Category: Training, Career Development, and Staff Retention – Work in progress

An Application that Extracts and Consolidates Adverse Events (AE), Concomitant Medication (ConMed), and Laboratory Results Data from Clinical Systems to Increase Clinical Trial Data Entry Efficiency, Trust, and Satisfaction

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1. Background
Manual abstraction of data from a site's clinical systems to a biopharmaceutical firm's electronic data capture (EDC) system is inefficient and error prone.

2. Goals
In partnership with data managers (DMs), we used a human-centered design thinking methodology to create a web application, CTDataHub, to reduce the effort associated with this process. CTDataHub extracts and consolidates AE, ConMed, and Lab's data from clinical systems and displays it in a user-friendly view for easy entry into EDCs.

3. Solutions and Methods
CTDataHub was launched to DMs in July 2023 at a large, high-volume academic cancer center. To evaluate the app's impact on DMs, we assessed: 1) App usage, 2) data entry efficiency, 3) trust in data (data is correct to enter in sponsor EDC) assessed via a 5-point Likert attitudinal trust scale, and 4) satisfaction using Net Promoter Score (NPS) by comparing two surveys. Survey 1 (*S1*) was sent to 313 DMs prior to receiving access to CTDataHub to establish a baseline. Survey 2 (*S2*) was sent to 102 meaningful users of CTDataHub; those who used the app and viewed data pages at least 10 times between 09/01/23-01/26/24. Behavioral usage on CTDataHub was tracked using Heap Analytics.

4. Outcomes
App Use
S1 had an 82 percent response rate (n=258), and *S2* had a 42 percent response rate (n=43); with all respondents of *S2* completing *S1*. Two invalid responses from *S2* were excluded from analysis. Meaningful use DMs in *S2* (102) used CTDataHub to view data 8,157 times, with 77 percent copying data values directly from the app (3,366 times) for abstraction.

Data Entry Efficiency
On average, *S1* respondents spend 10.2 hours/week abstracting AEs and ConMeds. In *S2*, the app increased DM efficiency by reducing average data abstraction time 22.85 percent (2.5h). Most respondents (77 percent, n=33) reported CTDataHub increased efficiency, 21 percent (n=9) noted no impact, and 7 percent (n=3) reported decreased efficiency by 18 percent. Notably, time savings were greater for DMs who used the app who were new to their role (<1 year) versus seasoned DMs (>1 year); 31 percent vs. 14 percent.

Trust in Data
DMs responded that CTDataHub was more likely to correctly retrieve ConMed, AE, and Lab's data when compared to their manual methods (4.12 mean (n=43) vs. 3.46 mean (n=258) on a 5-point Likert trust scale.

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App User Satisfaction

NPS for CTDataHub versus DM standard workflows using various clinical systems (on average 2.5 systems) used for data entry was 25.6 compared to 2.3, likely due to its ease-of-use.

5. Lessons Learned and Future Directions:

CTDataHub decreased data abstraction times for AEs and ConMeds for 77 percent of meaningful users by an average of 2.5h/week relative to other clinical systems. In addition to DM satisfaction, the app increased trust in data being abstracted. The app will be enhanced with additional data sets (tumor response) and automated EHR2EDC capabilities.