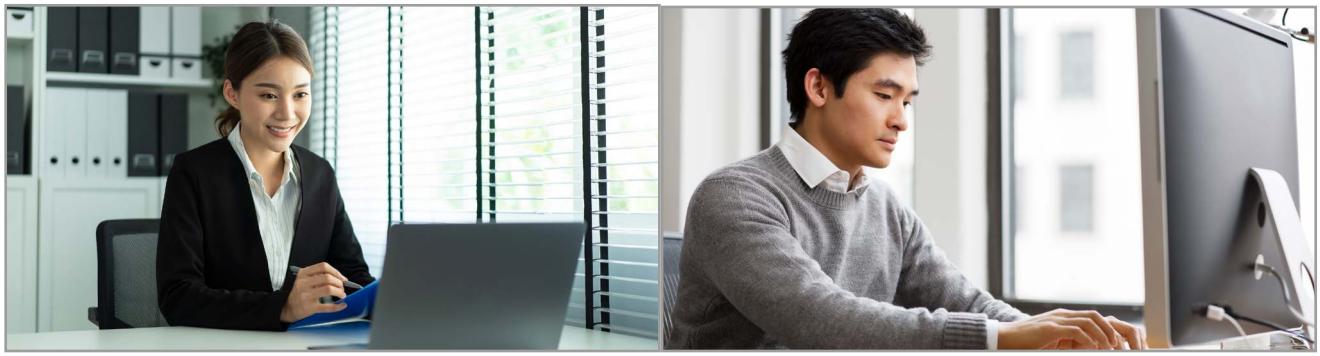
To optimize search for a specialized content library, here are some strategies that should be used for tagging content:

1. **Use descriptive keywords:** When creating metadata, use descriptive keywords that accurately reflect the content of the item.
2. **Use consistent metadata:** Make sure that metadata is consistent across all items in the library, so that users can easily search and sort content by relevant categories.
3. **Use controlled vocabulary:** Consider using a controlled vocabulary. This is especially true clinical trials data management which frequently uses specific acronyms or other descriptive terms. This ensures consistency in describing subject matter and provides standardized terms for searching.
4. **Prioritize relevant metadata:** Prioritize adding metadata that is most relevant to users. This will help users quickly locate the content they are looking for.

By employing these strategies, content libraries can optimize the discoverability and accessibility of their content, making it easier for users to locate and access the materials they need. This can lead to increased engagement and usage of the library, as well as streamline training of study participants.

The following sections will describe in detail how the Anzubridge® Learning Management System accomplishes these strategies.

Components of the Anzubridge® LMS



Library Administration

The Administrative Portal for the LMS has a robust set of features which allows the Administrator to manage users, add roles, and design and configure a multi-media library . Below is a summary of these capabilities:

User Management

The User Management feature allows an Administrator to add/edit/delete study participants into the LMS and create and assign customized roles. These roles will not only have visibility (access) to specific content in the library, but also are associated with different functions on the system:

1. User Registration
   - Add/Edit/Delete Users

2. Role Management
   This feature allows the Administrator to create customized roles (‘Primary Role”) in the LMS. These Primary Roles will have content access and feature access:
   - Primary Role: Feature and Content Access
     - » Administrator
       - ◊ “Super” Administrator
       - ◊ “Sub” Administrator
       - ◊ Site User
         - ▹ PI/SI
         - ▹ CRC
       - ◊ Sponsor3
         - ▹ CRA
         - ▹ Data Manager
         - ▹ Clinical Trials Manager/Clinical Study Manager
   - Content Access (Visibility) based on:
     - » Channel
       - ◊ Library
       - ◊ Category
       - ◊ Subcategory

Components of the Anzubridge® LMS

User Management (continued)

