

# Clinical Ops Teams: Are Video-Recorded Assessments Your Next Big Challenge?

## Breathe Easier with the Red Nucleus ITC Platform



Your medical teams are asking you to record videos of clinical trial assessments. You're pushing back, because you know managing privacy associated with video recordings is going to be a nightmare! Designing and running clinical trials has given your team enough work to do—you don't need to add worrying about GDPR or HIPAA compliance issues to their already-full plates.

*Does this sound like you?*

What if you didn't need to worry? What if you could record video assessments securely and compliantly? What if the results of those recordings were assessment scores that were more reliable and clinically valid?

Traditionally, the process for recording assessments of any kind has presented multiple compliance challenges. But managing privacy associated with video assessments in a decentralized trial doesn't need to be a nightmare. The secure, compliant, all-in-one iTakeControl (ITC) platform developed by Red Nucleus (RN) removes the compliance headache—and makes recording video assessments easier than ever.



## Recording video assessments has historically proved challenging

As many organizations are moving to decentralized trial models, clinical trial sponsors have needed to grapple with an important operational question: is the value of video assessments worth the issues recording them may present?

At many organizations, clinical ops teams have initially answered “no.” In their perspective, the benefits of video assessments—e.g., ease of use for the clinical trial participant, more convenient review for clinician raters, and greater granularity of data findings—do not outweigh the privacy and security costs they present. Here's why.

### Security and Privacy Issues

Historically, recording video assessments has been a fragmented process that uses multiple platforms—each of which has different security parameters.

For example, a single video assessment might be recorded on one device, such as an iPhone. That video might then be uploaded to a reviewing clinician's desktop computer, then emailed or transferred using the clinician's organization's system. For another rater to review the video, that rater must download the video onto a completely separate system.

Throughout that process, the video contains no associated metadata for the particular patient. Moreover, patients remain identifiable as these videos move across systems and channels. No audit trail exists that tracks where that data is moving; thus, recording, transmitting, and reviewing video assessments present multiple opportunities for security breaches that could expose patient information or the integrity of the data collected.

Clinical trial sponsors are already vulnerable to cybersecurity issues, as the amount of valuable patient healthcare information (PHI)—i.e., personal and healthcare-related data—the study investigators must collect proves attractive to cybercriminals.

Video data can contain patient-identifying information in both audio and visual components. Each time a raw video assessment file moves across systems and WiFi networks, it offers a new opportunity for privacy violations.

This is troubling for trial participants, but it's also incredibly challenging for global health authorities and international review boards—and can be costly for trial sponsors. HIPAA violations, for example, can cost trial sponsors thousands of dollars.

## Quality Issues

The privacy and security challenges presented by video assessments could potentially be offset when these assessments provide objectively superior quality.

Recording video assessments allows raters to keep accurate notes concurrent with their review, then ensure those notes correspond to the correct video. This also allows for an independent review of both scoring and administration of the assessment to provide greater inter-rater reliability. Without a central platform that easily maintains all relevant data for each video assessment, human error can occur.

## Solve These Challenges With ITC

Given the multiple challenges they've faced when recording video assessments, it's no wonder that many clinical ops teams are reluctant to employ video as an integral part of their decentralized trial strategies. Many of these historical obstacles, however, can be mitigated or removed when using a secure central platform like ITC. The ITC platform ensures security, enhances privacy, and offers a new world of quality and reliability in clinical trial assessments.

## Secure Platform

ITC solves a major challenge of decentralized trial video assessments by providing a secure, all-in-one platform where videos are uploaded and reviewed. The platform—which is GCP, HIPAA, and GDPR compliant—removes the audit trail issues that plague traditional forms of recording and reviewing video assessments. When using ITC, videos remain in the platform throughout the duration of the trial and never need to be transferred elsewhere. By eliminating video movement across networks, the ITC platform significantly reduces risk.

## Premium Privacy

RN's ITC platform is infused with tools that ensure the highest levels of privacy for trial participants. The platform offers the ability to automatically de-identify patients with facial blurring technology, and reviewers have the opportunity to manually blur any identifiable information that has not been automatically removed. Moreover, the ITC platform retains the metadata for each video, so trial sponsors have a clear record of each patient's trial journey.

## Enhanced Quality

The ITC platform not only makes video assessments a more secure and compliant endeavor—it also enhances quality of the data captured in the clinical trial.



**It's Time to Say  
"iTakeControl of  
My Studies"**

With ITC, sponsors need not worry about raters inputting confounding data. By using the platform, raters can easily and securely add and update their scores, which can be automatically transferred to an EDC system through a secure API. Moreover, by automatically de-identifying patients, ITC removes bias from the rating system. Raters can review the data purely against the scorecard while remaining blind to the patient's identification, time point, and other data. Removing this type of bias is simply not possible with other types of assessments.

Without the security and privacy issues that have historically plagued video assessments, trial sponsors can consider a new range of possibilities when it comes to the data they collect. By recording videos, trial sponsors have access to a higher level of granularity, repeatability, and accuracy in their review. With a single secure platform, multiple raters can easily review the same video. And if a question ever arises, raters can go back to re-review video assessments and verify their accuracy. This provides a completely new standard for accuracy in the research space.

### **Challenge Accepted: It's Time to Say "iTakeControl of My Studies"**

It's time to assuage the concerns of the entire clinical trial team in leveraging the power of video in decentralized clinical trials. ITC reduces risk, streamlines processes, and ultimately offers greater reliability and validity of assessment scores with an easy-to-use, easy-to-review platform.

Interested in learning more about how you can take advantage of ITC's benefits in your own decentralized trials? Reach out today for a conversation with our solutions team.