Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Operationalizing CTSU's Protocol and CIRB Update Listing for Processing Local Regulatory Documents

E. Arnold, J. Rarden, A. Willingham

The University of Kansas Cancer Center

1. Background

Regulatory documents for studies overseen by the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) must be processed and activated within 30 days of posting to the Clinical Trials Support Unit (CTSU) website. The University of Kansas Cancer Center (KUCC) Clinical Trials Office (CTO) regulatory team manages over 200 National Cancer Trials Network (NCTN) and Experimental Therapeutics Clinical Trials Network (ETCTN) studies. Staying on top of the posts proved difficult for a smaller staff of four from 2015 to 2019. At the time of development, CTSU's Dashboard feature filtered to all CIRB-approved studies for the site, which made it difficult for coordinators to focus on only the subset of studies each coordinator managed. The manager of the regulatory team and one of the regulatory coordinators worked together to develop a better method to track and distribute these updates to individual coordinators.

2. Goals

- Avoid missing important regulatory updates.
- Process amendments within 30 days of posting.

3. Solutions and Methods

An Excel-savvy regulatory coordinator developed a smart spreadsheet to map protocol updates posted on CTSU to the studies maintained by the KUCC regulatory team.

The report is updated by our NCTN administrator. She exports both Protocol Updates and CIRB Updates from CTSU to Excel once a week. Only postings from the previous week are pasted into the mapping spreadsheet. The columns used are Date, Protocol ID, and Update description. In addition, the CTO's Research Systems team distributes two weekly reports (start-up and maintenance) of all CTO-managed studies from our Clinical Trial Master System. This report includes the Disease Working Group, Study Status, IRB number, Protocol ID, Principal Investigator, IRB Expiration Date, and Regulatory Contact. These reports are also pasted into the mapping spreadsheet.

Studies not managed by KUCC populate with an N/A and are filtered out of the report. The resulting report includes all updates posted to CTSU for the prior week for only those studies maintained by our regulatory coordinators. The NCTN administrator pastes the table into an email and distributes it to the regulatory coordinators, manager, and program director.

4. Outcomes

Amendment processing timelines from CTSU posting to local activation improved from an average of 25.5 days to 11.9 days after implementation of the report. The team saw a high of 17 audit findings for delayed activation in 2017 to no regulatory audit findings in 2023.

5. Lessons Learned and Future Directions

A few errors have occurred since implementation, including new studies not being added to the Lookup mapping tab and typographical errors in Protocol IDs on the Lookup tab which made some studies show as N/A. This resulted in two instances of missed amendments.

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In 2022, we implemented having each regulatory coordinator's functional manager review the report weekly to ensure items are processed within the 30-day window required for NCI CIRB studies. Staff are also instructed that the report is a second check and should not be the sole source of truth for protocol and CIRB updates on the studies they maintain.

While the CTSU Dashboard can now be filtered to a coordinator's selected studies, the weekly report allows for cross-coverage when coordinators are out and enables managers to track the work being completed on the team.

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