Integrating Technology to Support Data Management Abstraction of Adverse Events (AE) and Concomitant Medications (ConMed) from the Electronic Health Record (EHR) to Sponsor Electronic Data Capture (EDC) Systems Using Design Thinking Methodology To Increase Efficiency and Help Reduce Staff Turnover

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Background

Manual abstraction of data from a site's EHR to pharmaceutical sponsor's EDC system is labor intensive, error prone and frustrating which results in Clinical Research Coordinator (CRC) burnout and staff turnover. To reduce the time and effort of this process for data managers, a web-based application, Clinical Trials Data Hub (CTDataHub), was developed using design thinking methods. It extracts and consolidates AE and ConMed data from the EHR and displays it in a user friendly, automated, and consolidated view for easy entry into EDC forms.

Understanding the CRCs and Their Painpoints

We first conducted user research to interview 12 CRCs at MSK to understand their current workflows and painpoints. We ran 12 1-hour remote sessions – 30-minutes for observation of their current workflow followed by a 30-minute interview. We used those insights to build empathy with the coordinators and understand their data management journeys.

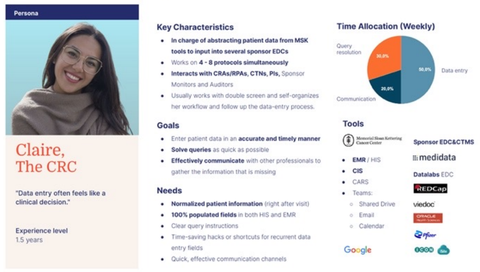


Figure 1 - Clinical Research Coordinator Persona

Our research found that CRCs oversee between 4-8 protocols at one time and spend approximately 2-15 minutes finding adverse event (AE) data, such as nausea or fever, and 30-90 minutes finding medication data per patient on a protocol each week using current clinical systems. The results from this initial user research found that CRCs spend up to 50% of their week doing data entry and that a primary, time-consuming painpoint for them is the time it takes to identify which medications are given to a patient in response to an AE.

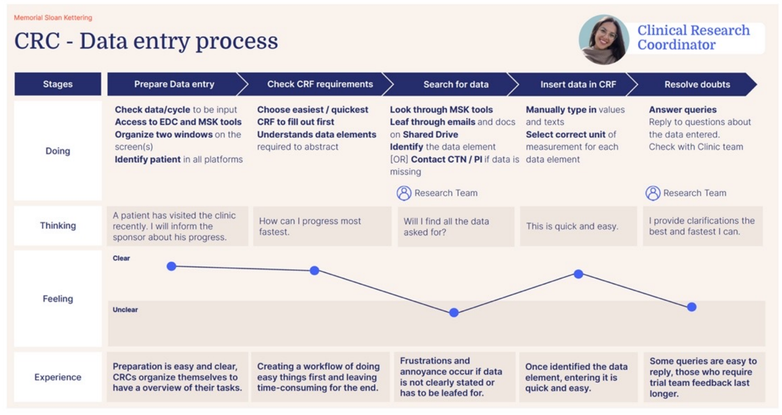
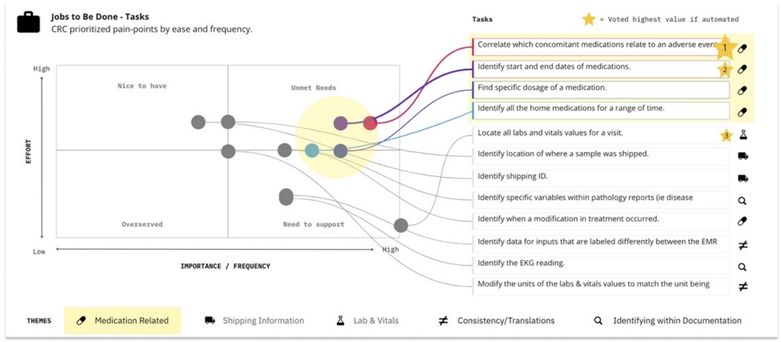


Figure 2 - Data Entry Journeymap

Defining our Focus, Together

We ran a Design Thinking workshop to prioritize which painpoint to focus on solving first. Participants included 13 representatives across Design, Engineering, Research, Product, and CRCs. Prior to the workshop, we conducted a Jobs-To-Be-Done survey to understand the greatest unmet needs and help prioritize the scope of the new solution. Participants agreed that most valuable goal of the solution would be to reduce CRC data entry time for medications and AEs by at least 25%, keep the same rate of accurate data identification, and be preferable to current clinical systems.

