

INNOVATIVE VOICE AND VIDEO SOLUTION CAPTURES PATIENT- CLINICIAN INTERACTIONS AND CLINICAL DATA TO IMPROVE CLINICAL TRIALS

Leading clinical management solution provider group taps Court Square to provide a 21 CFR Part 11 voice and video solution for rating patient-clinician interactions, using off-the-shelf tools.



Executive Summary

A company focused on reducing risk and increasing effectiveness of clinical trial practices sought a solution for remote patient-clinician interaction rating. Court Square Group delivered a solution using off-the-shelf voice and video applications that were enhanced to provide robust and compliant FDA 21 CFR Part 11 specific features to ensure regulatory requirements were met.

The client is a new pharmaceutical start-up division of a large medical device manufacturer that was tasked with producing the first pharmaceutical products for the company. The client had a drug candidate that they intended to bring to market within the year.

About the Client

Established in 2006 the company provides expert consulting services across a variety of disciplines to pharmaceutical companies and Contract Research Organizations (CRO) to reduce risks, improve quality and increase efficiency in clinical trials. The company has completed hundreds of projects that ensure successful clinical trials for bringing new pain treatments to market.

The Challenge

The client's risk mitigation services were given the challenge by a CRO to develop an innovative process to support remote clinical sites in the rating of interactions between patients and clinicians for central nervous system (CNS) studies. After reviewing a method that Court Square Group used with another client to capture patient-clinician interactions, they realized that they could expand the CRO's capabilities and further minimize risk. The client initially built the solution on a commercial off-the-shelf conferencing product.

Their original idea for three-way conferencing (patient, clinician, and reviewer) encountered numerous obstacles related to scheduling and resource allocation. Each study required the review and rating of hundreds of hours of patient and clinician interactions. The client decided the best way to improve efficiency was to record the interactions for review at a time of the rater's choosing. The challenge was that most commercial off-the-shelf products are not built to meet the FDA's regulatory requirements. Additionally, they did not take into consideration that the recordings would be stored in a public cloud environment. This raised a regulatory flag because public cloud storage does not meet the security, or the audit trails required by the FDA.



The company decided that it would enhance their trial capabilities to have the recordings available for their reviewers. This would help establish if there was any bias between the clinicians and patients and this would help identify other issues that could affect the measure of risk in the trial.

Court Square Group was asked to provide an FDA compliant solution that included flexible scheduling and ensured ease of use for patients, clinicians, and remote raters.

The Solution

Court Square Group was able to utilize an off-the-shelf solution for both voice and video conferencing by putting a 21 CFR Part 11 wrapper around the data. The data was pulled from the public cloud environment where it was initially stored and imported into RegDocs365 and Court Square Group's Audit Ready Compliant Cloud™ (ARCC) environment. The accelerated rating functionality pulls the data into the RegDocs365 environment where an alert is created to notify the rater that a new patient-clinician interaction had been recorded and uploaded. The reviewers were able to go into the system, listen to the recording at their convenience, and provide a rating score with an option to add additional information about the encounter

By using RegDocs365 in the Audit Ready Compliant Cloud™ (ARCC) the client was able to utilize all the data and the additional information for their clinical trial.

The Results

The clinical trial utilized RegDocs365 and Court Square Group's Audit Ready Compliant Cloud™ (ARCC) environment to review thousands of patient/clinician interactions and data over a multi-year study. The result was the approval of the client's drug application. The data was audited by the FDA who found that it met all the security safeguards and the necessary audit trail requirements in compliance with 21 CFR Part 11.

Call to Action

If you are looking to use off-the-shelf products for clinical purposes, Court Square Group can help you ensure those tools and the data created with them comply with all FDA requirements. Our innovative RegDocs365 platform, housed within our Audit Ready Compliant Cloud™ (ARCC), can put a 21 CFR Part 11 wrapper around your data by using our proprietary techniques to interface with off-the-shelf products and store your information in compliance with regulatory requirements.



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