White Paper

Media Capture

Upload and Review in Clinical Trials

Anzubridge®
Clinical

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Introduction

Media capture and review in clinical trials is the process of collecting and reviewing videos, images, audio, and other data generated using different media and technologies in the context of clinical trials. It is used to ensure the accuracy and consistency of data collection, as well as to facilitate the analysis and interpretation of results. This process is becoming increasingly important in clinical trials as technology advances, allowing for a more comprehensive understanding of the effects of treatments on patients. Through media capture and review, researchers can capture video and audio recordings of patient interactions, as well as collect images of patients that can be used for analysis. This also allows for the collection of data from other sources such as wearable devices, which can provide real-time information about patient health and lifestyle.

Definition of Media Capture and Review in Clinical Trials

Media capture and review in clinical trials is the process of collecting and reviewing relevant media from a trial. This includes images, audio recordings, videos, and other types of media that are used to document the trial's results. This media can be used to gain insights into the trial's progress, evaluate the efficacy of treatments, and assess safety issues. The review process involves analyzing the media to identify any potential issues, such as inconsistencies or errors, that could impact the trial results.

Benefits of Media Capture and Review in Clinical Trials

1. **Enhancing patient recruitment:** Media capture and review can help increase patient awareness of clinical trials and improve recruitment by providing patients with educational materials and other content to better understand the clinical trial process and its potential benefits.
2. **Reducing costs:** Media capture and review can reduce costs associated with clinical trials by eliminating the need for costly focus groups and surveys.
3. **Increasing efficiency:** Media capture and review can help streamline the clinical trial process by providing real-time data and feedback on patient experiences and satisfaction, allowing for a more efficient development and evaluation of clinical trial treatments.

Privacy Concerns of Media Capture and Review in Clinical Trials

Media capture and review of data in clinical trials can raise important privacy concerns for participants. These concerns relate to the collection, storage, and use of the data, and the potential for patient data to be shared with third parties, such as sponsors, regulatory bodies, and health care providers.

Data collection: Clinical trials may collect sensitive data from participants, such as health information, personal attributes, and biometric data. The collection of such data raises questions about the privacy of the participants and the security of the data. It is important for clinical trials to ensure that participant data is collected in a secure manner and that participants are fully informed of the purpose and scope of the data collection.

Data storage: Media capture and review data are usually stored in a secure digital repository. However, the security of digital repositories can be compromised if they are not properly secured. It is important for clinical trials to ensure that the data is stored in a secure manner, with appropriate access controls in place to limit access to sensitive data.

Data use: Clinical trials may use the data collected to analyze and interpret the trial results. This data can be shared with third parties, such as sponsors, regulatory bodies, and health care providers. It is important for clinical trials to ensure that data is only shared with parties who have a legitimate business or scientific reason to access the data, and that appropriate data security measures are in place.

Data sharing: Clinical trials may also share media capture and review data with third parties, such as sponsors, regulatory bodies, and health care providers. It is important for clinical trials to ensure that the data is only shared with parties who have a legitimate business or scientific reason to access the data, and that appropriate data security measures are in place. Additionally, participants should be informed of the purposes for which the data will be shared.

Technical Difficulties of Media Capture and Review in Clinical Trials

The use of media capture and review in clinical trials can present a number of technical difficulties that can interfere with the collection of data. These difficulties can include:

Inaccurate data capture: Media capture and review technologies may not accurately capture all the data that is being collected, resulting in incomplete or inaccurate data sets. This can lead to errors in the analysis of the data and can lead to incorrect conclusions being drawn.

Data security: Many media capture and review technologies require users to access data over a network, which can lead to potential security risks. Data can be accessed by unauthorized personnel, which may result in the data being lost, stolen, or tampered with.

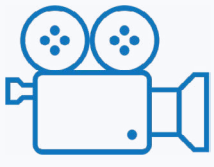
Data storage: Many media capture and review technologies require the use of large amounts of storage space, which can be expensive and difficult to manage. This can lead to delays in the collection and analysis of data, as well as a greater potential for errors.

User error: Media capture and review technologies require users to be trained in the use of the technology, which can be challenging and time consuming. If users are not properly trained, they may make errors in the data collection process, which can lead to incorrect data being collected.

Cost: Media capture and review technologies can be expensive to purchase and maintain, which can be a barrier to their use in clinical trials.

Complexity: Media capture and review technologies can be complex and difficult to use, which can lead to user errors and data security issues.

Time: Media capture and review technologies can be time consuming to use, which can lead to delays in the collection and analysis of data.



Regulatory Considerations

To ensure the ethical and regulatory compliance of media capture and review in clinical trials, it is important to consider the following:

Consent: All participants should be adequately informed of the recording and use of media capture in the clinical trial and provide explicit consent for the capture and review of the media.

Privacy: All participants should be informed of the measures taken to protect the privacy of the data captured and reviewed.

Confidentiality: All participants should be informed of the measures taken to ensure the confidentiality of the data captured and reviewed.

Data Security: All participants should be informed of the measures taken to protect the data from unauthorized access and tampering.

Data Retention: All participants should be informed of the measures taken to ensure the secure storage and disposal of the data captured and reviewed.

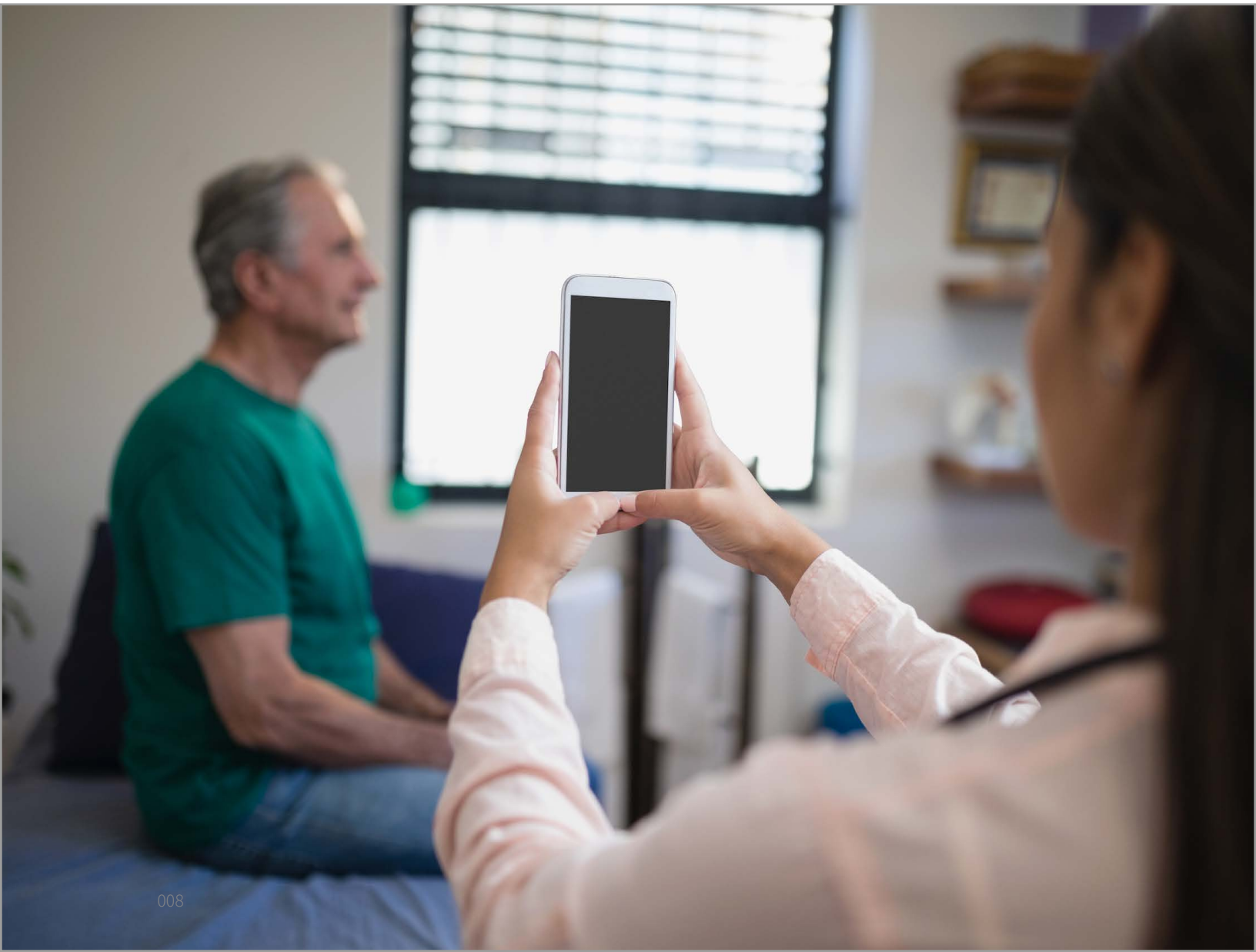
Quality: All participants should be informed of the measures taken to ensure the accuracy, quality, and integrity of the data captured and reviewed.