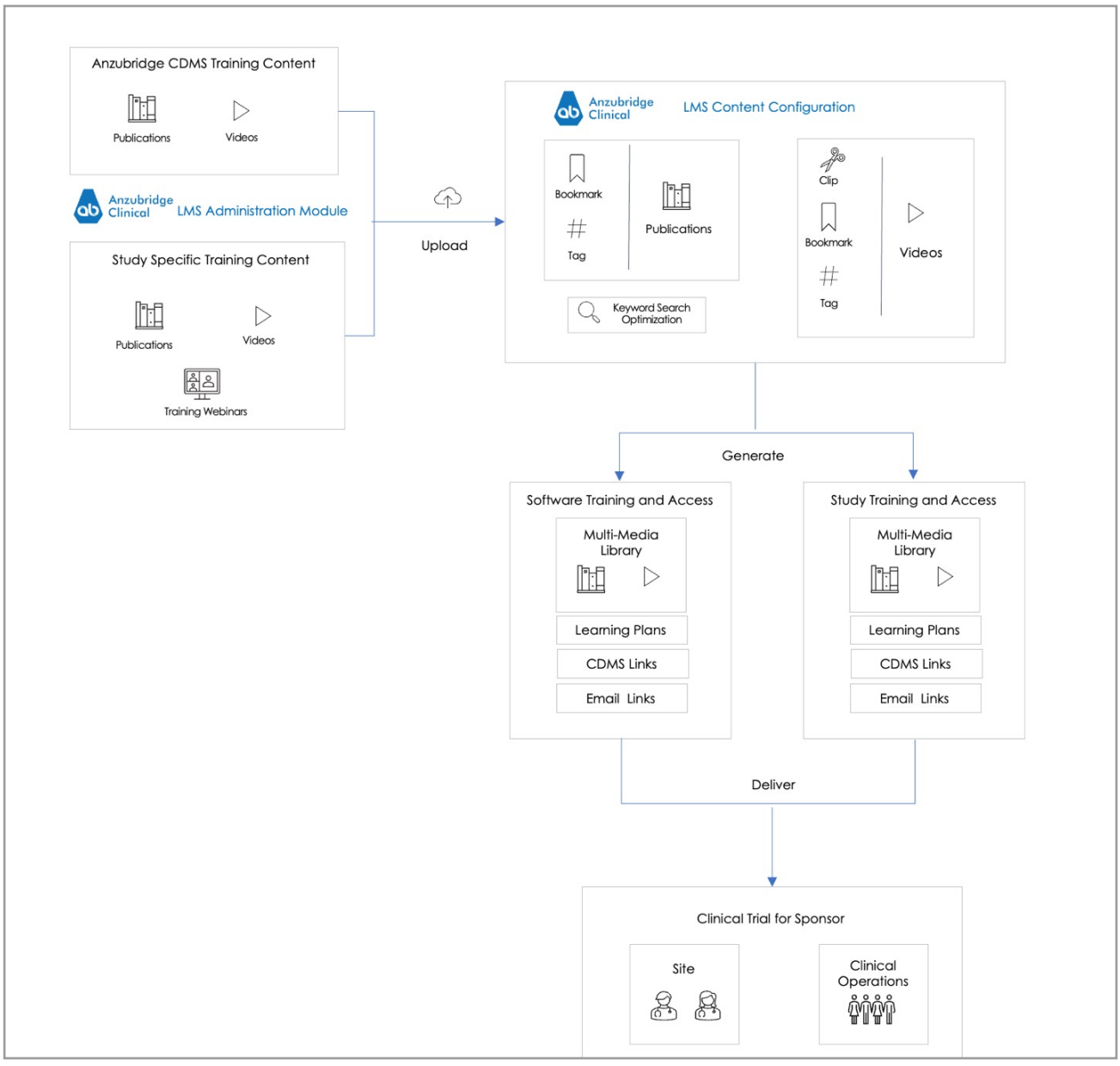
- Role-based User Feature Access
  - ◊ Content Type Configuration
    - ▷ Documents (PDFs)
    - ▷ Videos
  - ◊ Document and Media Upload
    - ▷ PDF/Word/Powerpoint
    - ▷ Video/Audio
  - ◊ Content Tagging System[1]
    - ▷ PDF
      - ▪ Tag Documents
      - ▪ Tag Articles
      - ▪ Customized Keyword Tagging[2]
      - ▪ Customized Library Tagging[3]
  - ◊ Video Clipping and Bookmarking[4]
    This feature allows the user to create bookmarks and/or clips inside a streaming video. These clips/bookmarks can be tagged which make them visible in search.

