Category: Trial Start-up and Activation – Completed Project

Use of a Site Profile to Streamline Site Selection and Feasibility

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1. Background

Feasibility questionnaires (FQs) and site selection visits (SSVs) require the same content repeatedly over time. This results in redundant, lengthy meetings; forms completion; and correspondence for different trials offered through the same sponsor or contract research organization (CRO), and across sponsors/CROs.

2. Goals

Our goal was to decrease time spent communicating redundant site details with sponsors/CROs for feasibility and site selection.

3. Solutions and Methods

Our solution was to package site-specific statistics, resources, capabilities, SOPs, processes, and timelines for sponsors in the form of a site profile. To create the site profile, we first polled our research managers about what content to include, focusing on sponsors' frequently asked questions. A designated point person created an outline of the desired content and began inserting information. The document covers the following areas: general overview of the cancer center (catchment area demographics, staffing, disease specialties, contact information), summary of study start-up process, descriptions of clinical facilities (inpatient floors, outpatient clinics, imaging/radiation therapy capabilities), research lab, investigational pharmacy, data management, and sponsor monitoring visit policy. For specific content, the coordinator reached out to clinical trials office staff (regulatory manager, budget manager, disease managers, lab staff, quality assurance manager), as well as hospital partners in pharmacy, service line management, radiation oncology, interventional radiology, and the hospital's compliance office. The coordinator organized all the responses into the site profile document and circulated for feedback. Once the site profile was ready, we began sharing it with sponsors. We try to refer sponsors to the document in lieu of completing their feasibility forms. When sponsors still require their FQ be filled out, we use the site profile as a reference and copy information into the FQ or write "see site profile." In preparation for SSVs, the site profile is emailed to sponsors along with a reverse FQ, and other commonly requested documentation to supplement the site profile. To see our site profile, please visit: https://www.mcw.edu/departments/cancer-center/clinical-trials/sops-for-research-staff

4. Outcomes

Sponsors/CROs were hesitant to rely on our site profile initially but have warmed up to the point of complimenting and remarking that few items remain for discussion. We have noted a marked decrease in the duration of SSVs, as well as necessary action items and correspondence with sponsor/CRO following the SSV. We expect there is increased consistency and efficiency of information sharing across teams.

5. Lessons Learned

Based on the outcomes described above, we feel that the site profile has been beneficial overall. Managers are responsible for FQs and SSVs, but we are considering administrative support for content packaged in our site profile to decrease expense and increase manager bandwidth. One downside is that the document requires ongoing maintenance. We update as needed when major changes occur and review annually to ensure it accurately reflects our site's current capabilities. We are planning to expand clinical trials at our network hospitals, so for next steps, we are considering creating a site profile for each community site. We are also planning to create a virtual (video) tour of our facilities with the hope of further streamlining pre-activation interactions with sponsors.