Transparency: All participants should be informed of the measures taken to ensure the transparency of the data captured and reviewed.

Compliance: All participants should be informed of the measures taken to ensure the compliance with applicable laws and regulations

How Media Capture and Review is Used in Clinical Trials

1. Electronic Data Capture (EDC) – EDC systems provide a secure and automated way to capture and store data from clinical trials.
2. Clinical Trial Protocols – Protocols are detailed documents that describe the research plan, objectives, and design of a clinical trial.
3. Video and Audio – Video and audio recordings can be used to capture patient responses to treatment, as well as the interactions between healthcare providers and patients.
4. Photography – Photographs can be used to document physical changes in a patient over the course of a clinical trial.



Types Of Analysis Used in Media Capture and Review

1. **Image Analysis:** Image analysis is used to identify objects, faces, and other visual elements in images. This is often used to detect brand presence, product placement, and other visual cues in media coverage.
2. **Audio Analysis:** Audio analysis is used to identify and analyze the audio content of media. This is often used to detect spoken language, music, and other audio elements in media coverage.
3. **Video Analysis:** Video analysis is used to identify and analyze the video content of media. This is often used to detect movement, facial expressions, and other visual elements in media coverage.

Best Practices: Data Protection in Media Capture and Review in Clinical Trials

1. Ensure that all data collection and review activities are conducted in accordance with applicable laws, regulations, and guidance.
2. Ensure that all data collection and review activities are carried out by appropriately trained personnel.
3. Establish roles and responsibilities for all personnel involved in data collection and review activities.
4. Establish policies and procedures for data collection and review that incorporate appropriate technical and organizational measures to protect the data from unauthorized access and use.
5. Ensure that all data collected is stored securely and accessed only by authorized personnel.
6. Ensure that all data collected is stored in a secure location and only for the duration of the clinical trial.
7. Monitor and audit data collection and review activities on a regular basis.
8. Ensure that all data is backed up regularly.
9. Ensure that all data collected is encrypted when in transit.
10. Ensure that all data collected is securely destroyed when no longer needed.
11. Provide training to personnel involved in data collection and review activities.
12. Establish a process for responding to security incidents related to data collection and review activities.
13. Establish a process for notifying stakeholders of any security incidents related to data collection and review activities.
14. Establish a process for reporting security incidents related to data collection and review activities to relevant regulatory authorities.
15. Establish a process for reviewing and updating policies and procedures related to data collection and review activities on a regular basis.

Defining Clinical Endpoints Using Virtual Video Clipping, Bookmarking and Concatenation of Streaming Videos

Recent advances in video streaming technology have significantly enhanced the process of review and analysis of videos that are captured during a clinical study.

Technology Overview

HTTP-based streaming techniques refer to the use of the Hypertext Transfer Protocol Secure (HTTPS) for the delivery of streaming media over the Internet. This technique enables the streaming of large media files such as video, audio, and images from a web server to a user‘s device, allowing for near real-time playback. Using this Hypertext Transfer Protocol Secure (HTTPS). The media is broken up into smaller chunks that are sent over the network as small data packets. These chunks are then reassembled at the receiving end and played as a continuous stream. The process starts with the client requesting a media file from the server. The server then responds by sending the requested file in small chunks. As each chunk is received, it is stored in a buffer until it can be played. The advantage of HTTPS-based streaming is that it is compatible with most web browsers and devices. This means that the process of streaming media is relatively easy and can be done without the need for additional software or plugins.

With HTTPS-based streaming, users can play media directly from the server without having to download the file to their device. This technique has enabled the development of video bookmarking and virtual video clipping and concatenation.

Video bookmarking is the ability to save a specific video file or timestamp in a video file to easily access later. This allows users to easily find and return to a specific point in a video, rather than having to search for it. It can also be used in combination with other tools, such as playlists or annotations, to create a more personalized viewing experience.

