Category: Investigator-Initiated Trials - Work in Progress

Managing Investigator-Initiated Clinical Trials Registration to Reduce Overall Reporting Errors at a Consortium Cancer Center

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1. Background

Registration of all clinical research studies in Clinicaltrials.gov (CTgov) has been required by law since 2007 (FDA U.S. Public Law 110-85), and further in 2017 (42 CFR 11.22). However, compliance with these regulations has been poor, with up to 50 percent of all studies failing to report or reporting late. The FDA intends to publicly announce all non-compliance and enforce civil penalties up to $10,000 (adjusted for inflation) a day for non-compliance. As of the date of this publication, there have been no fines levied. Recently, there have been several publications calling for greater compliance and reporting of clinical trials. Furthermore, there has been a focus on the lack of punitive civil action from the FDA. It is in the best interest of all NCI-Designated Cancer Centers to comply with these regulations to avoid receiving the initial financial penalty. To address this important issue, the clinical research office (CRO) offers centralized registration and results reporting support, but information must be provided and verified by the principal investigator (PI). Our office is able to pull some preliminary information from the clinical trials management system, OnCore™, such as participant flow, baseline characteristics, and some adverse event data. However, outcome measure data and remaining adverse event information must be provided to the CRO office by the PI in a timely manner. The CRO has worked to reduce these errors over time by implementing a two-part strategy:

1. Centralized registration of all studies prior to initiation
2. Reviewing quarterly reports from the Data Safety and Toxicity Committee (DSTC)

2. Goals

- Reduce reporting errors to fewer than 10 total
- Increase compliance with results reporting by following studies on a quarterly basis and at initial registration

3. Solutions and Methods

Registration:

- Scope: All Interventional trials that study cancer
- Deadlines: Must be registered in CTgov before any participants are enrolled
- Process: After PRMC approval, CRO will reach out to study team with record draft and clarifying questions > PI approval needed to release study for review > approved by CTgov or returned with QA comments > (repeat as necessary) > study approved and assigned NCT number

Results Reporting:

- Updated DSMP plan to include results reporting

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- DSTC provides reports quarterly to the CRO to stay up to date with results

4. Outcomes

Total errors reduced from January 2018 (40+) to January 2021 (less than 10)

5. Lessons Learned

- Development of standard registration process reduces errors over time
- Tracking errors through coordination with the DSTC allows for more efficient results reporting

Figure: