Category: Clinical Trial Operations – Work in Progress

Automated Reporting for Clinical Trial Operations

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1. Background

Day-to-day operations of a cancer center requires leveraging multiples sources of data from multiple systems. Data such as clinical trial accrual, start-up tasks and timelines, and protocol and subject deviations must be visible and accessible. Taussig Cancer Institute manages research operations across 12 different sites in northeast Ohio and Florida, with trials conducted across 18 program research groups (PRGs), running 239 active interventional trials (as of March 2022). Previously, reports were generated manually, either on a monthly or ad hoc basis. Automated reporting allows us to view critical operational data in real time.

2. Goals

- Provide cancer center leadership and management with accurate and up-to-date metrics for clinical trial operation, including tracking accruals, start-up times, and deviations
- Increase efficiencies with regards to trial oversight and regulatory management
- Ensure quality of trial data captured for NCI and other reporting purposes
- Free up time and resources for our research informatics team

3. Solutions and Methods

Data is primarily housed in the OnCore clinical trial management system. Oracle SQL is used to query the data, and the data is visualized using Tableau.

4. Outcomes

Currently we have automated three different reporting processes:

- Time to open: using the OnCore Tasklist functionality, we track designated milestones in the pending trial start-up process; teams review this data and are able to highlight barriers and holdups in the process
- Deviations: protocol and subject level deviations are tracked within OnCore, and the data can be reviewed in individual PRG meetings and in a monthly compliance meeting
- Accrual: clinical trial accrual is tracked in near real time by PRG and broken down by enrolling site and trial type

Both accrual and deviation reports have resulted in significant time savings (15 hours per month for accruals, 8 hours for deviations).

5. Lessons Learned and Future Directions

As a matrix style comprehensive cancer center (in collaboration with Case Western Reserve University and University Hospitals Cleveland), we found it difficult to report out data pertaining only to Taussig, and existing applications did not fill this gap. Our automating processes have allowed us to generate data relevant to Taussig clinical trial operations only. Adding visibility to the data has highlighted the need for rigorous QA of data entered into OnCore, and we will be expanding our efforts here. Moving forward we will continue to develop additional reports and visualizations, including expanding our trial start-up analysis, PRG specific dashboards and metrics, and tracking compliance and monitoring results for internal investigator-initiated trials.

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