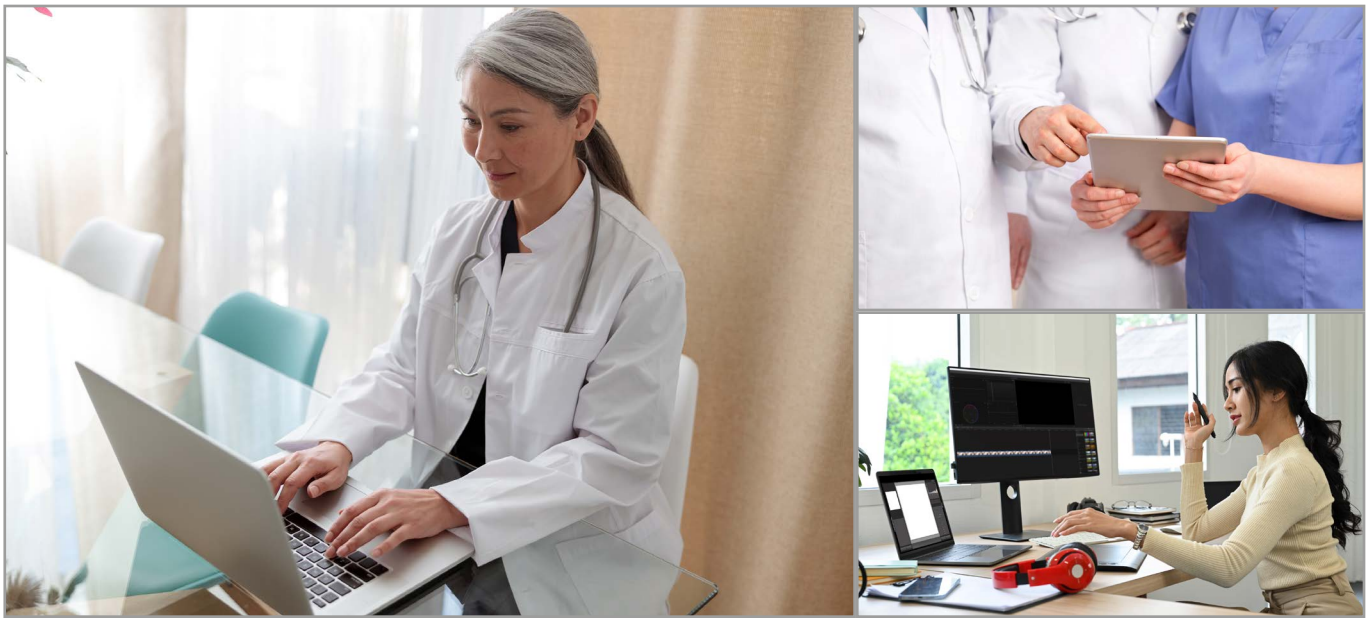
Virtual video clipping and concatenation is the ability to clip and join individual video files into one larger file, creating a single seamless video. This allows users to easily create a compilation of different video files without having to download and edit each individual file. It is also an effective way to store multiple videos in one place, making them easier to find and access. HTTP-based streaming techniques have enabled the development of these tools, making it easier for users to find and access video content. This has increased the popularity of streaming media content, as users can more easily access and share their favorite videos.

How Video Concatenation Works in a Clinical Trial

1. Video concatenation uses computer vision algorithms to stitch together multiple video clips into a single, continuous video sequence. This technology has potential to benefit clinical trials by providing a more efficient way to collect data on patient outcomes, improving the accuracy and precision of clinical trial results.

2. Video concatenation can be used to facilitate remote clinical trial monitoring, providing healthcare professionals with a better view of a patient‘s progress over time. By combining multiple videos into one continuous clip, healthcare professionals can observe changes in a patient‘s condition more quickly and easily. This data can then be used to assess the effectiveness of a particular treatment and inform clinical decisions.

3. Additionally, video concatenation can help improve the accuracy of the data collected during clinical trials. By combining multiple videos, it is easier to spot discrepancies or errors in the data, which can lead to more reliable results. Furthermore, video concatenation can help reduce bias in data collection, as it eliminates potential human errors that can occur when manually collecting data.



Use Cases in Clinical Trials

1. Data Collection: Media capture can also be used to collect and store data from clinical trials, such as images, videos, and audio recordings. This can provide a more comprehensive view of the trial and can be more easily shared and reviewed by sponsors, investigators, and other stakeholders. In addition, this data can be reviewed by 3rd party experts with their evaluations documenting outcomes of defined clinical end points.

2. Adverse Event Reporting: Media capture can help to improve the accuracy and timeliness of adverse event reporting. For example, images and videos of the event in question can be captured, stored, and shared quickly with trial sponsors and investigators.

3. Patient Engagement: Media capture can be used to facilitate patient engagement in clinical trials by allowing for patient-generated videos and other content to be shared with sponsors and investigators. This can help to provide a more comprehensive view of the trial from the patient's perspective.

The Anzubridge® CDMS Solution for Media Capture and Review

The Anzubridge CDMS is HIPAA and 21 CFR compliant and has many features:

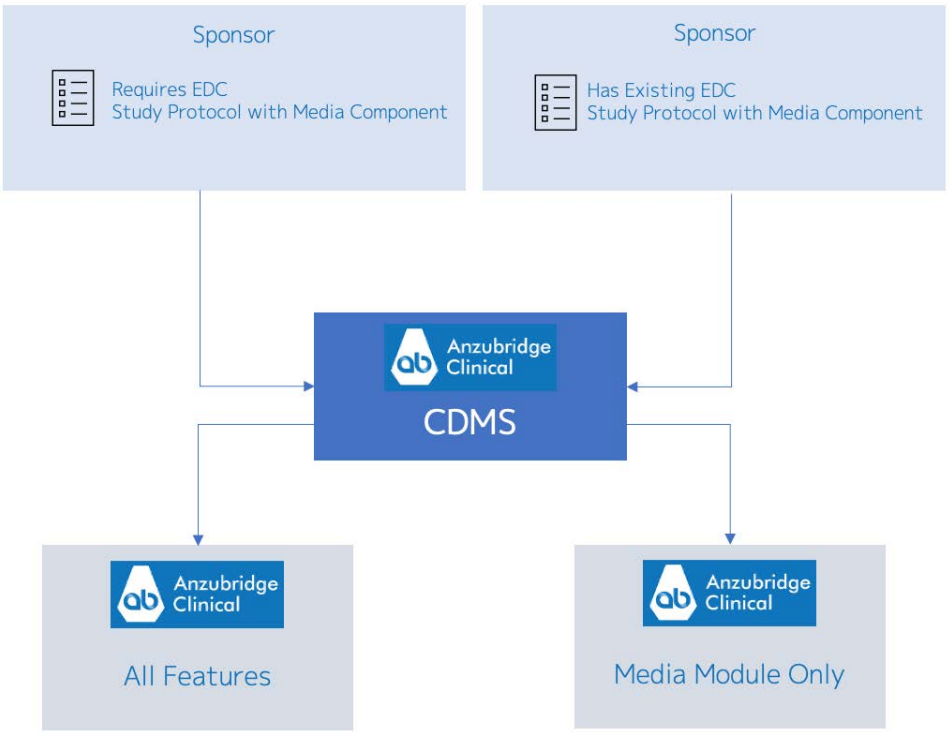
1. Electronic Data Capture
2. Electronic Informed Consent With Knowledge Checks
3. ePRO (Electronic Patient Reported Outcomes)
4. Media Module
   - Media Capture | Upload
   - Media Review
5. Laboratory Information Management System (LIMS) Connectivity
6. Learning Management System (LMS)
7. Integration and Data Exchange With Validated External Data Sources
   - Device Registration Platforms
   - Point of Care Device Analysis Modules

Options for Deployment

The Anzubridge® CDMS provides multiple Deployment Options to Sponsors:

Option 1: The Anzubridge CDMS with all features (including the Media Module)

Option 2: The Anzubridge CDMS with the Media Module only. This deployment is specifically for Sponsors who are using a different EDC, but require all the unique features of the Media Module to execute their study protocol. In this scenario, the CDMS can work as a parallel deployment and collect and review all media related data.



The SETA CDMS

The SETA CDMS is Is the branded version of the Anzubridge CDMS®. This product is licensed by the Aesthetic Surgery Education and Research Foundation (ASERF). The SETA CDMS has the following features:

1. Electronic Data Capture
2. Electronic Informed Consent With Knowledge Checks
3. ePRO (Electronic Patient Reported Outcomes)
4. Media Module
   - Media Capture | Upload
   - Media Review
5. Learning Management System (LMS)
6. Integration and Data Exchange With Validated External Data Sources
   - Device Registration Platform: The Aesthetic One Breast Implant Platform[1].

