Category: Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Virtual Monitoring and Auditing Digitization in Decentralized Clinical Trials: Source Document Verification, System Scheduling, and Real Time Protocol Performance Feedback

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1. Background

Onsite source document verification (SDV) of site clinical trial data is resource intense and inefficient. Our primary objectives were to show return on investment for:

1) Implementing virtual monitoring and auditing (VMA) versus onsite
2) Assessing monitor satisfaction with system performance
3) Using a real time digital feedback monitoring visit form (MVF) to improve clinical research (CR) protocol audit readiness

2. Goals

Our sponsor-site pilot compared virtual to onsite electronic health record (EHR) access for SDV. Side by side comparison of VMA with another comparable site's (accrual, geolocation, etc.) onsite method were captured and analyzed for: 1) productivity, 2) data latency, 3) cost savings, and 4) site and sponsor satisfaction. A 13-question satisfaction survey was sent to all active VMA users. Historical MVF performance was correlated to overall inspection readiness.

3. Solutions and Methods

VMA reclaimed monitor and site research staff productivity by three hour/visit/monitor, decreased query resolution from two to four weeks to five days, and increased sponsor cost savings by reclaiming monitor associated onsite travel costs. In comparison to other sites, survey respondent's overall satisfaction with VMA was 86 percent. Inspection readiness improved with real time MVF feedback and no FDA Form 483s were issued.

4. Outcomes

VMA decreased both data review latency and query resolution and allowed for more efficient use of staff time and effort. Establishing virtual monitoring in 2011 enabled rapid scaling to a completely virtual model during the COVID-19 pandemic. Real time digital MVF feedback lets teams focus efforts on specific areas of protocol compliance, increase data quality, and ensure inspection readiness.

Comparing their experience to other sites, monitors were able to navigate systems and perform their work virtually with high satisfaction rates. Inspection readiness was improved with real time MVF feedback to CRQA and study investigators; with no FDA Form 483s being issued for the 15 protocols inspected in 2019-2020.

5. Lessons Learned and Future Directions

Virtual systems access allowed a nimble response to COVID-19 and will position sites well for protocol compliance continuity in response to any future threats as well as the need to support decentralized or virtual trials as they are developed.