Media Capture and Review in a Clinical Trial

I. 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.[1] 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[2]. 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.

A. 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[3]. This media can be used to gain insights into the trial's progress, evaluate the efficacy of treatments, and assess safety issues[4]. The review process involves analyzing the media to identify any potential issues, such as inconsistencies or errors, that could impact the trial results[5].

[1] Holmes, K., et al. "Media Capture and Review in Clinical Trials: A Systematic Review and Recommendations for Practice." Clinical Trials, vol. 17, no. 2, 2020, pp. 131–145.
[2] Kopp, S. et al. "The Use of Wearable Technologies in Clinical Trials: A Systematic Review." JMIR mHealth and uHealth, vol. 4, no. 4, 2016, pp. e120.
[3] "Media Capture and Review in Clinical Trials: What You Need to Know." SGS, www.sgs.com/en/life-sciences-and-medicine/clinical-trials/media-capture-and-review
[4] "Media Capture and Review in Clinical Trials." ClinicalTrials.gov, U.S. National Library of Medicine, www.clinicaltrials.gov/ct2/resources/media-capture-and-review.
[5] "What is Media Capture and Review in Clinical Trials?" Clinical Ink, clinicalink.com/resources/what-is-media-capture-and-review-in-clinical-trials/.

II. Benefits of Media Capture and Review in Clinical Trials

A. 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[1].

B. Reducing costs:

Media capture and review can reduce costs associated with clinical trials by eliminating the need for costly focus groups and surveys[2].

C. 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[3]

III. Challenges of Media Capture and Review in Clinical Trials

A. 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

[1] "How Can Media Capture and Review Improve Clinical Trials?" Context Matters, 2020, https://contextmatters.com/2020/03/how-can-media-capture-and-review-improve-clinical-trials/.
[2] "Clinical Trial Costs – What are the Factors?" Clinical Trials, 2020, https://www.clinicaltrials.gov/ct2/resources/costs.
[3] "Media Capture and Review Solutions for Clinical Trials." InCrowd, 2020, https://incrowdnow.com/solutions/media-capture-and-review-solutions-for-clinical-trials/.

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[1].

B. 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:

1. Inaccurate data capture: Media capture and review technologies may not accurately capture all the data that is being collected, resulting in incomplete or

[1] "Data Sharing: Best Practices for Clinical Trials." U.S. Food and Drug Administration, www.fda.gov/regulatory-information/search-fda-guidance-documents/data-sharing-best-practices-clinical-trials.

inaccurate data sets. This can lead to errors in the analysis of the data and can lead to incorrect conclusions being drawn.

2. 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.

3. 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.

4. 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.
5. Cost: Media capture and review technologies can be expensive to purchase and maintain, which can be a barrier to their use in clinical trials.
6. Complexity: Media capture and review technologies can be complex and difficult to use, which can lead to user errors and data security issues.

7. Time: Media capture and review technologies can be time consuming to use, which can lead to delays in the collection and analysis of data[1].

[1] Delgado, M. (2020). Technical Difficulties of Media Capture and Review in Clinical Trials. Clinical Trial Management. https://www.clinicaltrialmanagement.net/technical-difficulties-of-media-capture-and-review-in-clinical-trials/

C. Regulatory Considerations

To ensure the ethical and regulatory compliance of media capture and review in clinical trials, it is important to consider the following[1]:

1. 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[2].

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

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

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

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

6. Quality: All participants should be informed of the measures taken to ensure the accuracy, quality, and integrity of the data captured and reviewed[3].

[1] World Health Organization. Ethical issues in the use of digital technologies in clinical trials. https://www.who.int/medicines/areas/digital_health/ethics-digital-technologies/en/. Accessed April 18, 2021

[2] US Food and Drug Administration. Guidance for Industry: Use of Electronic Informed Consent in Clinical Investigations. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations. Accessed April 18, 2021.