Specialized Deployment of the SETA CDMS

The SETA CDMS provides multiple Deployment Options to Sponsors:

Option 1: The SETA CDMS with all features:
This option provides a sponsor with a full-featured CDMS for their clinical trial. This system is HIPAA and 21 CFR part 11 compliant. This option includes the patented video bookmarking and concatenation technology[2].

Option 2: The SETA Media CDMS:
This option is for a sponsor who has an existing EDC but wishes to deploy a Media (Capture | Upload | Review) platform based on their study protocol. This unique system can exist in parallel with their existing EDC

Option 3: The SETA CDMS and The Aesthetic One Platform:
This option is specific for Sponsors of studies pertaining to breast implant surgery.
The Aesthetic One platform is a paired physician and patient application (web and mobile) which allows a physician to register breast implant with the manufacturer and generate a separate operative summary of the procedure.
Device information and the operative summary are used to create a Breast Implant ID card which is shared to the physician and the patient.

The Aesthetic One platform has a patient recruiting and information exchange interface with the SETA CDMS:

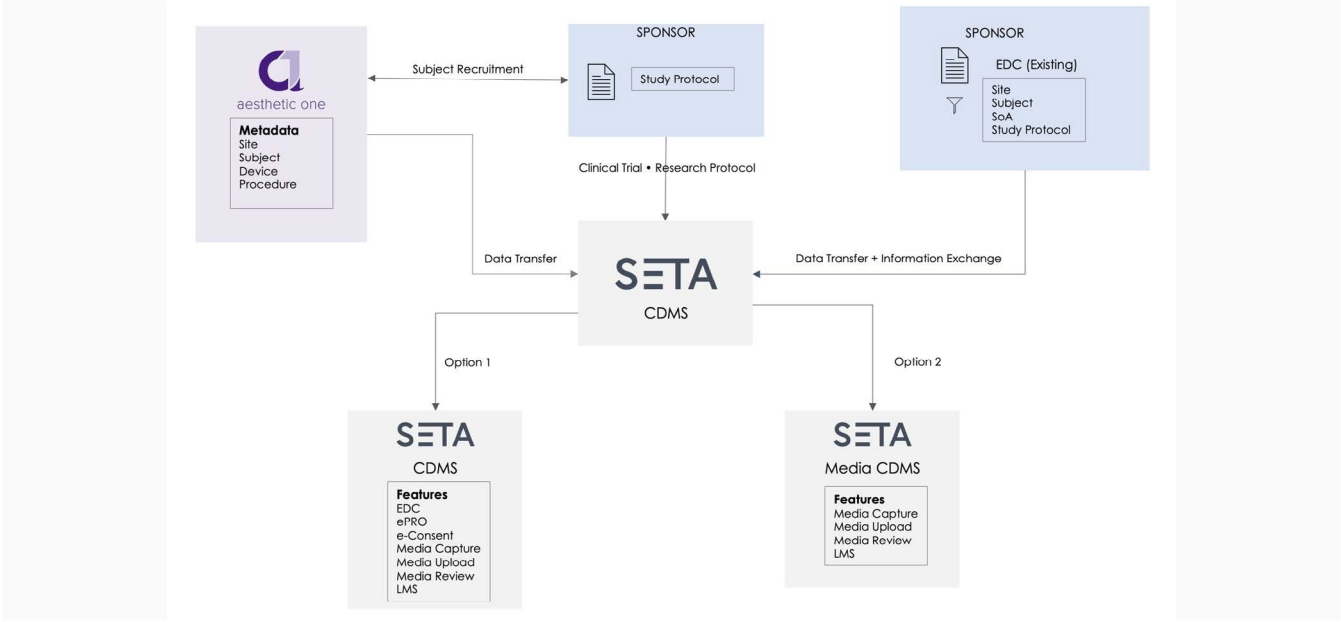
1. Physicians can identify potential patients as candidates for a SETA study
2. The patient is registered on the SETA study
3. A configured study on boarding workflow will be activated
4. Data regarding device information and the operative procedure are securely transmitted after the breast implant procedure is performed.

1 Designed and developed by Anzubridge®. This device registration platform has registered over 30000 breast implants and shared this information with patients.
2 SETA is built on the Anzubridge CDMS Platform and uses patented technology. Art Research and Technology (DBA Anzu®) US Patents: 9451001, 10084840, 10609442, 10681103

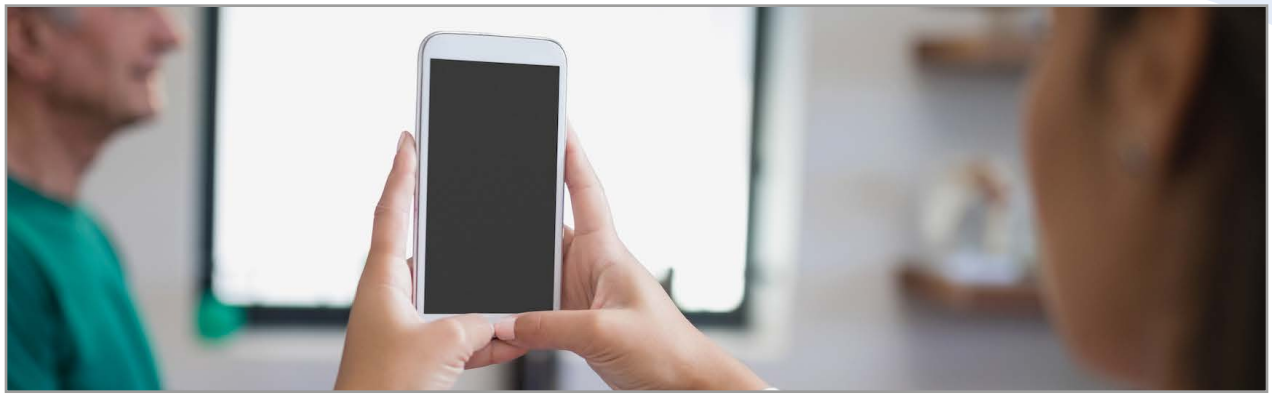
Specialized Deployment of the SETA CDMS

The diagram below demonstrates the flexibility of the SETA CDMS. This system allows a Sponsor to follow several different paths based on their protocol, and their existing capabilities:

1. Conventional deployment allows the Sponsor to access the full suite of products in the SETA CDMS.
2. A Media CDMS only.
3. A study deployment which incorporates an automated patient recruitment and device registration data) and clinical data collection from the Aesthetic One Platform.



