A More Efficient Approach to Clinical Trial Data Collection: The SWOG-nCartes Pilot Collaboration

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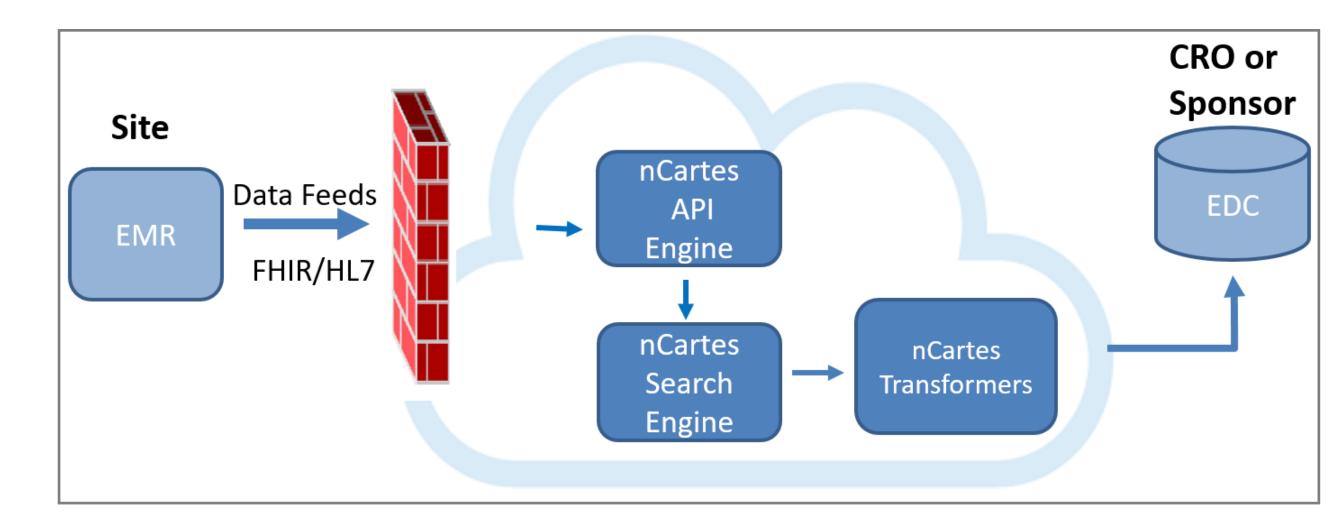
Abstract

Collecting clinical trial data can require duplicative and time-consuming data entry. Data are often entered into the medical record and then have to be re-entered into a separate, differently structured Electronic Data Capture (EDC) system for research purposes. This duplicative process can be laborious, expensive, and error-prone. This process remains in place for many sites due to the difficulty of harmonizing data structures across disparate sites and the lack of widely adopted standards.

Although there are large efforts to standardize medical records to ease data integration (e.g., mCODE), these efforts that take time and data across locations can still have many attributes unique to each site. In the SWOG Cancer Research Network's case, there are 1,200+ sites across 47 US states and seven countries. It's difficult to get all of these organizations to collect data in the same manner without doing redundant data entry. Accordingly, SWOG is investigating an approach using a cloud software platform called nCartes to largely automate the transfer of research data from the site medical record system to the research database. The nCartes system, developed by nCoup, allows for a single, consistent point of contact for data extraction from the medical record system to the EDC system. It also enables SWOG to have access to the relevant research data without access to the sensitive personal health information contained in medical records.