1The tagging system is using patented Anzu® technology. Art Research and Technology DBA Anzu® US Patent: 10609442.
2 Customized keyword tagging is used for search optimization. Keywords such as acronyms that are commonly used in clinical trials are tagged to content, thus allowing rapid targeted access in search.
3 The Anzubridge® tagging system also allows tagging of content into system designated categories specific to this library. Examples include “videos”, Study-Specific (library), System (library). The user can filter content at these levels using the filtering system located on the left side of the home screen.
4 This feature is using patented Anzu technology. Art Research and Technology DBA Anzu® US Patents: 9451001, 10084840, 10609442, 10681103

Content Management Workflow

This workflow diagram demonstrates the high-level process of content management in the Anzubridge LMS:

1. Content upload for each library
2. Content configuration using multiple tools available in the LMS system
3. Library generation. This not only includes generation of the multi-media library, but also the ability for the Administrator to generate links to specific content including publication and video bookmarks. These links allow targeted access to specific content in the library and will be used in both the CDMS help screens and in email communications with users. In addition, links can be generated for Learning Plans.



Content Tagging and Distribution Using Patented Anzubridge Technology

This sophisticated system streamlines 2 processes in complex library management:

1. Organization of content in multi-level folder hierarchies that are System or Sponsor configured. The content in the library can be organized at multiple levels:
   - Channels (folders)
     - » Category
     - » Sub-category (n-level)
2. Tagging of content at multiple levels:
   - Channel
     - » Category
     - » Sub-category
   - Library type
     - » System (software training)
     - » Study Specific (study training)
   - Document Tagging
     - » Document Category
       - ◊ Learning Module Software
       - ◊ Reference Document Software
     - » Document Source
       - ◊ System (generated)
       - ◊ Sponsor (generated)
     - » Document Type
       - ◊ Software Learning Plan
       - ◊ Software Training Manual
       - ◊ Study Training Manual or Document
       - ◊ Study Learning Plan
   - Video Tagging
     - » Reference Library Videos
     - » Study-Specific Videos
   - LMS Category
     - » EDC
     - » LMS Administrator Training
   - Role Access[1]
     - » Site
       - ◊ PI/SI
       - ◊ CRC
     - » Sponsor
       - ◊ CRA
       - ◊ DM
       - ◊ CTM/CSM
   - Keywords[2]

     The System allows custom keyword tagging of content based on multiple factors specific to clinical trials. The search algorithms in the LMS are programmed to prioritize keyword search. An example of this process:
     - » Electronic informed consents. Similar terms include:
       - ◊ eIC
       - ◊ ICF
       - ◊ Informed Consent
       - ◊ E Consent
     - » The user can type in any of these terms and the relevant content will surface.

1 Search queries can be filtered by role access. This is an Administrator feature.
2 As previously noted, keyword tagging allows customized search optimization.

Distribution of Content to the User

The tagging infrastructure allows distribution of content across multiple folder hierarchies and roles. Examples of this include:

1. Single source distribution to all channels. (ex. Anzubridge® training content)
2. Distribution of specific content including publications, publication bookmarks, videos, and video bookmarks across multiple folder categories.
3. Distribution of content noted above by role.