Media Capture and Upload in the CDMS



Media Capture in the CDMS

Media Capture in a clinical study can be either:

1. Image Direct Capture (by configured mobile device)
2. Image Upload
3. Video Capture (by configured mobile device)
4. Video Upload
5. Specialized File Uploads (DICOM)

Standardization of Captured Media

To review captured media, standardization parameters must be applied. These are defined in the study protocol, and must apply to Direct Capture, and Media Upload. These parameters can include:

1. Captured Object Parameters (Examples)
    - View
        - » Object in Viewfinder (what part of object is being captured)
            - ◊ Front
            - ◊ Right
            - ◊ Left
            - ◊ Oblique
            - ◊ Lateral
            - ◊ Close-up
            - ◊ Other
    - Lighting
    - Distance to object
2. Capture events as defined in the SoA
    - Direct Media Capture
        - » Image Capture
        - » Video Capture
            - ◊ Media Upload
            - ◊ Image Upload
            - ◊ Video Upload
            - ◊ Specialized Files Upload

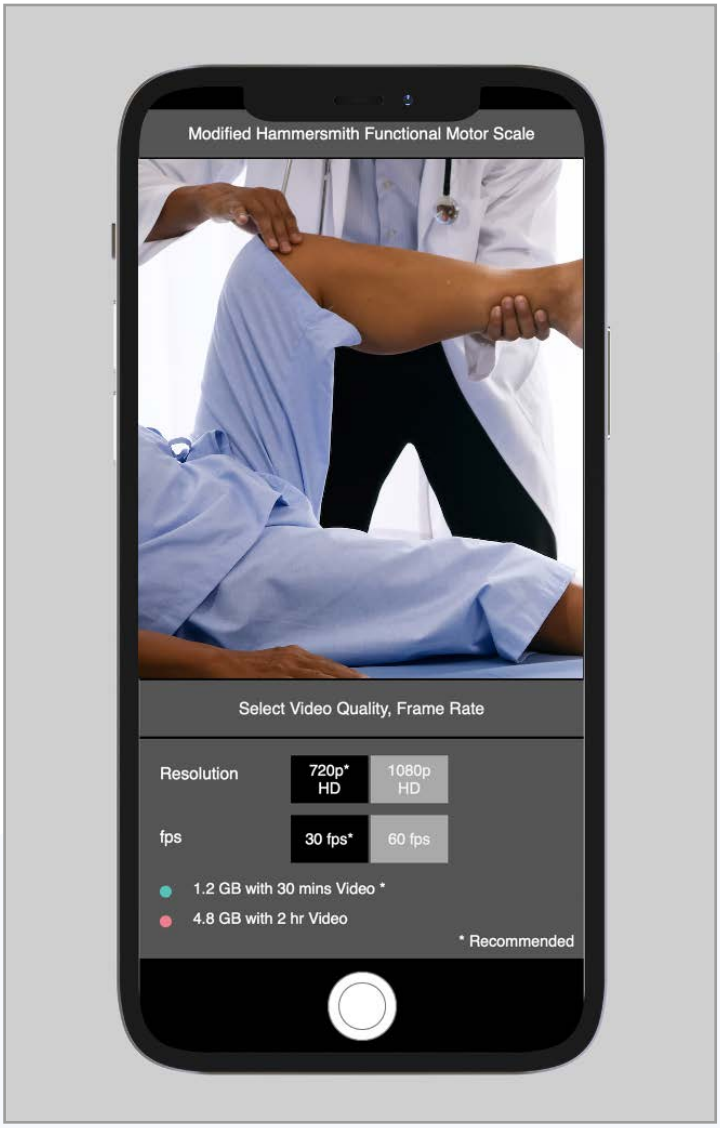
Workflow Optimization in the Media CDMS

The process of media capture has many pre-defined parameters that can present challenges for sites to implement. The CRFs associated with the SoA for Media Capture can define this entire process in an organized fashion:

1. Media Capture Forms (CRFs)can be presented in the SoA based on the protocol with role-based access
2. The forms (CRFs) can be identified as:
    - Image Direct Capture (Mobile device)
    - Image Upload (Web and/or Mobile Device)
    - Video Direct Capture (Mobile device)
    - Video Upload (Web and/or Mobile Device)
    - Specialized Files Upload (DICOM)
3. CRF Design and Configuration
    - A CRF can be designed where all the required captures (Object in Viewfinder) parameters are sequentially identified and captured individually. All meta data associated with the capture will be pre-configured and attached to the media.
    - The forms can be configured to require the user to complete all capture events before saving the form.
    - The forms can be configured with standard data monitoring features:
        - » Data Verification
        - » Data Review
        - » CRF Status
        - » Query Management
            - ◊ Manual Queries
            - ◊ Auto Queries
4. Media Capture Optimization
    - Image Capture
      A mobile device can be configured in the Media CDMS to capture images. This configuration can include:
        - » Image view in viewfinder. A grid can be applied to the camera viewfinder which can allow the user to center the objects
        - » Apply camera settings
            - ◊ Capture object when it is parallel to the capture device
            - ◊ Capture object when it is in focus
            - ◊ Capture object when the lighting is adequate
    - Auto Capture Image if all parameters are optimized noted above are met .

Video Capture

The Media CDMS uses patented technology which is incorporated into the video review and analysis process. Video bookmarking and virtual clipping, allow reviewers to precisely identify data endpoints defined by the protocol. Virtual video concatenation allows the Sponsor or the reviewer to assemble playlists of virtual clips from different subjects with similar data endpoints. These advanced features provide unique insights on the progress of a clinical trial.



Video Capture Features on a Mobile Device

1. Configurable media capture CRF with role-based access.
2. Configurable recording settings[1].
3. Multiple simultaneous video file uploads allowing the user to continue recording different videos required for a specific video.
4. Encrypted, high speed upload with packet validation.
5. The upload process is restarted if data transmission is interrupted with no packet loss.
6. No media stored on native device.

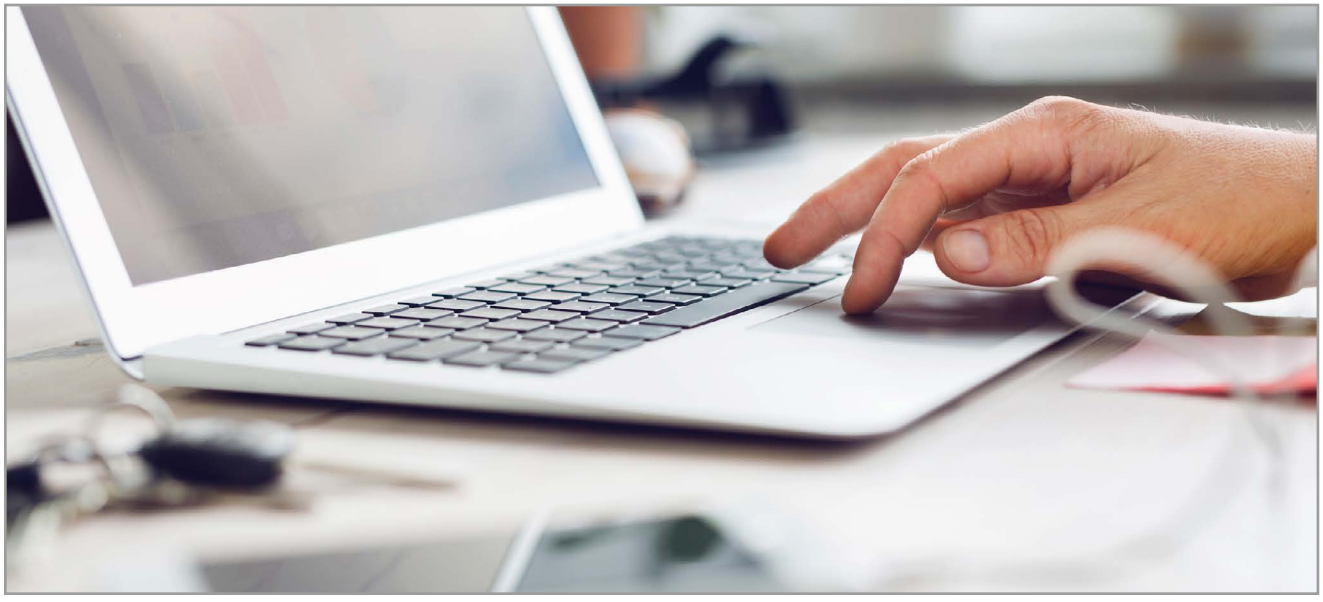
1 The System can configure the optimal video capture settings (resolution + fps) based on study protocol

