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

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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 OSU-CCC, clinical research coordinators (CRCs) and clinical research nurses (CRNs) document AEs and disease response in EPIC Research Encounters, which are then routed to the PI/Sub-Is, who provide relatedness attributions or confirm the response, and sign the encounter. Data entry by a clinical research assistant (CRA) can only take place after these steps are completed. The timeliness for completion of these steps had historically 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.

Objectives

- Create a CTO wide culture with the expectation for 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 signatures if encounters remain unsigned after routing in EPIC.

Goal Setting

Specific goals for data timeliness were set for disease team staff as part of their annual reviews in June 2023. CRCs and CRNs were given the set expectation 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. Clinical research managers were expected to provide oversight, guidance, and support to enable the CRCs and CRNs to meet the goal of writing and routing Research Encounters within five business days. For example, managers may arrange patient coverage and “library days” for CRC/CRNs who were behind in their notes, to allow focused time for this documentation.

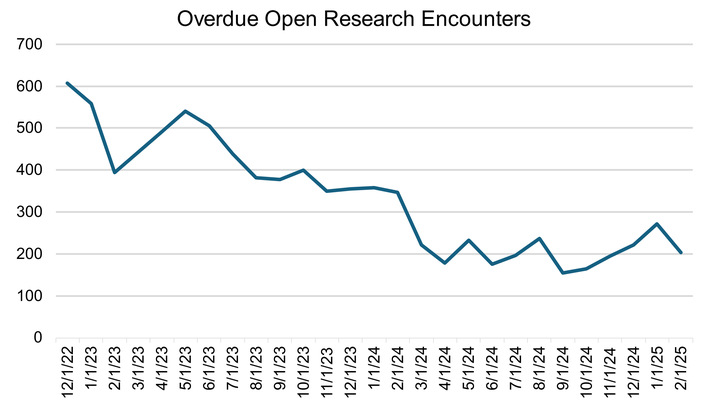
New Process

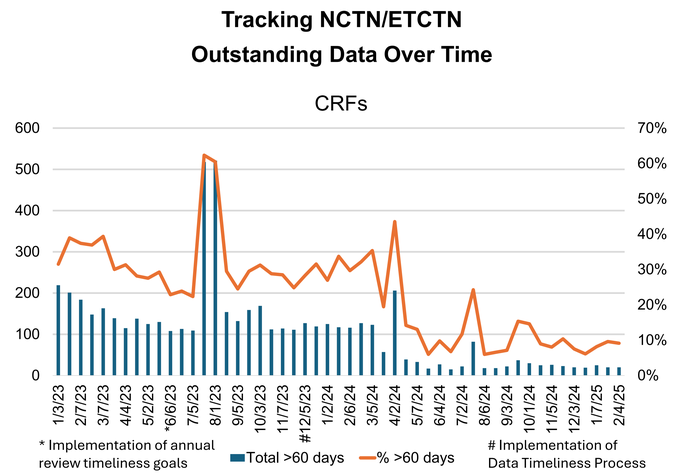
A CTO Data Timeliness Process was implemented in December 2023. Along with the timeliness expectation for CRCs and CRNs, it included an escalation process for unsigned encounters after five business days, progressing to include higher levels of leadership as more time passed without signature. Messaging went out to both the CTO disease teams and the Disease Specific Research Group Leaders (DSRGLs) regarding this new documentation process.

Monthly reports of open EPIC research encounters and outstanding NCTN/ETCTN CRFs and queries were monitored closely. From these, data timeliness metrics were extracted and shared with CRCs and CRNs at quarterly meetings throughout 2024. Metrics were shared with DSRGLs at annual meetings.

Outcomes

The number of open Research Encounters >30 days overdue in EPIC decreased by 60 percent from June 2023 (506) to February 2025 (203). For NCTN/ETCTN trials, the number of 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 the CRCs/CRNs to route their 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 back up of several cycles of toxicity notes.





Lessons Learned and Future Directions

CRCs and CRNs 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.