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

Using a Standardized Communication Document for Nursing in Clinical Trials to Improve Patient Care

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1. Background

Memorial Sloan Kettering (MSK) is a high-volume National Cancer Institute (NCI) designated center with about 2000 active protocols. To ensure a timely and accurate collection of trial-specific data that must be collected at certain timepoints during the patient visit, nurses rely on a communication document known as Pharmacokinetic (PK) sheets. Prior to 2023, the clinical research team at MSK manually created these documents, using Microsoft Word (MS). This resulted in inconsistent formatting, varying language, and is error prone. PK-sheet issues can lead to delay in data collection and patient care and can cause a deviation from the protocol. When PK-sheet issues occur, nurses report them in MSK's Reporting to Improve Safety and Quality (RISQ) System. In 2022, there were 55 incidents reported by nursing related to PK sheets.

2. Goals

To address these challenges, the goal was to:

- Reduce the number of PK-sheet related RISQ reported by nursing.
- Standardize the PK sheet format to improve clarity and readability for nursing staff across all MSK locations.
- Integrate it with an existing internal system at MSK, which already contained relevant collection data, to reduce staff time and effort in creating the PK sheets.

3. Solutions and Methods

The PK Tool Application was rolled out at MSK in 2023. To assess the effectiveness of the application, the number of PK sheet RISQ reported from 2022 to 2024, were analyzed. Additionally, clinical research staff who used the PK Tool were surveyed about their satisfaction and the time and effort required to create PK sheets compared to the previous MS method. A literature review was conducted to explore how other institutions outside of MSK capture timed trial-specific data during patient visits. Google scholars and PubMed were searched using the following key search terms: clinical trials, clinical trial patient schedule of assessment, oncology clinical trial documents, pharmacokinetics documents, and pharmacokinetics sheets.

4. Outcomes

From 2022 to 2023, the number of PK sheet RISQ reported decreased by 15 percent (55 to 47). In 2024, the number of incidents reported decreased by 9 percent (47 to 43) in comparison to 2023, which was the year the application rolled out. Additionally, PK Tool users were surveyed with (37% response rate, 68/183) 85 percent reported saving an average of 12 minutes per PK sheet created and 88 percent preferred using the PK Tool over the previous manual method of using Microsoft Word. Currently, PK sheets from 582 protocols are managed in the PK Tool application.

5. Lessons Learned and Future Directions

We are collaborating with other NCI institutions to understand how they ensure the timely and accurate collection of trial-specific data. We are also evaluating whether, given our protocol volume, we can

utilize the Epic Beacon Order set to streamline this process or integrate Epic into our application to further reduce manual data entry and improve data quality.