Media Review in the Anzubridge® CDMS

Features

The Anzubridge® CDMS Media Review Module allows the Sponsor multiple different options and features to validate media in their study:

1. Reviewer role access is configurable
2. Review features are configurable
   - Review only
   - View only
3. Review workflows are configurable
   - Single reviewer
   - Sequential reviewers
   - Parallel reviewers
4. Visuals on the review screen are configurable
   - Single visual
   - Multiple visuals
5. Screen Review Combinations are configurable
   - Photo + Video
   - Photo + Photo
   - Video + Video
   - DICOM + DICOM
   - DICOM + Video
   - DICOM + Photo
6. Specialized video features for reviewers
   - Video clipping
   - Video bookmarking
   - Video concatenation



Content Integration Into the Media Review Module

This high-level overview shows the conceptual workflow of various types of media integration into the CDMS. A variety of different sources can be utilized as noted above .

Once the media is processed multi-reviewer analysis workflow can be configured. The final configuration involves creation of viewer screens customized to a Sponsor's requirements.

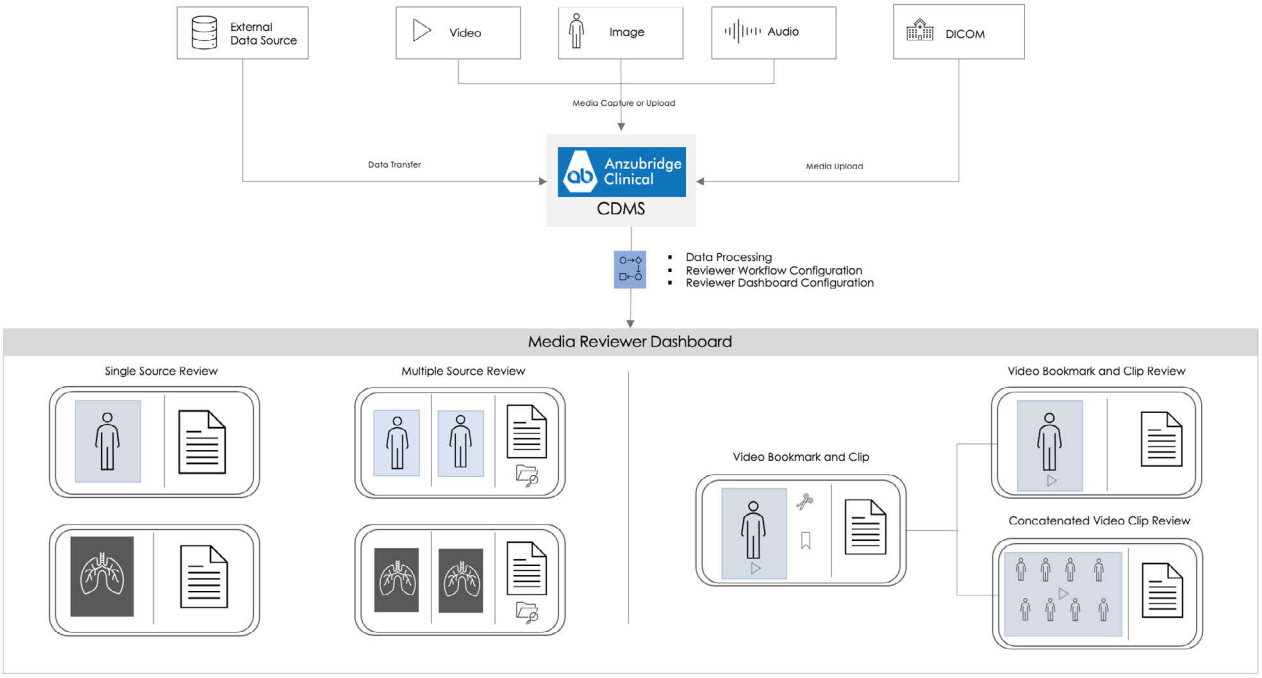
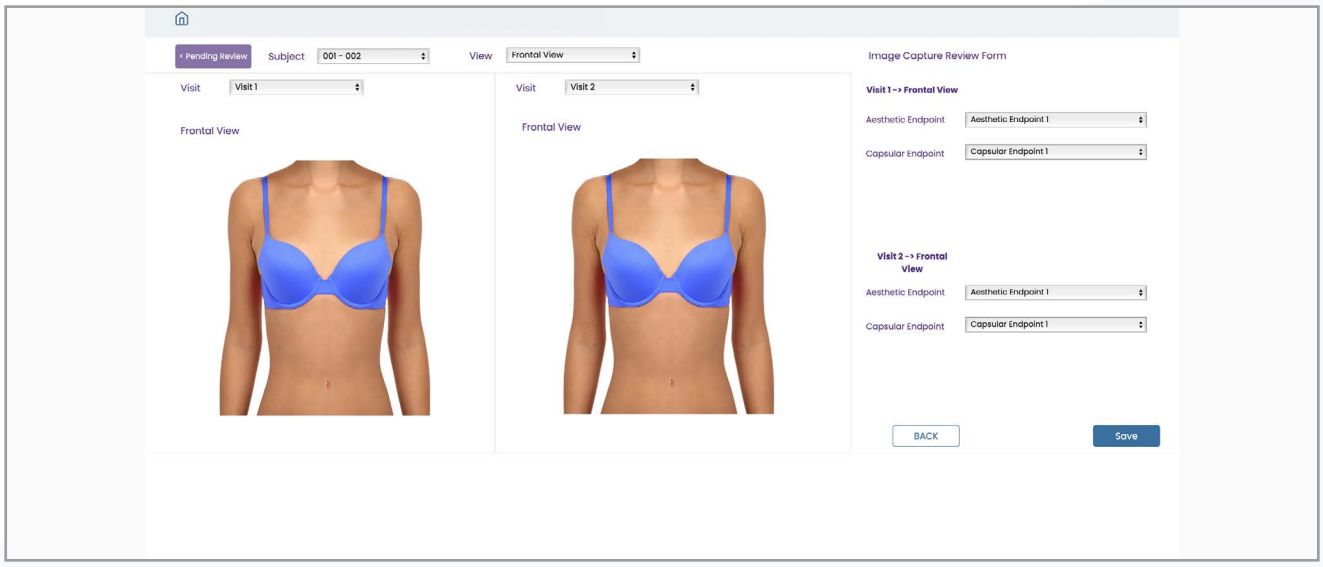


Image Review | Side by Side Different Visit

This is an example a reviewer screen with a dual image view . Configuration of the reviewer screen in the CDMS is flexible and based on protocol requirements. In this example the review screen has 2 image sections for a given subject in the study. The reviewer can perform the following functions:

- Filter both image reviews by subject
- Filter both image views by view (ex. frontal view, lateral view)
- Filter each image by visit. This feature allows side by side comparison of any image from any visit.
- On the right side is the CRF with the defined endpoints. This CRF view will vary depending on which combination of visits are evaluated.