Figure 3 -Jobs-To-Be-Done Outcomes



Testing our Hypothesis

We developed a working proof-of-concept application, CTDataHub, using Splunk [2] as a pilot to test whether it could help reduce the time it takes to find the right medication and AE data. CTDataHub enabled CRCs to look up patients on the protocols they oversee and aggregated a single view of adverse events and medication data for those patients.

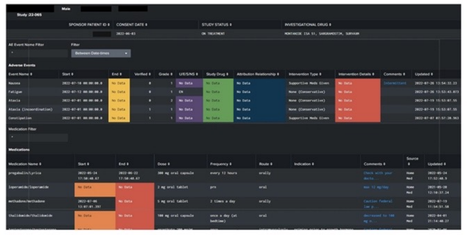


Figure 4 - Pilot of CTDataHub Developed with Splunk

To inform the desirability of features within CTDataHub, we ran a KANO [1] survey to validate which needs must be met for our tool to provide value. We then conducted A/B testing with 6 CRCs for 2 use cases (use case 1: basic easy to find medication linked to the AE, and use case 2: complex, where the medication linked to the AE was buried in a 33-page document) using their current workflow (A) versus CTDataHub (B) where a 5-minute training occurred prior to testing. We hypothesized that CTDataHub would outperform current systems across 3 primary outcomes: 1) correct data identification, 2) time to identify data, and 3) using a modified Single Ease Question (SEQ) rating scale to assess how difficult users found the task.

Results

The results of A/B testing are below in Figure 5.

	Use Case 1		*Use Case 2 (more complex)*	
	Current clinical systems	CTDataHub	Current clinical systems	CTDataHub
Correct data identification rate	83%	80%	50%	75%
Time to identify data (minutes)	10.25	7.25	8.37	3.38
SEQ (1 = difficult, 5 = easy)	2.9	4	2	4.25

Figure 5 - Results of A/B Testing

Use case 1 showed that CRCs using CTDataHub reduced the time to find a medication linked to an AE by 41%. The rate of correct identification was 3% higher for current clinical systems, and the easiness for which they completed the use case scored higher by 1.1 points for CTDataHub. Use case 2 showed that CRCs using CTDataHub reduced the time to find one medication linked to an AE by 148%, saving ~5 minutes in one task. The accuracy of the data identified increased by 25%, and CTDataHub scored 2.25 points higher on ease of use than current clinical systems. 5 of 6 participants preferred CTDataHub to existing clinical systems. CTDataHub shows higher likelihood to decrease time spent finding medication and adverse event data for patients with more complex use cases, such as having a longer medication history or higher-than-average volume of medication and AE documents within the EHR. This research was conducted in Jan-Aug 2022.

Limitations and Confounding Factors

The first limitation for the A/B testing was the small sample size of 6 participants. Our survey and behavior data are subject to positive experience bias due to experiencing CTDataHub one time for < 1 hour through curated use cases which were chosen based on completeness of data. Working with live data created minor variability between test sessions.

Conclusion and Future Direction

Our pilot findings suggest that CTDataHub allows CRCs to 1) identify AE and ConMed data required for EDCs more quickly than in current workflow, 2) identify data more accurately to be entered in sponsor EDCs, and 3) perceive the task of identifying this data to be easier. CTDataHub reduces the time CRCs spend searching clinical systems and documents and has the potential to save meaningful time per patient per study. This type of time-saving data abstraction can expand beyond ConMed and AE data to other clinical data such as lab results, shipping IDs and biospecimen data. CTDataHub will launch into production in July 2023.

Figure 6 - Screenshot of CTDataHub

Digital product development using design thinking methodology has the potential to improve operational efficiency and the clinical staff user experience. This is particularly important in an industry that has struggled with burnout, cost containment, and high turnover.

References

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