Improvement in Adverse Event Review Times:
Piloting the Epic Adverse Event Module and New AE Collection Workflows

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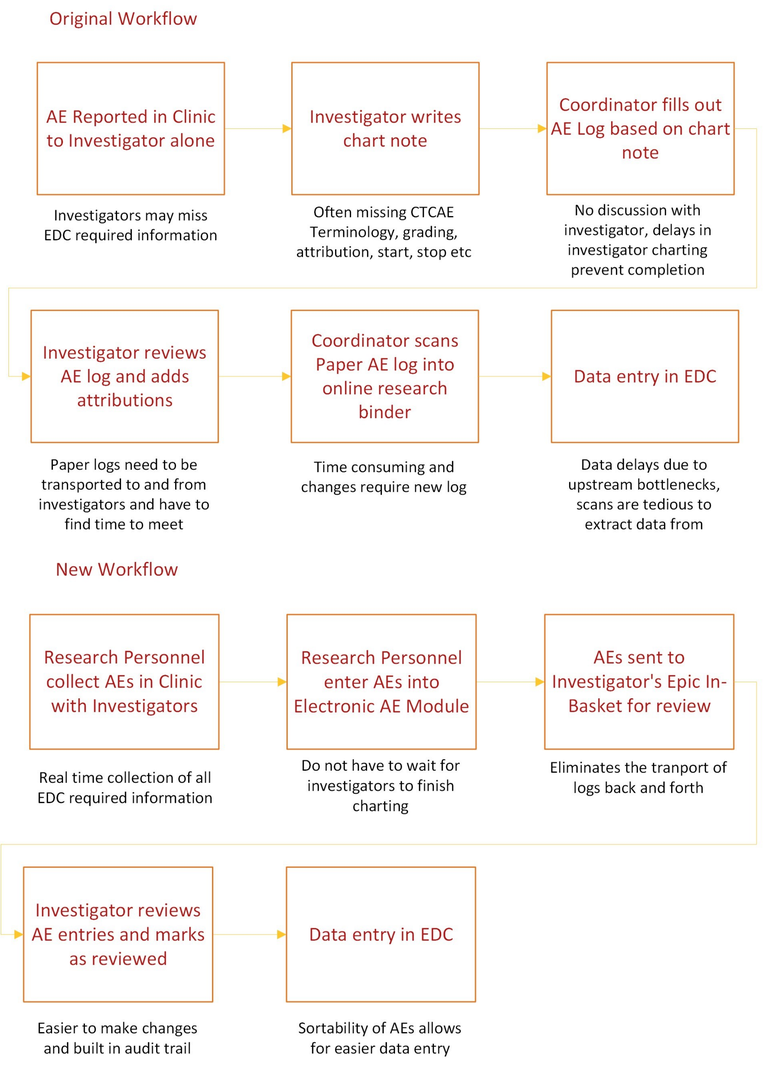
Background and Solution

At the Weill Cornell Medicine Meyer Cancer Center Cancer Clinical Trials Office (MCC CCTO), paper adverse event (AE) logs were used for collection, and investigator grading and attribution of AEs. This workflow resulted in missing data and long review/sign-off times.

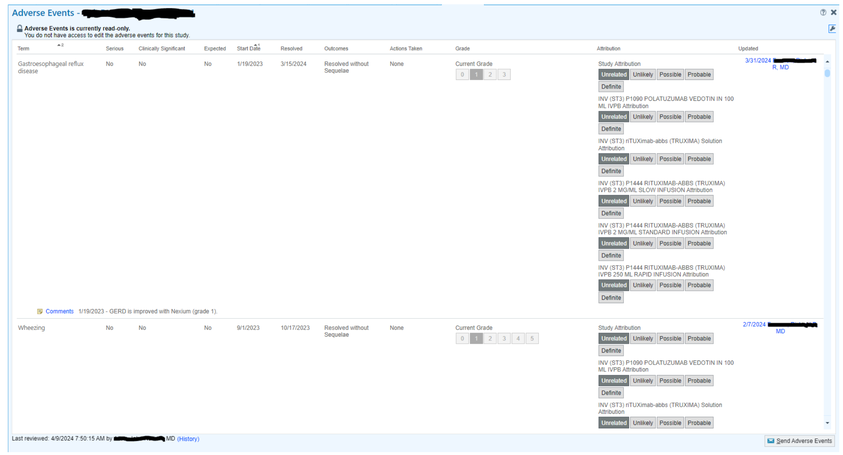
To streamline procedures and improve AE review times, with a goal of 5 days to review, the CCTO piloted the



Methods

1) Forty three AEs reviewed using Paper and 39 AEs reviewed using Epic were identified.
2) Date each AE was reported and date of investigator review were collected.
3) Difference in the number of days between the AEs report date and Investigator review date were calculated.
4) Mean Days to Review was calculated for both Paper and Epic.

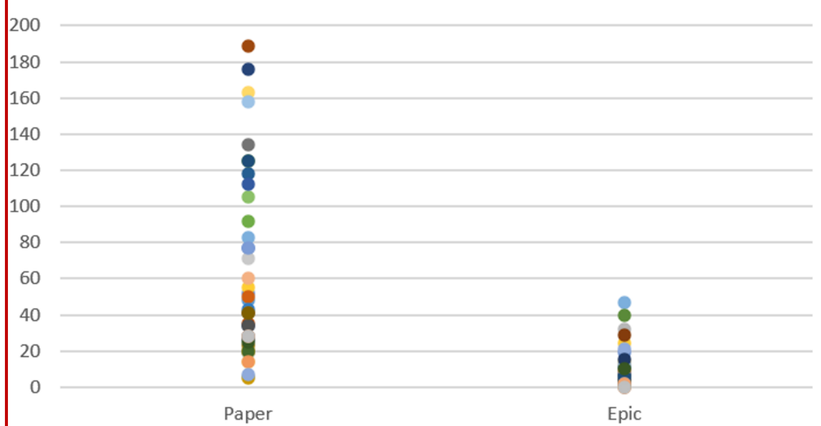
Epic AE Module Example



Outcomes

Mean days between study visit and Paper and Epic review were 61 days and 11 days, respectively. The ranges for Paper and Epic were 184 days and 47 days, respectively. Figure 1 shows days to review for each group. One out of 43 Paper AEs and 13 out of 39 Epic AEs were reviewed within five days.

Figure 1: Days to Review



Lessons Learned and Future Directions

The new AE workflow and use of the Epic AE module decreased review timelines. Despite the reduction, AEs were not reviewed within the targeted 5 day timeline. Further evaluation of research coordinator and investigator timelines will help identify bottle necks and direct education and oversight to help bring review of AEs closer to the 5-day goal. It was unclear how much improvement in timelines was due to establishing expectations and moving the workflow into clinic versus being due to using the electronic Epic system instead of paper. The MCC CCTO plans to roll out the new AE capture workflow and use of the Epic AE module across all research teams. An analysis following the broad roll out is planned to measure the impact of the

Acknowledgements

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