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

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Background

Traditional onsite source document verification (SDV) of site clinical trial data in the Electronic Health Record and Regulatory binders is resource intense and inefficient.

Primary Objectives

Show return on investment (ROI) for:

1) **Implementing and scaling a virtual monitoring and auditing (VMA) program** versus onsite SDV.
2) **Assessing monitor and staff satisfaction** with Memorial Sloan Kettering Cancer Center's (MSK) VMA system performance.
3) **Using a real time digital feedback Monitoring Visit Form** (MVF) to improve clinical research (CR) protocol audit readiness.

Methods

1) Our sponsor-site pilot compared virtual to onsite Electronic Health Record (EHR) access for SDV.

2) A 13-question satisfaction survey was sent to all active MSK VMA users.

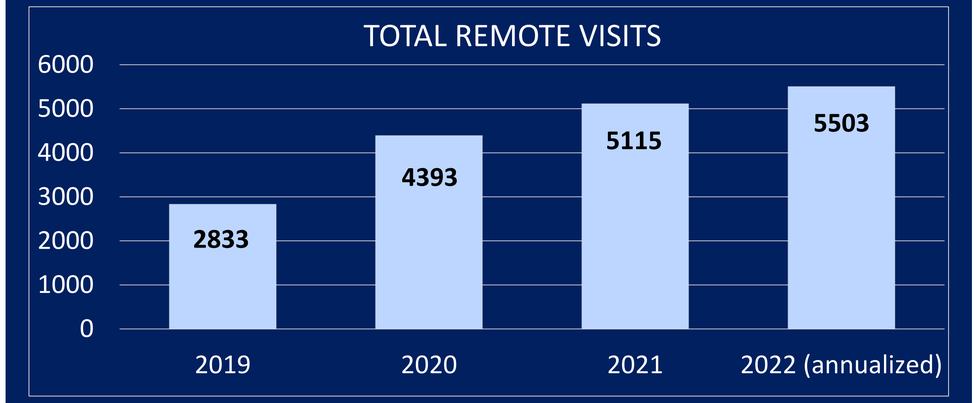
Side by side comparison of VMA with another comparable site's (accrual, geolocation, etc.) onsite method were captured and analyzed for:

a) Productivity
b) Data latency/query response time
c) Cost savings
d) Site and sponsor satisfaction

1) Historical MVF performance was correlated to overall inspection readiness.

Primary Objective Outcomes

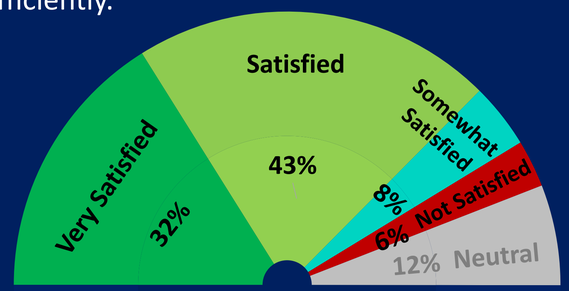
1) **Implementation of VMA started in 2011 with 1 monitor and scaled to a 100% virtual program in 2020.**



2) **Monitor and staff satisfaction with VMA performance,**

- When comparing MSK to other sites' VMA systems, 85% of VMA survey respondents (15% response rate; 959 sent, 144 responses) felt that MSK's training helped them better navigate and use our VMA systems more efficiently.

- **Overall satisfaction of monitors with MSK VMA was 83%**



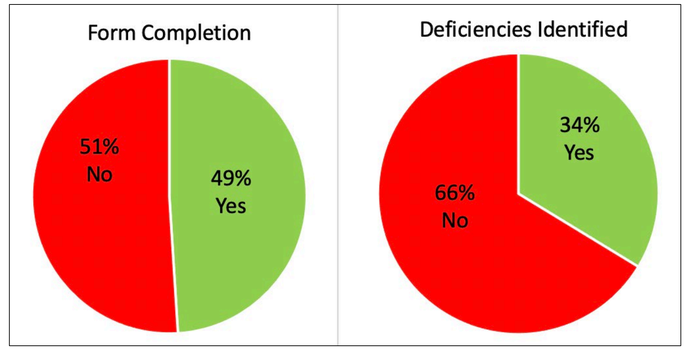
- VMA reclaimed monitor and site research staff productivity by 3 hr/visit/monitor

- Decreased query resolution from 2-4 weeks to 5 days

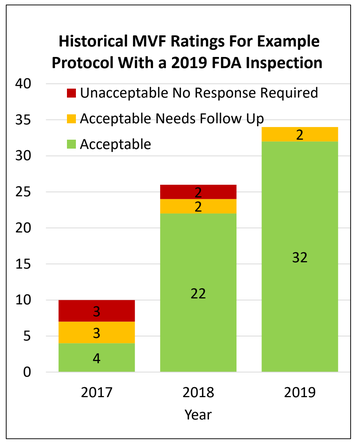
- Increased sponsor cost savings by reclaiming monitor associated onsite travel costs.

3) **Real Time Digital MVFs add transparency and speed to the protocol and data quality feedback loop not possible in a paper-based format.**

Monitoring Visit Feedback Form Completion and Deficiency Rates (2014-April 2021)



- MVFs are reviewed by CR Quality Assurance in a Tableau dashboard, and deficiencies are escalated in real time to the data management team for correction.
- This allows for focused efforts & creation of process improvement that turn around problem areas & ensure inspection readiness.
- For the 15 protocols audited by the FDA at MSK in 2019 to 2020 no FDA 483 letters were issued.



Conclusions

- Establishing VMA in 2011 and eRegulatory in 2015 enabled rapid scaling to a completely virtual model during the COVID19 pandemic.
- VMA decreased both data review latency and query resolution and allowed for more efficient use of staff time and effort.
- Real time digital MVF feedback lets teams focus efforts on specific areas of protocol compliance, increase data quality, and ensure inspection readiness.