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

Proactive Quality Assurance Through Dual Review of Eligibility and Consent

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1. Background

Enrolling participants on clinical trials that meet protocol specified eligibility criteria not only establishes a homogenous patient population, allowing for adequate data analysis, but it is critical for the safety and well-being of participants. One of the most common U.S. Food and Drug Administration (FDA) Bioresearch Monitoring Program Information (BIMO) audit findings across clinical investigator and sponsor-investigator observations, as assessed by findings on the FDA Form 483, has consistently been "inadequate subject protection; informed consent issues." Research continues to show that protocol complexity continues to rise, despite the awareness that trial complexity adds to the increase in the number of deviations. One area of complexity for oncology trials remains participant eligibility criteria. The ramifications of this can create a perfect storm for enrolling ineligible subjects, as well as subjects not being fully informed of their participation during the consent process.

2. Goals

We took a proactive quality assurance approach to reduce the number of deviations related to consent and eligibility in relation to the number of participants enrolled on therapeutic trials.

3. Solutions and Methods

A standard operating procedure (SOP) was created for dual review of eligibility and consent. This in-depth assessment is performed by experienced study managers and quality assurance professionals. After a new potential participant has provided informed consent, completed all screening procedures, and prior to registration, the dual review process confirms the following:

- Eligibility criteria appear to be met
- Consent forms are complete
- Informed consent process is documented
- Screening procedures have been completed with results
- Regulatory requirements and version control
- General good clinical practice/ALCOA+ standards have been followed

The policy requires that all source documents must be compiled and presented to the reviewer, including medical history assessments, concomitant medication review performed by a trained pharmacist, and any other trial specific checklists. This process complements the review provided by the coordinator and physician by providing an additional level of review. On average, this process takes approximately 60 minutes. Because dual review is required at Huntsman Cancer Institute (HCI), the study team plans for these reviews so that participant registration is not delayed.

4. Outcomes

Although we've had the SOP in place since 2012, we amended the SOP in 2017 requiring the dual review of eligibility process to be performed by a manager or QA professional. The data below indicates the positive trends we've seen since formalizing this process into a requirement performed by senior level management at HCI. The line shows a decrease in percent of patients accrued with deviations entered in OnCore related to consent and eligibility. Overall, we've seen a decrease in the percent of deviations related to consent and eligibility from 7.37 percent in 2016 to 2.56 percent of total accruals in 2021.

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5. Lessons Learned and Future Directions

Since implementing an SOP in 2012, HCI has made many adjustments to streamline the process including the following:

- Original SOP allowed another independent coordinator to perform the review
- Added a review for registration/randomization assignments for accuracy prior to enrollment
- Added departmental review of re-consents
- Account for hybrid, virtual setting with reviews, such as confirming witness, Adobe sign is Part 11 compliant, etc.

Figure: