CTDataHub: 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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Background

Clinical Research Coordinators (CRCs) play a critical role in the completion of clinical trials, conducting extensive data work to support the clinical research team. The manual abstraction of data for clinical trials from a site’s various clinical systems to biopharmaceutical firm’s electronic data capture (EDC) systems is labor intense, open to errors and inefficient, and can risk delaying the completion of a trial. The volume of data collected in oncology trials has an average number of 10,000 data points entered per patient.

Archetype

Using human-centered design thinking methodology in partnership with CRCs at MSK, we created a web application, CTDatahub, to reduce the time and effort associated with this process for clinical research coordinators (CRCs). CTDatahub extracts and consolidates AEIs and concomitant data from clinical systems and displays it in a user-friendly view for easy entry into EDCs. CTDatahub was launched and rolled-out to CRCs to 313 CRCs between July - December 2021.

Methods

To evaluate CTDatahub's impact on CRCs, we assessed: 1) CTDatahub usage, 2) data entry efficiency, 3) trust in data (data is correct to enter in sponsor EBC) 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 CRCs prior to receiving access to CTDatahub to establish a baseline of current clinical systems such as CIS, EMR, CTMS. Survey 2 (S2) was administered to 59 meaningful users of CTDatahub; those who used and viewed a patient data page at least 10 times between 09/01/23-10/31/23. S1 had a 72% response rate (n=225), and S2 had a 51% response rate (n=30); with all respondents of S2 completing S1. Behavioral usage on CTDatahub was tracked using Heap Analytics.

Results

1. Efficiency: CTDatahub is saving CRCs time on data entry.

Respondents reported an average decrease in time spent of 18% (2h/week). 70% of meaningful users reported that using CTDatahub decreased the time they spend on data related activities, 20% noted no impact, and 10% reported increased time. The decrease in time was greater with CRCs that had less than 12 months of experience in their role.

2. Satisfaction: CTDatahub scored higher than other clinical systems.

CTDatahub has proved to be an easier, more satisfying data entry experience relative to previous methods. The NPS for CTDatahub versus other clinical systems (on average 2.5 systems) was 23 compared to 4.

3. Trust: CTDatahub scored higher than other clinical systems.

CRCs reported that CTDatahub was more likely to correctly retrieve ConMed and AE data when compared to other clinical systems. One possible reason is that CTDatahub provides a holistic and transparent view of what data is available and what is missing. This enables CRCs to uncover potential issues with the data quality more quickly.

Conclusion

Our preliminary data shows that CTDatahub has decreased data abstraction and entry time for AEIs and ConMed for 70% of meaningful users by an average of 2h/week relative to other clinical systems. CTDatahub increased trust in data being abstracted, and user satisfaction increased. As meaningful usage increases, we will continue to compare how CTDatahub use versus traditional workflows impact CRC efficiency, trust in data, user satisfaction, and accuracy. CTDatahub will be enhanced with additional data sets (site local labs, vitals, tumor response) and automated EHR/EDC capabilities in 2024.

CRC Quotes

"Nobody gives us attention as much. We have to work with what the clinicians and nursing do, so it's nice to be getting attention on how to make our lives easier so I appreciate that."

"CTDatahub definitely helps to consolidate a lot of the information very well! Makes it easier to retrieve medications off of first glance."

"I have previously worked as a CCI in Rad Onc for 2.5 years so I was familiar with where to access this information but having it all in one spot that is easy to use is a great improvement. I love the copy and paste feature and the ability to search for a specific conmed or AE."