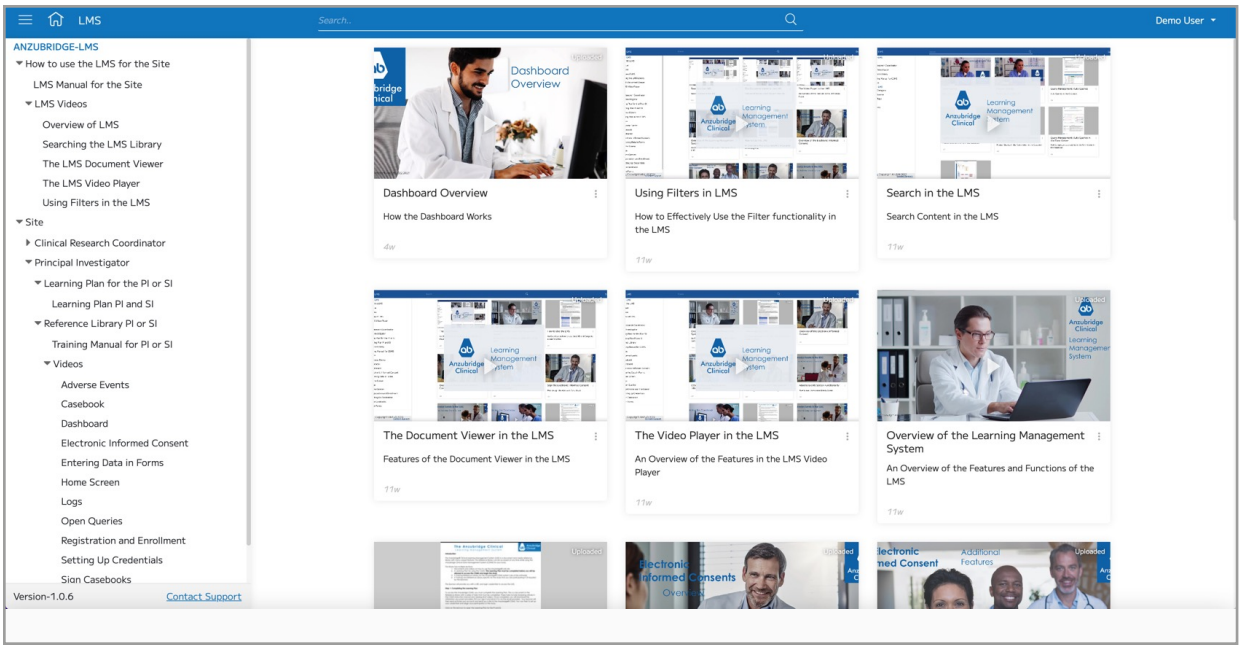
Below is a screenshot of the LMS library for the site. It provides an example of how a user can rapidly surface relevant content through filters. The central panel has all the content from the library, specific to a role in the study.

In this example, the library is for software training for a site. Content includes:

1. Manuals and video tutorials on the using the system.
2. Software Training
   - Learning Plans
   - Training Manuals
   - Training Videos

Filters based on folders hierarchy are located on the left panel. Content is placed in the folders based on tagging.

The user can rapidly surface content by clicking on the left panel filters.