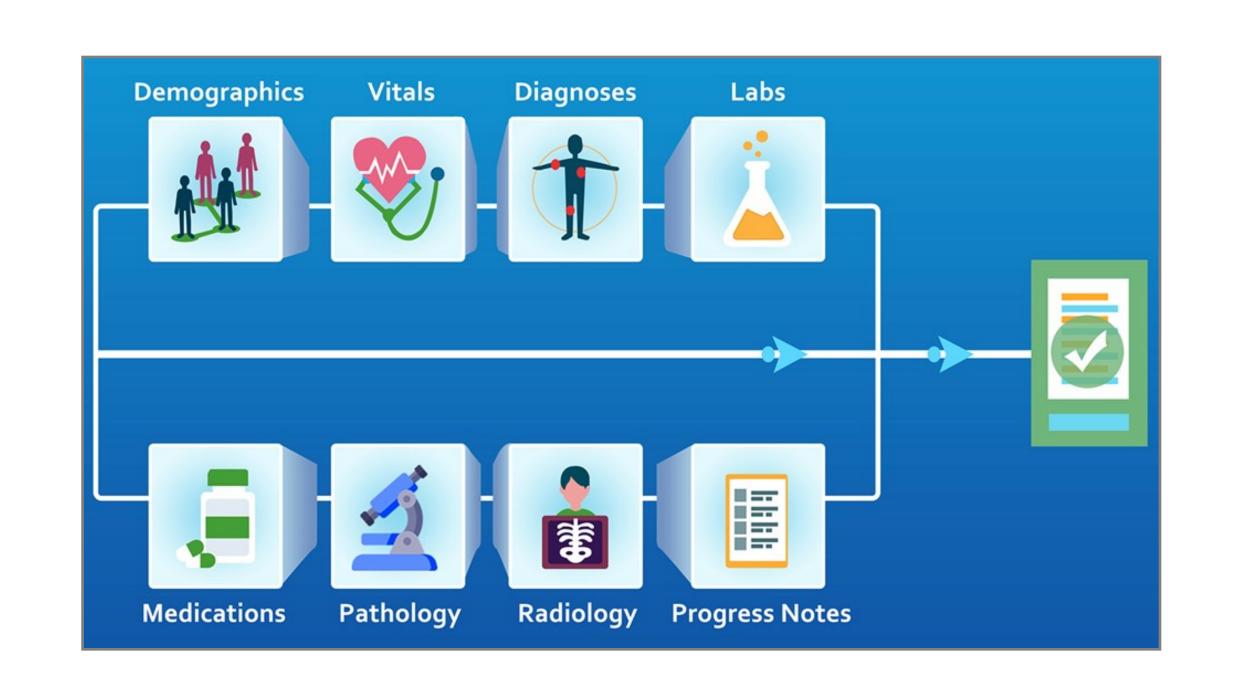
SWOG has been working with nCoup to pilot this approach on three of its active trials. As of October 2021, the system is in User Acceptance Testing (UAT) and will be launched at three sites. Preliminary findings are below.
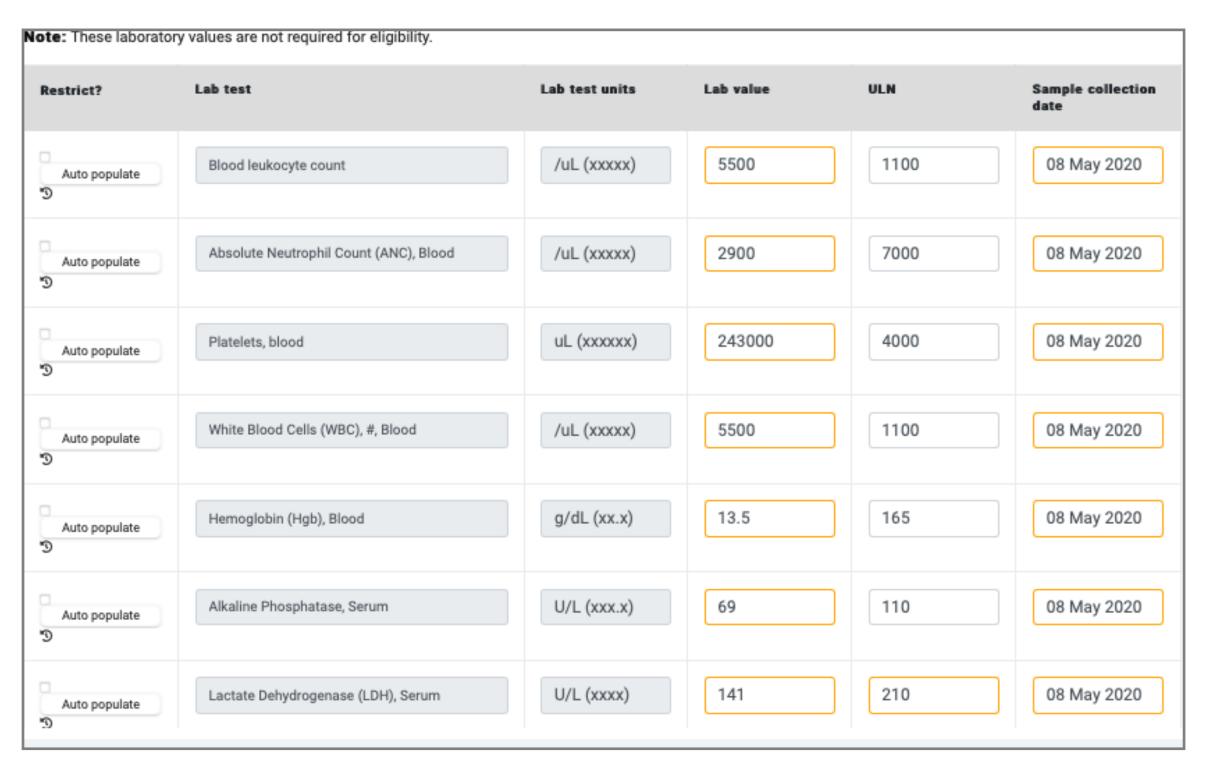
Background

An ideal data entry model is that data are entered once and that data can be easily reused downstream in other systems without any duplicative manual data entry. The SWOG Cancer Research Network has been investigating ways to enhance and automate data entry to help improve site efficiency and overall data quality. In 2021, SWOG partnered with nCoup to deploy