

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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1. 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 data manager (DM) burnout and staff turnover.

2. Goals

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.

3. Solutions and Methods

Following design thinking methodology to develop CTDataHub, we interviewed 12 DMs to identify data entry bottlenecks, and ideated solutions. To evaluate CTDataHub's value, we built a functioning prototype using Splunk and conducted pilot A/B testing with 6 DMs for 2 use cases (Case 1: basic easy to find ConMed linked to the AE, and Case 2: complex, where the ConMed linked to the AE was buried in a 33-page document) using their current workflow (A) versus CTDataHub (B) where a five-minute training occurred prior to testing. We hypothesized that CTDataHub would outperform current workflows across three 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. This study was conducted in Jan-Aug 2022 at a large single-center cancer hospital.

4. Outcomes

DMs spend ~20 hours/week on data entry; the majority of which is spent searching the EHR for which ConMeds are associated with an AE. A/B testing results are noted in Table I (shown in the uploaded file).

Use case two showed that DMs using CTDataHub reduced the time to find one ConMed linked to an AE by 148 percent, saving ~five minutes in one task. Five of six participants preferred CTDataHub to existing clinical systems.

5. Lessons Learned and Future Directions

Our pilot findings suggest that CTDataHub allows DMs 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 DMs spend searching clinical systems and documents and has the potential to save meaningful time per patient per study. CTDataHub will launch into production in May 2023.

Digital tool 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.

Figure

Table 1

	Use Case 1		Use Case 2 (more complex)	
	Current	CTDataHub	Current	CTDataHub
Correct data identification	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