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

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Background

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

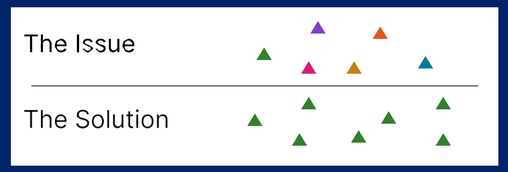
PK sheet templates are documents created by the clinical research staff and serves as a communication tool that outlines research assessments such as vitals, electrocardiograms (EKGs), pharmacokinetics (PKs), and investigational product administration, along with their corresponding collection timepoints to be performed by RNs or PK technicians on a specific protocol timepoint. 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.

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

A DTU nurse can attend to **2-8** patients in a day, each with a different variation of a PK sheet template...

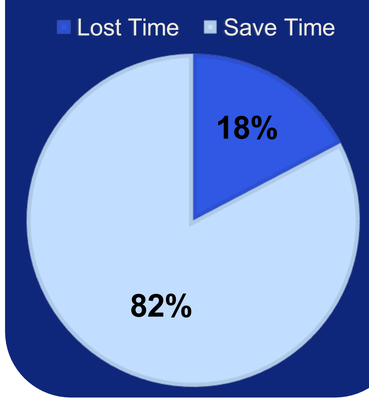


Results

We surveyed all new users of the PK Tool application and have collected 54 out of 118 responses (46% response rate).

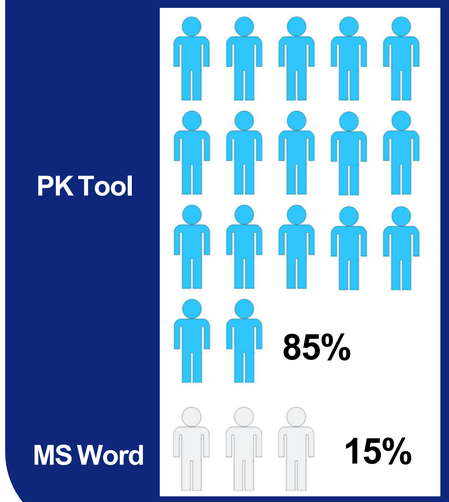
Efficiency

82% of users who completed the survey are saving time creating PK sheet templates on the PK Tool application over the previous method of using Microsoft Word.



Preference

85% of users who completed the survey prefer to create PK sheet templates on the PK Tool application over the previous method of using Microsoft Word.



User Quotes

*PK Tool is **by far superior to a word document**. All the PK Tool templates are saved and can be **easily edited as needed**. A fantastic tool!"*
- Clinical Research Associate

*"We all are really loving it and excited for how this will help achieve our **goal of standardized PK sheets across MSKCC**. We feel this will **help cut down nursing editing time**, as well as **cut deviations with more clear and concise information on the sheets.**"*
- Registered Nurse (RN)

*"The PK sheet templates in the tool are so organized. **I know that I am always working with the latest updated version."***
- Clinical Research Associate

Methods

The application development process involved three phases:

1. User Research: Conducted interviews with clinical research staff to understand the process of creating and managing PK sheet templates and shadowed DTU RNs to see how they reviewed and utilized them. A minimal viable product (MVP) was then developed aimed at capturing the creation and management of PK sheet templates.
2. Pilot Launch: Introduced pilot to two DMTs (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. Enhancements and Full Roll-Out: 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.

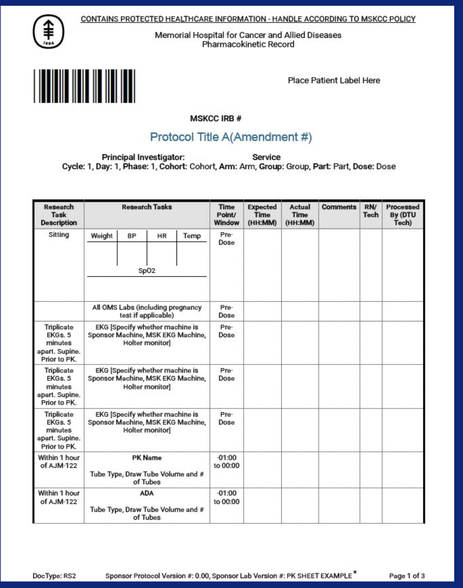
Future Directions

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.

Example of a Standardized Template from the PK Tool Application



CONTAINS PROTECTED HEALTHCARE INFORMATION - HANDLE ACCORDING TO MSKCC POLICY

Memorial Hospital for Cancer and Allied Diseases
Pharmacokinetic Record

Place Patient Label Here

MSKCC IRB #

Protocol Title A(Amendment #)

Principal Investigator: Service
Cycle: 1, Day: 1, Phase: 1, Cohort: Cohort, Arm: Arm, Group: Group, Part: Part, Dose: Dose

Research Task Description	Research Tasks	Time Point/ Window	Expected Time (HH:MM)	Actual Time (HH:MM)	Comments	RN/ Tech	Processed By (DTU Tech)
Sitting	Weight | BP | HR | Temp; SpO2	Pre-Dose					
	All OMS Labs (including pregnancy test if applicable)	Pre-Dose					
Triplicate EKGs. 5 minutes apart. Supine. Prior to PK.	EKG [Specify whether machine is Sponsor Machine, MSK EKG Machine, Holter monitor]	Pre-Dose					
Triplicate EKGs. 5 minutes apart. Supine. Prior to PK.	EKG [Specify whether machine is Sponsor Machine, MSK EKG Machine, Holter monitor]	Pre-Dose					
Triplicate EKGs. 5 minutes apart. Supine. Prior to PK.	EKG [Specify whether machine is Sponsor Machine, MSK EKG Machine, Holter monitor]	Pre-Dose					
Within 1 hour of AJM-122	PK Name Tube Type, Draw Tube Volume and # of Tubes	01:00 to 00:00					
Within 1 hour of AJM-122	ADA Tube Type, Draw Tube Volume and # of Tubes	01:00 to 00:00					

DocType: RS2 Sponsor Protocol Version #: 0.00, Sponsor Lab Version #: PK SHEET EXAMPLE* Page 1 of 3