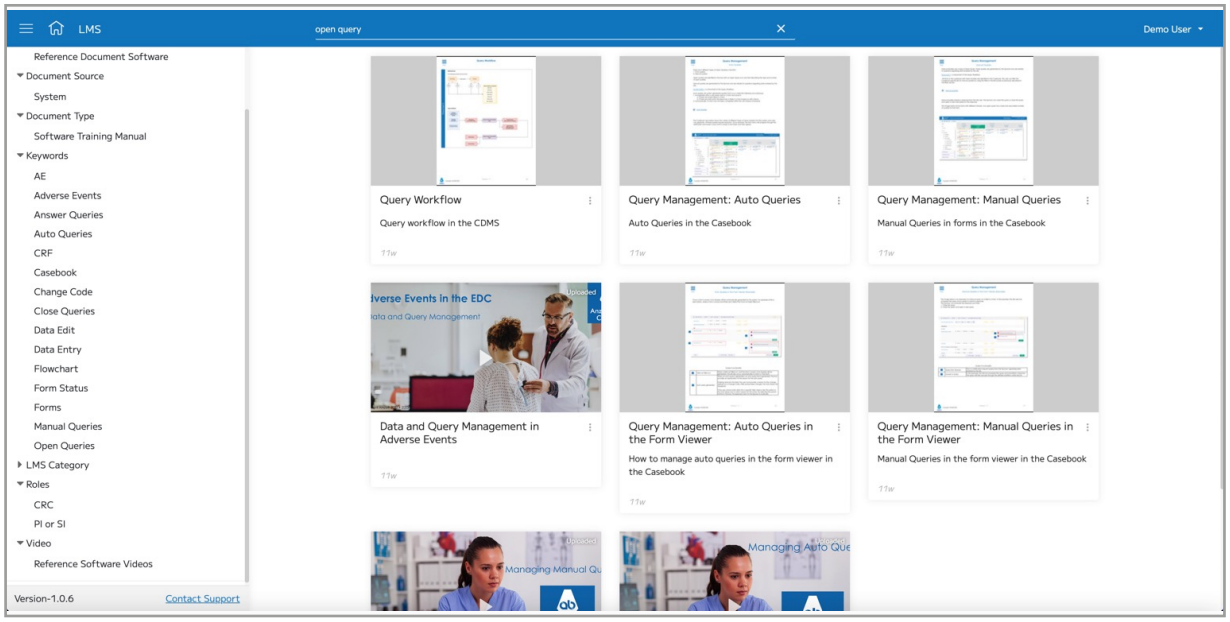


Search Optimization in the Anzubridge® LMS Library

Tagging of the content in a manner relevant to study participants in a clinical trial allows rapid, target-specific surfacing of information.

Once a search query is executed, the system delivers all the content in the library that is relevant to that query. The left menu will identify all the content tags (previously discussed) that are associated with that query. The user can filter the content at multiple levels to further refine the query. Search queries will also deliver bookmarks of videos.

In the example below, the user has searched for content related to “open queries”. Multiple videos, video bookmarks, documents and document bookmarks are provided to the user. The user can further refine the search by selecting content tags in the left menu.



Links to Videos Demonstrating LMS Features

1. LMS Overview Video
2. LMS Video Player
3. Using Filters in the LMS
4. Search in the LMS
5. LMS Document Viewer

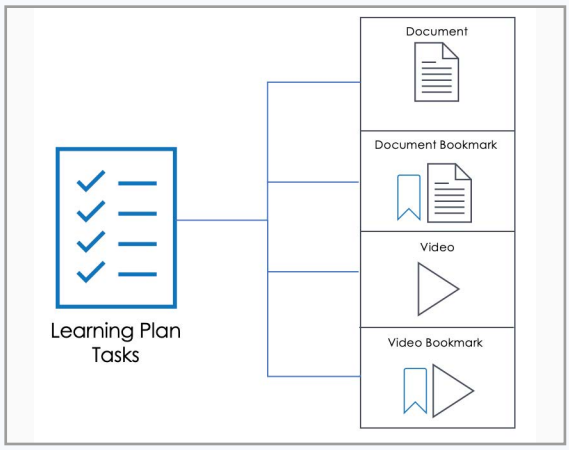
Learning Plans in the Anzubridge® LMS[1]

Training materials in the form of manuals and videos have been created for the use of the software and can be available for any study. As noted previously, the Anzubridge® LMS has optimized the approach to organize, distribute, and surface this content to the user.

Documenting training is the next important component of clinical trial training compliance. An ideal approach is to document system and study training utilizing a Learning Plan.