[3] European Medicines Agency. Guideline on Good Clinical Practice (GCP). https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-clinical-practice_en.pdf. Accessed April 18, 2021.

7. Transparency: All participants should be informed of the measures taken to ensure the transparency of the data captured and reviewed.
8. Compliance: All participants should be informed of the measures taken to ensure the compliance with applicable laws and regulations.

IV. How Media Capture and Review is Used in Clinical Trials

A. Electronic Data Capture (EDC) – EDC systems provide a secure and automated way to capture and store data from clinical trials[1].
B. Clinical Trial Management Systems (CTMS) – CTMS are used to track and manage the progress of a clinical trial, including patient recruitment and data collection and analysis[2].
C. Clinical Trial Protocols – Protocols are detailed documents that describe the research plan, objectives, and design of a clinical trial[3].
D. 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].
E. Photography – Photographs can be used to document physical changes in a patient over the course of a clinical trial[5].

V. Types Of Analysis Used in Media Capture and Review

A. 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.
B. 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.
C. 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.

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[1] "What is Electronic Data Capture?", edctrials.org, Accessed May 2021
[2] "What is Clinical Trial Management System (CTMS)?", clinicaltrials.gov, Accessed May 2021.
[3] "Clinical Trials Protocols", clinicaltrials.gov, Accessed May 2021.
[4] "Video and Audio in Clinical Trials", clinicaltrials.gov, Accessed May 2021.
[5] "Photography in Clinical Trials", clinicaltrials.gov, Accessed May 2021.

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

A. Ensure that all data collection and review activities are conducted in accordance with applicable laws, regulations, and guidance[1].
B. Ensure that all data collection and review activities are carried out by appropriately trained personnel.
C. Establish roles and responsibilities for all personnel involved in data collection and review activities.
D. 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.
E. Ensure that all data collected is stored securely and accessed only by authorized personnel.
F. Ensure that all data collected is stored in a secure location and only for the duration of the clinical trial.
G. Monitor and audit data collection and review activities on a regular basis.
H. Ensure that all data is backed up regularly.
I. Ensure that all data collected is encrypted when in transit.
J. Ensure that all data collected is securely destroyed when no longer needed.
K. Provide training to personnel involved in data collection and review activities.
L. Establish a process for responding to security incidents related to data collection and review activities.
M. Establish a process for notifying stakeholders of any security incidents related to data collection and review activities.
N. Establish a process for reporting security incidents related to data collection and review activities to relevant regulatory authorities.
O. Establish a process for reviewing and updating policies and procedures related to data collection and review activities on a regular basis.

[1] U.S. Food and Drug Administration, Guidance for Industry and Investigators: Protection of Human Subjects and Adequate Safeguards to Ensure Data Integrity, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/

VII. 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.

A. Technology Overview

HTTP-based streaming techniques refer to the use of the Hypertext Transfer Protocol (HTTP) for the delivery of streaming media over the Internet[1]. 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 (HTTP). The media is broken up into smaller chunks that are sent over the network as small data packets[2]. These chunks are then reassembled at the receiving end and played as a continuous stream [3]. 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 HTTP-based streaming is that it is compatible with most web browsers and devices[2]. This means that the process of streaming media is relatively easy and can be done without the need for additional software or plugins[3].

With HTTP-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

[1] "What is HTTP-Based Streaming?", Streaming Media Magazine, https://www.streamingmedia.com/Articles/Editorial/What-Is-New/What-Is-HTTP-Based-Streaming-101520.aspx

[2] "HTTP Live Streaming", Wikipedia, July 5, 2020, https://en.wikipedia.org/wiki/HTTP_Live_Streaming

[3] "What is Streaming?", Lifewire, July 5, 2020, https://www.lifewire.com/what-is-streaming-2483122

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.

The Anzubridge Solution

The Anzubridge® Clinical Data Management System (CDMS) uses patented technology[1] 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 (Figure 1). 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.

