Category: Quality Assurance and Remote Monitoring and Auditing – Work in progress

A Robust ICF Review Tool to Facilitate GCP Adherence and Broaden Study Team Knowledge of Regulatory Requirements: Framework and Outcomes

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1. Background

The Clinical Trial Office (CTO) of the University of Arizona Cancer Center (UACC) provides clinical and regulatory support for all human subject research conducted under the auspices of the institution. Previous audit and internal monitoring findings of CTO studies identified a need for a proactive review of Informed Consent Forms (ICFs). As such, the UACC's Compliance Department implemented a centralized ICF review process, whereby all original ICFs undergo rigorous review by internal compliance monitors to ensure adherence with International Council for Harmonization's Good Clinical Practice guidelines (ICH-GCP), regulatory requirements, and institutional policy.

2. Goals

The primary goal of this project is to identify deviations from ICH-GCP/regulatory/institutional requirements and rectify them in real time. The secondary goal is to generate benchmark data on compliance trends, identify gaps in the study team's understanding of ICF requirements, and leverage this data to create tailored, staff-centered trainings for the CTO collectively.

3. Solutions and Methods

First, a robust ICF Review Checklist, which comprised all required elements of the ICF per ICH-GCP/regulatory/institutional requirements, was developed and used as tool to document deficiencies. Data from the ICF Review Checklist was simultaneously collected in a database to:

1. Track ICF status (i.e., "Open" if deficiencies identified; "Closed" if ICF was completed accordingly or all deficiencies have been resolved)
2. Generate data on coordinators' knowledge of ICH-GCP/regulatory/institutional requirements as indicated by nature and frequency of deficiencies
3. Provide an ICF "chain of custody" audit trial

Once the ICF review is completed, the original ICF and checklist are returned to the coordinator(s) to complete all necessary modifications, during which internal compliance monitors confirm comprehension of corrections and expectations. Lastly, trends gathered from the database are consistently analyzed and utilized to develop proactive initiatives.

4. Outcomes

Since the ICF Review implementation in January 2023, the quality assurance and quality control (QAQC) program has reviewed 865 individual ICFs. Of the 865, 754 have a "Closed" status with all observed deficiencies adequately resolved. The remaining 111 ICFs have an "Open" status and are being diligently monitored by our compliance department. Further, in the last year, the CTO has undergone 6 audits, all of which received favorable outcomes and resulted in no ICF deficiencies. While we cannot ascertain this was due to the ICF Review process, we can deduce that all deficiencies and subsequent corrections facilitated by the review process contributed to the successful audit outcomes. Additionally, a "Checking in With Compliance" segment, directed by internal compliance monitors, was instituted during standing

meetings for the CTO's clinical and regulatory departments and is utilized to disseminate observed trends and tailored educational opportunities.

5. Lessons Learned and Future Directions

A significant efficacy improvement we are exploring is the timepoint at which the ICF reviews are executed. At present, ICFs are collected from the research offices every 2-3 weeks due to the location difference of the compliance department offices. However, strategies are being developed to perform this review in real time, including a standardized review schedule. Additionally, as a proactive initiative, we are exploring creating a pre-ICF checklist to provide study teams as a resource, ensuring full understanding of expectations prior to initiation of an ICF process.