Learning Plans in the Anzubridge® LMS are user-friendly to design, deploy and monitor. It does not require programming skills. Sponsors can design their plans on a word document. Design is a simple process. The document will have a series of sequential tasks to complete. The Learning plan will require the user to complete the sequence of tasks defined in the document. These tasks are based on reviewing targeted content. Here are the review options:

1. Review a publication
2. Review a sequence of publications
3. View a video
4. View a bookmark inside a video



1 Anzubridge® offers a service which includes:
- Management of the study-specific library for the Sponsor
- Creation of fully narrated videos on study specific training
- Creation and configuration of Learning Plans based on Sponsor specifications

Learning Plans in the Anzubridge® LMS (continued)

Once the document and the tasks are designed, the next steps are:

1. Upload The document into the library in the desired folder

2. Configure the document with an e-sign. By doing this, the system will attach a signatory capability to the learning plan and attach an attestation checkbox.

3. Attach the targeted links noted above to the tasks. The interface will allow attaching links to library content to each of the tasks.

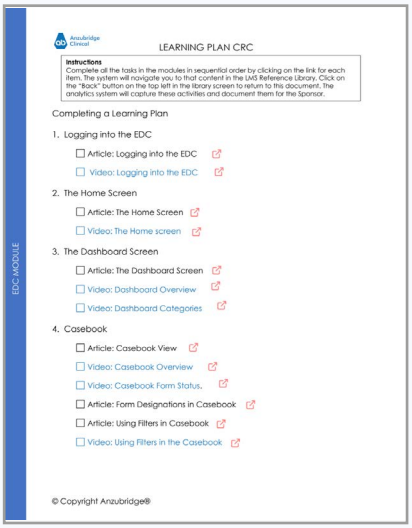
Once all these steps are completed, the Learning Plan will allow the study participant the following features and functions:

1. Access to content-specific Learning Plans
   - » Directly in the Anzubridge Learning Management System Library[1] .
   - » Via a targeted link to a specific learning plan which can be distributed via email, or in an onboarding document created by the sponsor[2].
2. A simple task-oriented Learning Plan interface
3. The ability to sign an attestation that the training on this Learning Plan has been completed.
4. The participant can share this signed attestation with the Sponsor by downloading a PDF.
5. The system will generate metrics ("Sign History") around this process which will be accessible to the System and Site Administrator.
6. Once the participant has completed specific Learning Plans, the study participant will receive access to the EDC to begin the process of execution of the study protocol.

Using Links to Access Content

The LMS creates links attached to the following content:
1. Documents (PDFs) and Document Bookmarks
2. Videos and Video Bookmarks

These links are used as access points in the following:
1. Help Screens in the EDC
2. Email correspondence with study participants


LEARNING PLAN CRC

Instructions
Complete all the tasks in the modules in sequential order by clicking on the link for each item. The system will navigate you to that content in the LMS Reference Library. Click on the "Back" button on the top left in the library screen to return to this document. The analytics system will capture these activities and document them for the Sponsor.

Completing a Learning Plan

1. Logging into the EDC
   - Article: Logging into the EDC
   - Video: Logging into the EDC
2. The Home Screen
   - Article: The Home Screen
   - Video: The Home screen
3. The Dashboard Screen
   - Article: The Dashboard Screen
   - Video: Dashboard Overview
   - Video: Dashboard Categories
4. Casebook
   - Article: Casebook View
   - Video: Casebook Overview
   - Video: Casebook Form Status.
   - Article: Form Designations in Casebook
   - Article: Using Filters in Casebook
   - Video: Using Filters in the Casebook

EDC MODULE

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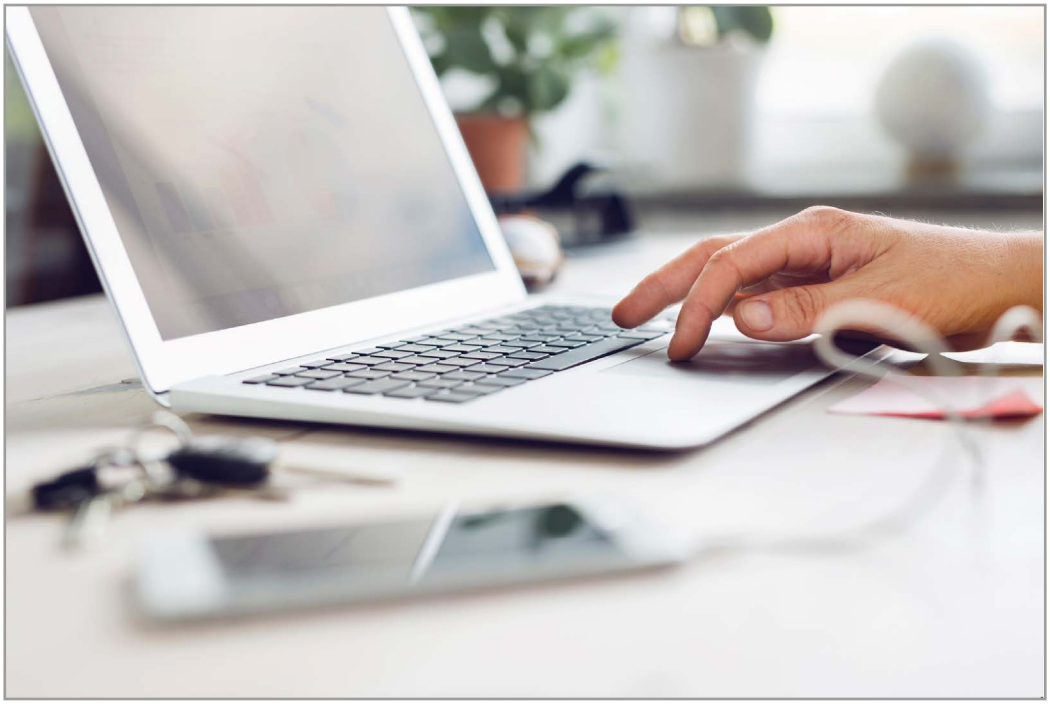
1 The Study Administrator will configure a study participant access to the LMS for the study
2 In this scenario the user has an existing LMS account, and the link will direct them to the specific Learning Plan

Value Propositions of the Anzubridge® LMS

This system adheres to the strategies previously described, to surface relevant content to the end-user in the most efficient manner. Features include:

1. Streamlined set-up and configuration for every study.
2. User-friendly interface designed to surface precise content to study participants, through patented video bookmarking and content tagging technology.
3. User-friendly interface for study participants to access multi-media content from a Study Library
4. Role-based access to features and content
5. Access to all library content from the EDC.
6. 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.
7. Complex content distribution options.
8. Multiple options for surfacing target content to study participants.
9. Simple user interface to create Learning Plans for study participants.
10. Create customized training videos to study participants



Summary of Benefits of Using a Learning Management System

- **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.
- **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.
- **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.
- **4. 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.

About the Anzubridge® Clinical Data Management System (CDMS)

Innovative Features | Creative Deployments | Patented Technology

The Anzubridge® CDMS is the culmination of years of multiple product design and development by a team of innovators and engineers.
This system is HIPAA and 21 CFR compliant and has many features:

1. Electronic Data Capture
2. Electronic Informed Consent With Knowledge Checks
3. ePRO (Electronic Patient Reported Outcomes)
4. Media Capture
5. Media Review
6. Laboratory Information Management System (LIMS) Connectivity
7. Learning Management System (LMS)
8. Integration and Data Exchange With Validated External Data Sources
    - Device Registration Platforms (The Aesthetic One Breast Implant Platform)
    - Point of Care Device Analysis Modules (in development)

Multiple patents awarded to the company, are incorporated into the Media, LIMS, LMS, and Point of Care Device Analysis Modules.

The seasoned team of engineers have years of multi-stack development of complex platforms.

Our goal is to provide unique and innovative solutions that streamline onboarding, data access, training and education to all stakeholders.

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