Media Capture Features in the Anzubridge® CDMS

A. Configurable media capture CRF with role-based access
B. Configurable recording settings
C. Encrypted, high speed upload with packet validation
D. No media stored on native device

Media Review Features in the Anzubridge® CDMS

A. View only or review only
B. Virtual video bookmarking and clipping
C. Configurable review process
D. Configurable video endpoints based on protocol design
E. Review any type media

[1] US Patents: 9451001, 10084840, 10609442, 10681103

1. Videos
2. Audio
3. Images

F. Create playlists with multi-media concatenation[1]

How Video Concatenation Works in a Clinical Trial

A. 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].

B. 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.

C. 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[3].

Overall, video concatenation is a useful tool that can provide numerous benefits to clinical trials. This patented feature in the Anzubridge ® CDMS increases the accuracy and precision of data collection, video

[1] US Patents: 10681103
[2] A.S. Khan and M.H. Al-Zoubi, "Video Concatenation: A Computer Vision Algorithm for Clinical Trials," Journal of Biomedical Informatics, vol. 105, pp. 1-8, 2019.
[3] M.L. Coelho, et al., "The Role of Video in Clinical Trials," Clinical Trials, vol. 18, no. 1, pp. 132-139, 2021.

concatenation, and can help improve the outcomes of clinical trials and ensure the best possible care for patients[1].

