Category: Quality Assurance and Remote Monitoring and Auditing – Completed project

Sponsor Monitoring Office: A New Way to Facilitate Remote Interim Monitoring

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1. Background

In 2015, an evaluation was completed on the process for vetting sponsor monitor access requests for Moffitt electronic medical record (EMR). This was due to the complexity of the process and the time it took to obtain approval and troubleshoot access issues. This burden was on the study team at the time, which took too much time away from the limited resources we had already.

The decision was made to centralize the process, which established the Sponsor Monitoring Office (SMO) in September 2015. The office consisted of one (1) full time employee (FTE), who worked with both Human Resources (HR) and IT to get sponsor monitors vetted through our HR policy, set up their accounts with IT, load patient lists in the EMR, and facilitate troubleshooting access issues.

2. Goals

The main goals of this office were to remove the facilitation of vetting and monitoring by reducing the amount of time the study team must spend on these administrative tasks.

3. Solutions and Methods

This office was developed with one FTE in 2015 to manage the following:

- Schedule monitoring visits
    - Coordinate with Moffitt coordinator and data team members
    - Send confirmation letters and instructions for monitoring visits
- Provide the Moffitt vetting and self-registration packets to sponsor monitor/auditor
- Work with HR on completion of the vetting process
- Submit HR approval to IT to provide system access
- Management of vetted sponsor monitors/auditor:
    - Responsible for managing the accounts and their access
    - Responsible for internal audit on sponsor monitor/auditor accounts
    - Requests termination of accounts
- Load the research participants to the appropriate sponsor monitor's account or each monitoring visit
- Invoice for monitoring/auditing visits, as applicable

In 2019 an additional FTE was added, due to growth with sponsor monitors/auditors. At this time, Moffitt's SMO was managing over 750 accounts. In 2022, the SMO streamlined the FDA inspector vetting process with HR and IT to have seamless access for inspectors.

4. Outcomes

To date, this office has invoiced and generated revenue for monitoring visits, scheduled over 21,000 monitoring visits, vetted over 750 monitors, and facilitated access for over 100 FDA, the Southwest Oncology Group (SWOG), Theradex, Eastern Cooperative Oncology Group (ECOG), NRG, and sponsor inspectors/auditors.

Below will provide a detail of growth within a year:

- In January 2023, Total Monitors scheduled for the month: 269
- In January 2024, Total Monitors scheduled for the month: 430

The office has continued to allow the study team members to do what they do best and focus on the on the study.

5. Lessons Learned and Future Direction

- Initially, it took the sponsors a little time to get used to reaching out to a new office to schedule monitoring visits
    - The key to making the change was consistency so we did not allow anyone to go around the new process
- Since many sponsors have closures during the holidays, the team takes advantage of that, and the office is closed for 1-2 weeks each year around the holidays
- The monitoring policy is key to holding all parties accountable to the process
- This team will continue to expand as Moffitt's needs expand
- The team continues to streamline operations, scorecards of each monitor, and our processes as they evolve over time