their nCartes system at SWOG sites to help advance data collection. With nCartes, the site enters their data once into the Electronic Medical Record (EMR) and the data (e.g., labs, medications) are automatically fed to the nCartes system and prepared for the EDC. Below is a systems diagram of this process that shows how data feeds and nCartes processing are managing most of the data migration instead of a study coordinator manually copying data to an EDC system.
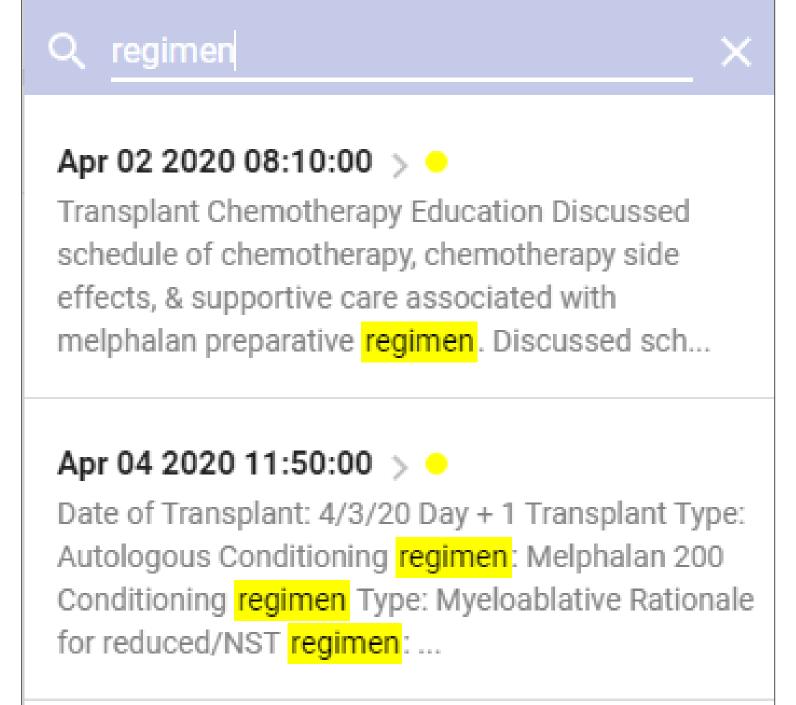

Data that are already well structured in the EMR system have the most potential to see efficiency gains. These data include demographics, vital signs, labs, and medications.