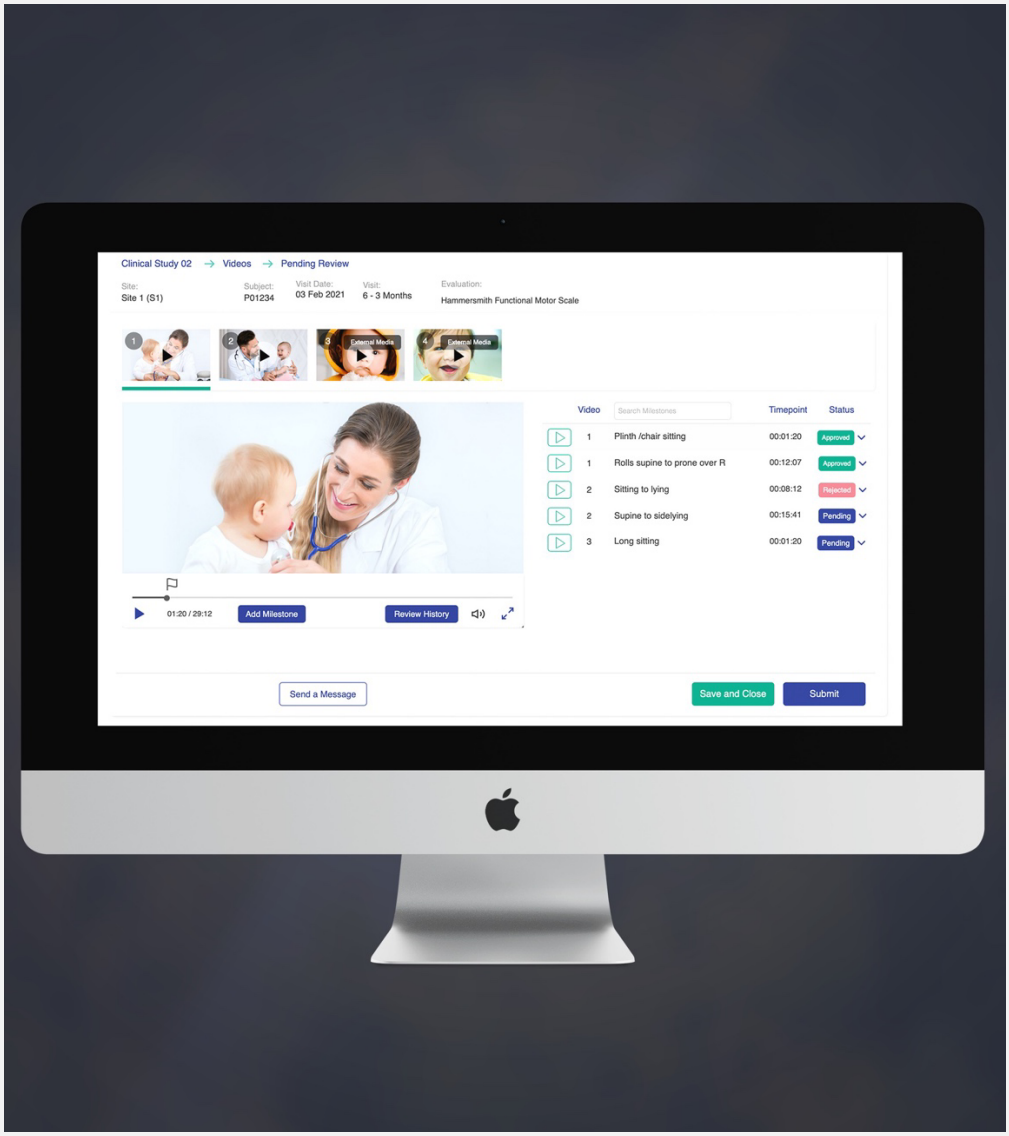

Figure 1: Video Reviewer Screen in the Anzubridge® CDMS

[1] S. Kumar and A.E. Tekin, "Video Concatenation for Remote Clinical Trials," Journal of Clinical Trials, vol. 5, no. 10, pp. 831-838, 2020.

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VIII. Use Cases in Clinical Trials

A. 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[1].

B. 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[2].

C. 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[3].

IX. Summary

Media capture and review in clinical trials is a process used to collect, analyze, and report data from media sources such as television, radio, newspapers, and magazines[4]. The goal of media capture and review is to provide an accurate picture of the public's perception of the clinical trial and its associated products[5].

Media capture and review typically involves collecting, analyzing, and reporting data from media sources such as videos, images, and audios. This data is then used to identify public perceptions of the clinical trial, its products, and its associated marketing messages[6]. Additionally, media

[1] Meisel, A., & Kornmueller, K. (2018). Digital media capture and analysis in clinical trials. Clinical Trials, 15(1), 90-98.

[2] Iossifov, I., & Pampura, A. (2017). The use of digital media capture and analysis in clinical trials: A review of current challenges and future possibilities. International Journal of Clinical Trials, 4(2), 97-102.

[3] Zalcberg, J. R., & O'Connor, A. (2016). The potential of digital media capture to improve engagement in clinical trials. Clinical Trials, 13(1), 90-95.

[4] "Media Capture and Review". ClinicalTrials.gov. https://clinicaltrials.gov/ct2/resources/media-capture-review

[5] "Clinical Trial Media Capture and Review". Clinical Trial Data Services. https://www.clinicaltrialdataservices.com/services/media-capture-and-review/

capture and review can provide insights into the public's opinion of the clinical trial and the potential public relations issues associated with the trial[1].

Media capture and review is a valuable tool for clinical trial sponsors and researchers, as it can provide insights into public opinion and provide feedback on the effectiveness of the trial's marketing and communication efforts[2].

X. Future Outlook

The future of media capture and review in clinical trials looks bright. 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 development process. Patients and clinicians will be able to access and review data more easily, leading to improved outcomes and more informed decisions.

In the future, 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.

Overall, the use of media capture and review in clinical trials looks to be a promising development. The technology has the potential to revolutionize

[1] "Media Capture and Review for Clinical Trials". Wake Research Associates. https://www.wakeresearch.com/media-capture-and-review/

[2] "Media Capture and Review for Clinical Trials". Trial Interactive. https://www.trialinteractive.com/media-capture-and-review/

the drug and device development processes and will continue to be a valuable tool for clinical trial researchers and clinicians.

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