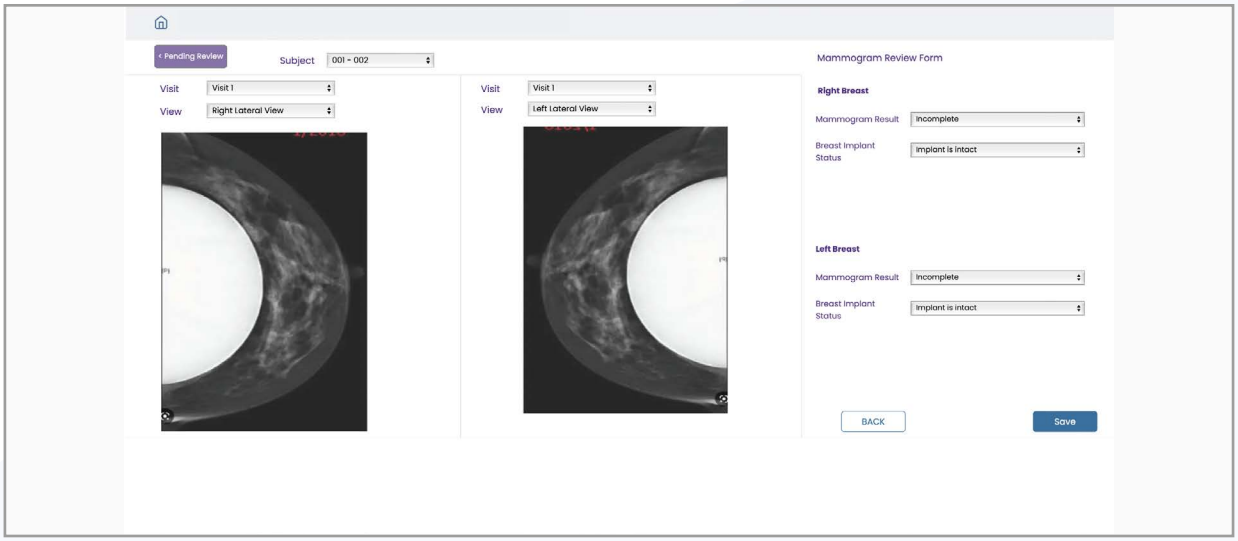


Radiologic Image Review

This is an example of dual image review for a radiologic image (mammogram) that has been uploaded into CDMS. In this scenario, different views of an image from the same visit are being evaluated by the reviewer. The reviewing screen can accommodate single image views depending on protocol requirements of the study.

The review form is designed in the Study Design Portal of the CDMS and can be configured to in the data review process. Queries can also be raised and answered between the reviewers (for a specific form) and the clinical operations team.

The image review screens can accommodate a DICOM viewer.
The DICOM viewer will have additional analysis tools that can be configured depending on the radiologic test being evaluated.

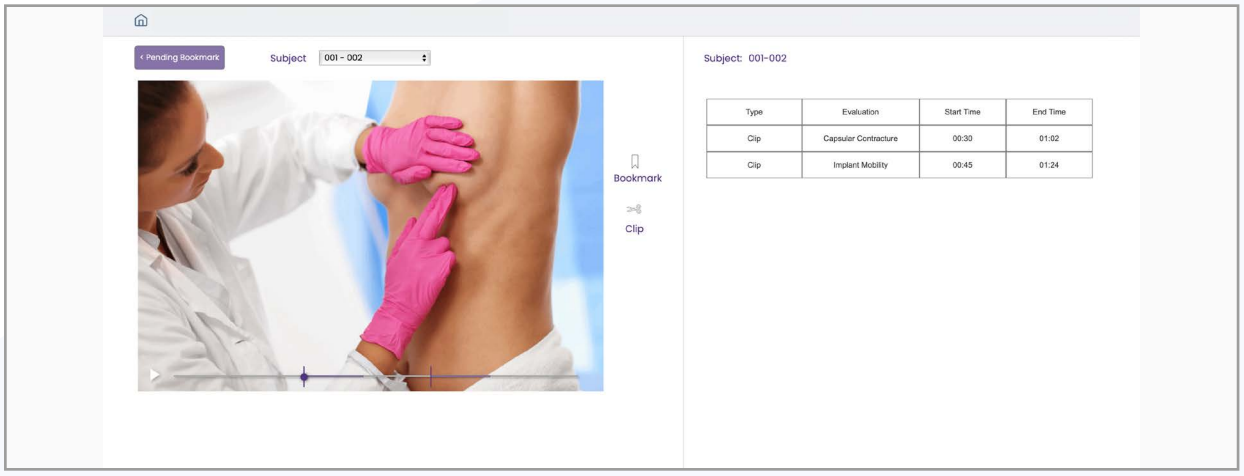


Video Clip | Bookmark

This example demonstrates one of the patented features of the CDMS system . In this example, a role-based user has access to the virtual clipping and bookmarking features of the system. After a video is captured by the site, the user can clip or bookmark the video securely streaming from the CDMS server.

The event that is clipped or bookmarked is defined in the protocol as a clinical endpoint. When performing either function, the user will attach a pre-defined endpoint to the clip or bookmark. This will generate the table on the right side which defines the attached end points and the appropriate time stamp. The system allows fine-tuning (editing) of the timepoints.

Once this process is completed, the video with its endpoints will be submitted to the media reviewers for evaluation. When the reviewer clicks on a designated clip, the video will play at that time point. The clipping and bookmarking are attached the primary video. The reviewer can view the video segment in toto if desired.

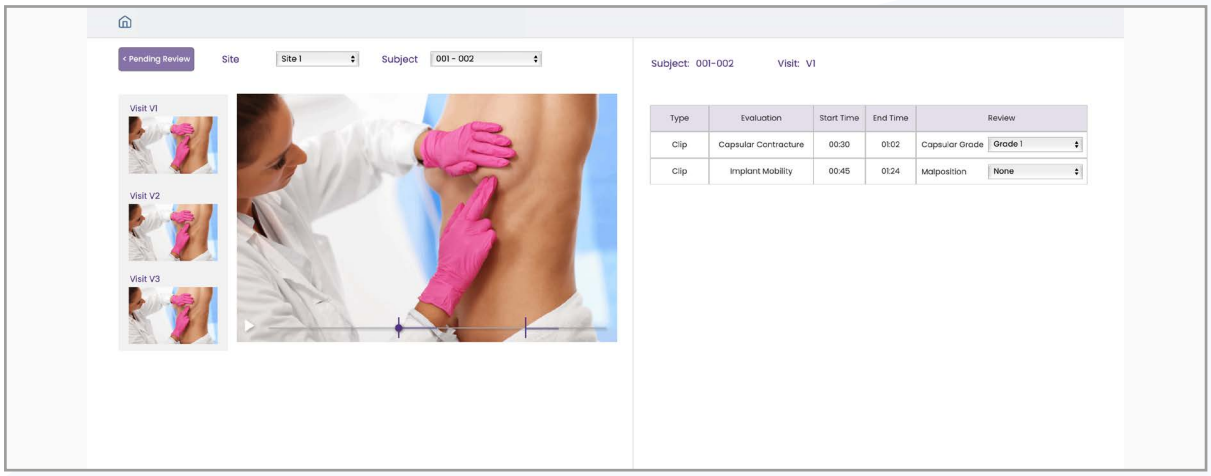


Video Review

This an example of the Video Reviewer screen in the CDMS. In this example, the video has been previously clipped and/or bookmarked to clinical data endpoints defined in the protocol and submitted to the designated video reviewer.

