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

Improving Data Timeliness by Developing a CTO Process and Shifting Cultural Expectations

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1. Background

Data entry timeliness is important for real time safety review of investigational agents. An essential portion of the reported data includes adverse events (AEs) and disease response, which are more time consuming to document than other data elements. At The Ohio State University Comprehensive Cancer Center (OSU-CCC), clinical research coordinators (CRCs) document AEs and disease response in EPIC Research Encounters, which are then routed to the principal investigator (PI)/Sub-Is, who provide relatedness attributions, confirm response, and sign the encounter. Data entry by a clinical research associate (CRA) can only take place after these steps are completed. The timeliness for completion of these steps had been largely driven by the individual disease team culture. Some disease teams completed their encounters within a few days of the study visit while others were months behind.

2. Goals

- Create a clinical trials office (CTO) wide culture with the expectation of contemporary completion of toxicity and disease response documentation
- Develop a data timeliness process to address timely documentation of research encounters by CRCs
- Provide an escalation process to obtain PI/Sub-I signature if encounter remains unsigned after routing in EPIC

3. Solutions and Methods

Specific goals for data timeliness were set for CRCs and CRAs as part of annual reviews in June 2023. CRCs were expected to write their research encounters and route them for physician signature within five business days of the visit. CRAs were empowered to escalate requirements for missing data to their manager.

A CTO Data Timeliness Process was implemented in December 2023. Along with the timeliness expectation for CRCs, it included an escalation process for unsigned encounters after five business days, progressing to include higher levels of leadership as more time passed. Messaging went out to both the clinical teams and the Disease Group Leaders (DSRGLs) regarding this process.

Data timeliness metrics were shared with CRCs at quarterly meetings throughout 2024. Metrics were shared with DSRGLs at annual meetings.

4. Outcomes

The number of open overdue Research Encounters in EPIC decreased by 60 percent from June 2023 (506) to February 2025 (203). For National Cancer Trial Network (NCTN)/Experimental Therapeutics Clinical Trials Network (ETCTN) trials, the number of case report forms (CRFs) and queries >60 days overdue decreased by 81 percent and 88 percent respectively from June 2023 to February 2025. Impact was made in shortening the time for both CRCs to route the encounters and for physicians to sign encounters. In addition to better data metrics, these timely encounters provide physicians the

opportunity to attribute AEs in real time and prevent discrepant attributions often caused by the backup of several cycles of toxicity notes.

5. Lessons Learned and Future Directions

CRCs have many competing priorities, so setting expectations for prioritization of contemporary research documentation across the CTO required a combined effort of specifically set goals, a department-wide process, and ongoing communication of metrics and achievements. Involving managers and DSRGLs to assist in escalation and prioritization of these research encounters was essential to success. To remain at the forefront of CTO culture, contemporary documentation in research encounters as outlined in the annual goals and Data Timeliness Process are introduced early in new employee tenure as part of the onboarding classes and as an expectation for preceptors to pass on good habits and workflows.