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Case Study

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MITIGATING 50% OF DEVIATIONS: MEDEX HEALTHCARE RESEARCH

Medex Healthcare Research uses Clinical Research IO's workflow-based eSource tool to reduce protocol deviations, thus reducing exposure for their Principal Investigators. An auditor's review of the system confirmed that the system has safeguards against 50% of the most common audit findings.

From EDC to CRIO

Medex Healthcare Research, Inc. is a three-site, multi-therapeutic network with facilities in New York, St. Louis and Chicago. It was founded by Dr. James Greenwald, who serves as the network's CEO and the New York site's Principal Investigator.

In 2010, Dr. Greenwald decided to move to electronic source. After a review of market-based solutions, his team settled on a popular electronic data capture (EDC) system used by many sponsors.

Moving to electronic source allowed him to collaborate with, and oversee the work of, his investigators, as well as enhance data integrity and quality. Dr. Greenwald deployed the system on over 100 studies without any resistance from sponsors, or from the FDA, who audited one of the studies it was deployed on.

However, the EDC system was primarily designed as a data repository and was not optimized for real-time, site-based data collection. Designing studies was not easy, and Dr. Greenwald relied on outside programmers for configuration.

When Dr. Greenwald saw an early, pre-release version of the CRIO system, he immediately grasped its value. "The CRIO system is easier to navigate, and we could build the studies ourselves," he said.

What impressed him the most was that the system had a lot of workflows customized for research. These workflows provided further protections against protocol deviations.

For example, when a user schedules a subject for the next visit, the system takes them to a calendar where the days that are in window are color coded. It then can send text reminders ahead of the visit, not just for the appointment but for compliance-related matters such as fasting or medication changes.

"The overall goal of the CRIO software is to facilitate protocol and GCP compliance at every step of the process. That's important because it reduces protocol deviations, which, from a Principal Investigator perspective, are extremely high risk," he said.

While electronic systems inherently improve data transparency and accuracy, they cannot eliminate all protocol deviations, which can be caused by gaps in workflow outside of data capture. Once it occurs, a protocol deviation cannot be "undone", or easily corrected with a late entry.

"Rightly or wrongly, Principal Investigators are personally liable for the conduct of the study, even on matters that are reasonably handled by others," said Dr. Greenwald. "Any system that reduces protocol deviations provides protection for the Principal Investigator."

Dr. Greenwald signed up for the system shortly after its initial release.

An auditor's view

The Clinical Research IO team wanted to quantify the impact of its system on protocol deviations. To do this, it retained ClinPharm Network, a clinical research quality consulting firm, to perform an evaluation of the system.

The firm compiled a list of the most frequent audit findings from their past 47 audits. For each finding, CRIO and the firm reviewed whether the system had a safeguard that would help prevent the occurrence of the finding.

To qualify as a safeguard, the feature had to offer a level of protection that could not be matched in a paper-based environment. For example, the CRIO software system has an Informed Consent version tracking feature. When the user uploads a new version of the Informed Consent, the system will invoke the associated ICF procedure and prompt the user with the most current version at each subject's next visit. This feature provides a level of protection that cannot be replicated in a paper-based environment since it's impossible to "bring" a hard copy ICF version into the source visit with only one action (i.e., upload).

The study concluded that CRIO has a safeguard against 50% of the most common audit findings.

Sample audit findings with CRIO safeguards

Finding	CRIO safeguard(s)
Inclusion of subjects that do not meet eligibility criteria	Real-time alerts; forced completion of I/E criteria; auto-calculations
Screening log not kept up to date, especially with screen failures	Automated screening log
Lack of documentation on the consent process for each consent/re-consent	Separate ICF procedure tied to each consent; automated version tracking; ability to track multiple ICF's
Inconsistent documentation of weight from visit to visit	Use of "history" view which provides immediate recall of trendline data

Conclusion

Dr. Greenwald knew from experience and intuition that the CRIO system reduces protocol deviations. As a result, he was not surprised by the 50% figure the auditor identified. “So much of what happens at a site can be improved upon through automation,” he said. “In this day and age, every Principal Investigator should be giving strong consideration to how they can use technology to facilitate oversight of their studies. It’s important not just from an efficiency and convenience perspective, but from a basic risk management perspective.”

ABOUT THE PROFILE

Dr. Greenwald is CEO and Medical Director of Medex Healthcare Research, which he founded in 2000. Past positions include Medical Director of a network of medical testing sites and Assistant Professor at Washington University School of Medicine. He has an MD and PhD from Ohio State University, and completed his residency at Johns Hopkins.