Implementing “Protected Time” to Increase Clinical Research Coordinator Data Entry Efficiency

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BACKGROUND

Clinical Research Coordinators bear many responsibilities, including, but not limited to, facilitating communications, data entry, sample processing, and regulatory reporting[1, 2].

CRCs on the Genitourinary Oncology team at Mount Sinai balance the completion of these tasks across a workload of approximately 30 active clinical trials. The myriad of daily responsibilities that require prolonged efforts are difficult to complete within sponsor-defined timelines. As a result, data delinquency continuously worsens. A literature review revealed that, while data entry is a task frequently performed by CRCs, few interventions to improve the research enterprise have been developed, implemented, and evaluated.

Implementing the use of “Protected Time” was done to increase team efficiency and productivity and to address the outstanding data delinquency.

METRICS/GOALS

1. Decrease the number of data delinquencies over >90 days old by >50% across all trials.
2. Identify impact of protected time by comparing quantifying number of query responses and pages completed on days utilizing protected time versus days without for all CRCs for 6 months
3. Each CRC will increase number of queries responded to and pages completed by >25% when utilizing protected time for 6 months
4. Create an inclusive environment and empower coordinators by gathering feedback and engaging in weekly team discussions to improve process or incorporate new ideas over 6 months

METHODS

During weekly team meetings, each coordinator identifies and verbalizes their “protected time” for the upcoming week to their manager and teammates. The purpose of this “protected time” is to prioritize specific data entry and query resolution and to diminish interruptions. During this time coordinators place an automatic reply on their email and calendar to avoid interruptions. This step provides workload transparency. It also decreases the amount of pressure placed on the CRCs to multitask mitigating distractions and data entry errors. Weekly meetings are scheduled with the CRCs to discuss feedback and suggestions for this quality improvement process.

RESULTS

There is a positive change in the quantity of data queries resolved per day as a result of implementing “protected time”. Data analysis from November 2021 to February 2022 revealed CRC query resolution increases by an average of 42% on “protected time” days. As of February 2022, the delinquent data backlog for all trials in the GU portfolio has improved by 41% since November 2021. Positive verbal feedback from the CRCs has been given regarding the protected time workflow change. CRCs feel a decrease in pressure and can fully focus on addressing data delinquencies and find it is a supportive tool in task management.

	Outstanding EDC Queries	Outstanding EDC Missing Pages	Outstanding Data Items Total
November 2021	391	80	471
February 2022	225	49	274
Net Change	-166	-31	-197
Percent Change (%)	-42.46	-38.75	-41.83

LESSONS/FUTURE DIRECTIONS

Implementation of “protected time” is an effective method for prioritizing specific tasks and addressing data delinquencies. Consistently implementing weekly “protected time” for our team is not without challenges. A potential future solution is to determine a consistent day and time for each CRC to implement “protected time” weekly. Patient study visits are primarily scheduled for Tuesdays and Thursdays. Thus, assigning a time for each of our CRCs on Monday, Wednesday or Friday would be effective.

Implementing this system may discourage sponsors from contacting or assigning tasks to CRCs during their “protected time” because this is communicated to them in the CRC’s automatic email reply window. Creating a guidance document or SOP may be necessary to help ensure open communication and transparency between site and sponsor teams is preserved.

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