The reviewer can view clip which is attached to a defined endpoint and assess the outcome. This unique capability streamlines the review process by immediately taking the reviewer to a defined endpoint in a video. As noted previously, the reviewer can also review the video in toto.

This process can be subject to data review and query management as previously described if required in the study protocol.

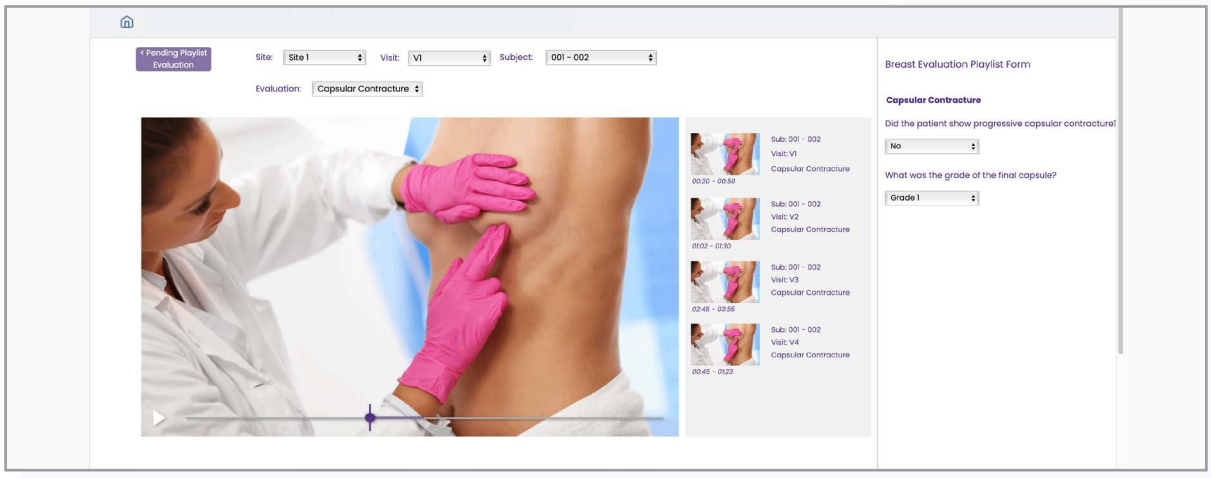


Video Playlist Review

Throughout the course of a study, or at the completion of a study, the reviewers may be required to review the progress of the clinical endpoint evaluations and generate a final or “global” assessment. This requires the reviewer to generate a “playlist” of video clips which can be evaluated between different visits.

This unique interface[1] , allows the user (in this example) to review a playlist of concurrent clips for a clinical endpoint spanning multiple visits, and generate a global assessment.

1 This process of assembling concurrent virtual clips into a single playlist is called video concatenation. This feature has been patented as noted previously.



Training in the Anzubridge® CDMS

Overview

Training of the site, clinical operations, and reviewer personnel on the use of the software and the study requirements can be challenging to the Sponsor. This is especially true when dealing with media.

The Anzubridge ® Learning Management (LMS) facilitates this process with integration into the SETA CDMS. It provides the following capabilities:

1. Reference and Training Library for the SETA CDMS
    - Document Library
    - Role-based training manuals
    - Multi-media (video/audio/image)
    - Video bookmarking
    - Role-based Learning Plans
    - Targeted Search using patented tagging technology
    - User Analytics

2. Study Specific Reference and Training Library
    - Administrative Portal
        - » Manage users
        - » Create study-specific folder hierarchy
        - » Upload content
            - ◊ Documents (PDF/PPT/Word)
                - ▪ Create Table of Contents
                - ▪ Tag articles for search
        - » Upload multi-media (video/audio/image)
            - ◊ Video bookmarking and tagging
    - Study-Specific Document Library
        - » Role-based and study-based training manuals
        - » Multi-media (video/audio/image)
        - » Video bookmarking
        - » Role-based and study-based Learning Plans
        - » Targeted Search using patented tagging technology
        - » User Analytics

Final Thoughts

- The use of media capture in clinical trials will continue to increase as the technology becomes more accessible and cost effective. Additionally, advancements in artificial intelligence and machine learning will help automate the review process, allowing for a more efficient way of collecting and analyzing data. This technology can also be used to identify patterns in patient behavior and outcomes, which can be used to inform treatment decisions.

- Furthermore, the use of media capture and review in clinical trials will help to bring greater transparency to the drug and device development process. Patients and clinicians will be able to access and review data more easily, leading to improved outcomes and more informed decisions.

- Clinical trials will likely become more streamlined and efficient due to the use of media capture and review. The combination of these technologies will help to reduce the time and cost of clinical trials, making them more accessible to a wider range of patients. Additionally, the use of media capture and review will help to ensure data accuracy and integrity, making clinical trial outcomes more reliable.

- The technology has the potential to revolutionize the drug and device development processes and will continue to be a valuable tool for clinical trial researchers and clinicians.

Testimonials

Working With the Anzubridge® Team

Peter Bryant-Greenwood MD, MBA FACHE.

President, CEO Healix Clinical Laboratories

Anzu are valued clinical trial partners. Healix Clinical Laboratories is committed to novel diagnostics and devices that support the care and treatment of neurology patients, including Traumatic Brain Injury. Anzu's proprietary video capture technology is critical for demonstrating device compliance as well as neurologic and cognitive improvement on standardized neurological assessments. Working together, Anzu has created unique digital solutions for the device-patient interface, as well as supporting IT infrastructure for clinical trial management, including data analytics and biobanking. The Anzu team is highly intelligent, integrated, and collaborative to work with. Anzu has the fastest turn-around-time in the business and has a firm understanding of the strategic and business implications of software development and integration. Thank you, Barry and Ted! You guys are amazing!

Kelly W. Elliott, RN MS

Founder, President and CEO

Eminence Clinical Research, Inc.

Eminence Clinical Research, Inc. has worked with many clinical data management system (CDMS) technologies. The Anzubridge CDMS system is THE MOST comprehensive system that our company has ever experienced. With all of the unique features and benefits, when study sponsors look to Eminence for selecting a robust CDMS for their trials, we recommend Anzu! In addition to this cutting edge technology that streamlines the data collection process, we select Anzu because the senior executives down to the technologists understand the needs of the sponsor to optimize each study-specific platform, they know that time is money thus minimizing response time, and make every effort to build and maintain a cohesive team between Anzu and Eminence Clinical Research, Inc. Anzubridge is our go-to technology and Anzu is our go-to CDMS team.

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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