A Pharmacokinetic (PK) Tool App: Automating PK Sheet Templates Creation for Standardization and Efficiency in Clinical Research

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1. Background

The Department of Quality and Safety (DQS) in Memorial Sloan Kettering (MSK) identified areas in clinical research that contributed to prolonged patient wait times, patient dissatisfaction, redundant processes, and reduced interaction time between registered nurses (RNs) and patients. A major contributor to these issues were delays in the creation, review, and approval of pharmacokinetic (PK) sheet templates during protocol development and activation.

PK sheet templates, created by the clinical research staff and based on the protocol schedule of events, serves as a communication tool that outlines research assessments such as vitals, electrocardiograms (EKGs), PKs, and investigational product administration, along with their corresponding collection timepoints to be performed by RNs or PK technicians. However, the lack of standardization and platform (Microsoft Word) used to create these templates has led to variations based on disease management team (DMT) preferences, and delays in the review and approval of the template.

2. Goals

The goal was to develop an application aimed at:

(1) Standardizing the PK sheet templates (e.g., ensuring a uniform design and layout) to minimize the format variations encountered by RNs
(2) Reduce the amount of time it takes to draft PK sheet templates

3. Solutions and Methods

The application development process involved three phases:

(1) <u>User Research</u>: Conducted interviews with clinical research staff to understand the process of creating and managing PK sheet templates and shadowed Developmental Therapeutics Unit (DTU) RNs to see how they reviewed and utilized them. A minimal viable product was then developed aimed at capturing the creation and management of PK sheet templates.
(2) <u>Pilot Launch</u>: Introduced pilot to two DMT (Early Drug Development and Leukemia). Feedback was gathered from pilot users to evaluate their experience and identify areas for improvement. This phase aimed to gauge how the application can be refined to align with user requirements.
(3) <u>Enhancements and Full Roll-Out</u>: Implemented enhancements to address limitations in the application's functionality for creating and managing PK sheet templates. Then, initiated the full roll-out of the tool to all clinical research staff.

4. Outcomes

We surveyed all new users of the PK Tool application and have collected 54 out of 118 responses (46 percent response rate). Out of the 54 responses, 82 percent of our users reported that utilizing the PK Tool application to create templates saved on average 12 minutes of time per template, and 85 percent

expressed a preference for the PK Tool application over the previous method of creating PK sheet templates using Microsoft Word.

5. Lessons Learned and Future Directions
The implementation of the PK Tool application has increased clinical research staff's efficiency in creating PK sheet templates.

Our future directions include:

(1) Removing manual data entry for patient details such as full name and date of birth on the PK sheet templates by extracting this information from an internal MSK system. Currently, patient information is applied to the templates via printed labels. This enhancement will increase accuracy of patient information and save labels and ink.
(2) Creating the functionality for PK sheet template review and approval within the application. Currently, the review and approval process occur through another software, and via email communication.