Category: Trial Recruitment and Study Conduct (IITs) - Work in Progress

Improving Data Entry for Clinical Trials: A Review of REDcap's Clinical Data Pull in the Clinical Research Setting

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1. Background

In investigator-initiated trials (IITs), the online software, Research Electronic Data Capture (REDCap), is a common data collection tool. Entering clinical data parameters such as laboratory results and vitals into REDCap can be time-intensive, inefficient, and error-prone. Clinical data pull (CDP) is a REDCap feature that uses Fast Healthcare Interoperability Resources to automatically retrieve these clinical data parameters from the electronic medical record and import these results into data capture forms within REDCap.

2. Goals

Our project demonstrates CDP's ability to increase the speed and accuracy of data collection for IITs.

3. Solutions and Methods

The investigators compared the speed of data entry into a CDP-enabled database to two similar databases without CDP functionality. The metric for speed was the time taken to complete the visit's data entry divided by the number of data points entered per study visit. All databases were for IITs at the Perlmutter Cancer Center and required similar data entry. Staff entered 75 different patient visits (N=36 with 1409 data points for CDP enabled, and N=39 with 862 data points for manual entry) with an average of 30.28 data points of clinical laboratory results per visit. A one-tailed Wilcoxon Rank Sum Test tested our hypothesis that CDP increases data entry speed.

To determine accuracy, we checked a random sample of 1126 data points from the CDP-enabled database against the original values displayed in the EMR. A binomial test ensured our measured amount of error was less than 5/1000, one-tenth of our error of five percent in non-CDP enabled databases. We used R Studio enabled with R Version 4.2.2 and GGPlot2 for statistical analysis and data visualization.

4. Outcomes

The mean time per data point with CDP was 1.58s as opposed to 5.41s without CDP (Plot 1). The Wilcoxon Sum Rank Test showed that this difference of 3.83 was significant with a p-value of less than 2 x 10-16. Furthermore, CDP also reduced the standard deviation of time spent inputting lab results from 1.56s in databases without CDP to 0.58s in databases with CDP. We found zero errors in the 1126 data points we randomly sampled, and our binomial test was significant with a p-value of 0.003538 and a 95 percent confidence interval of 0 percent to .26 percent error for the CDP-enabled database.

5. Lessons Learned and Future Directions

Informatic tools like CDP will improve clinical data collection in future IITs. We have seen that CDP is superior to manual input due to its increased speed and accuracy. In 2022, our research team entered approximately 90,000 data points into manual entry REDcaps. CDP usage would have eliminated 4200 data errors and reduced the time spent on data collection by 25 hours (i.e., approximately $1000 salary support) across 3 active studies.

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As we continue implementing CDP, we will compare it to manual data entry and validate our results in other disease groups and studies. We will also investigate how CDP collects data outside the parameters used in this abstract, including demographic and medication data.

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