While the nCartes system is optimized for structured data similar to the lab form example below on the left, the nCartes system also allows sites to fill in any additional unstructured data. Some unstructured data (e.g., progress notes) can be made simpler to input via their search tool that's depicted below on the right. Within nCartes, users can search the progress notes to look up information more easily and/or copy and paste information from the notes.
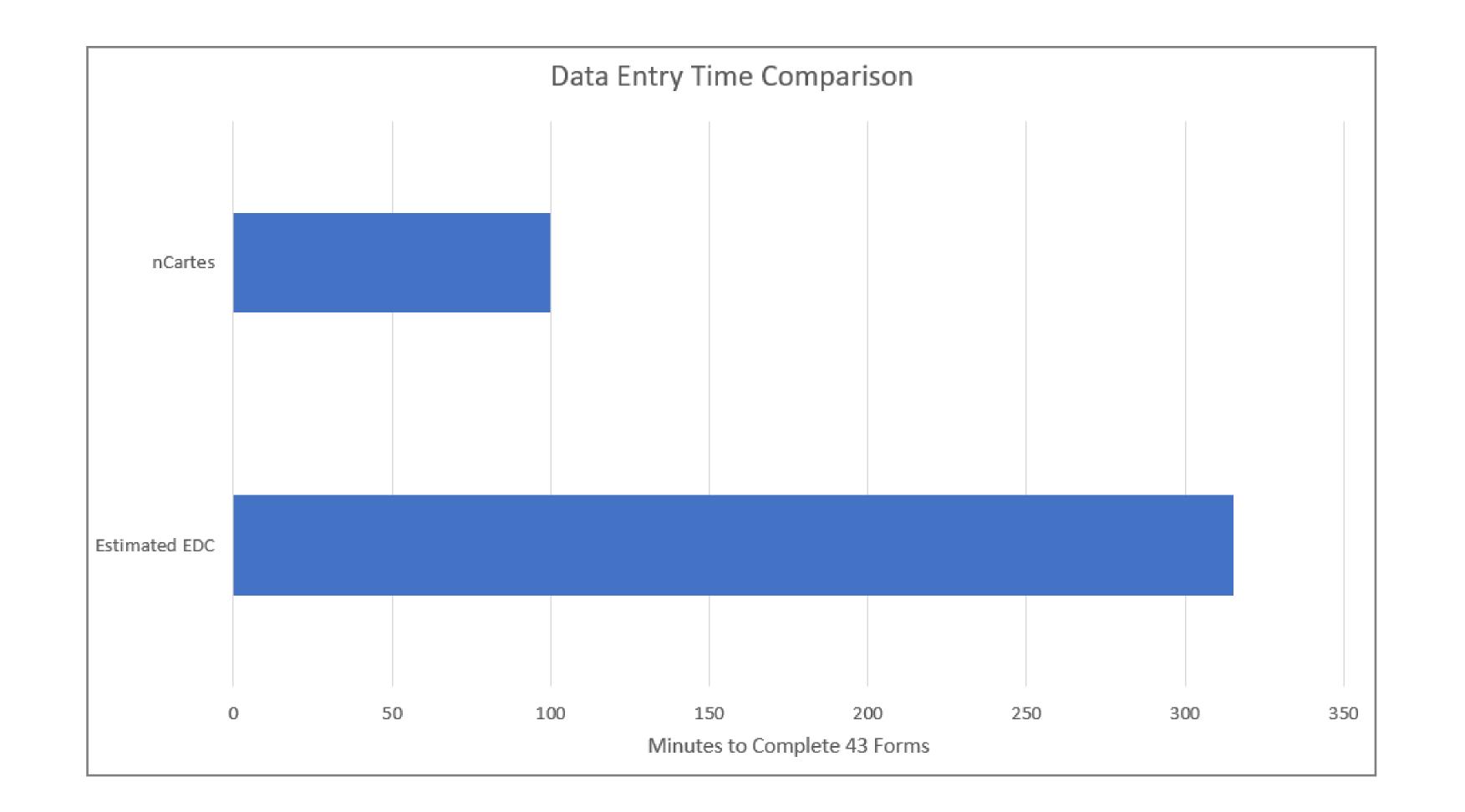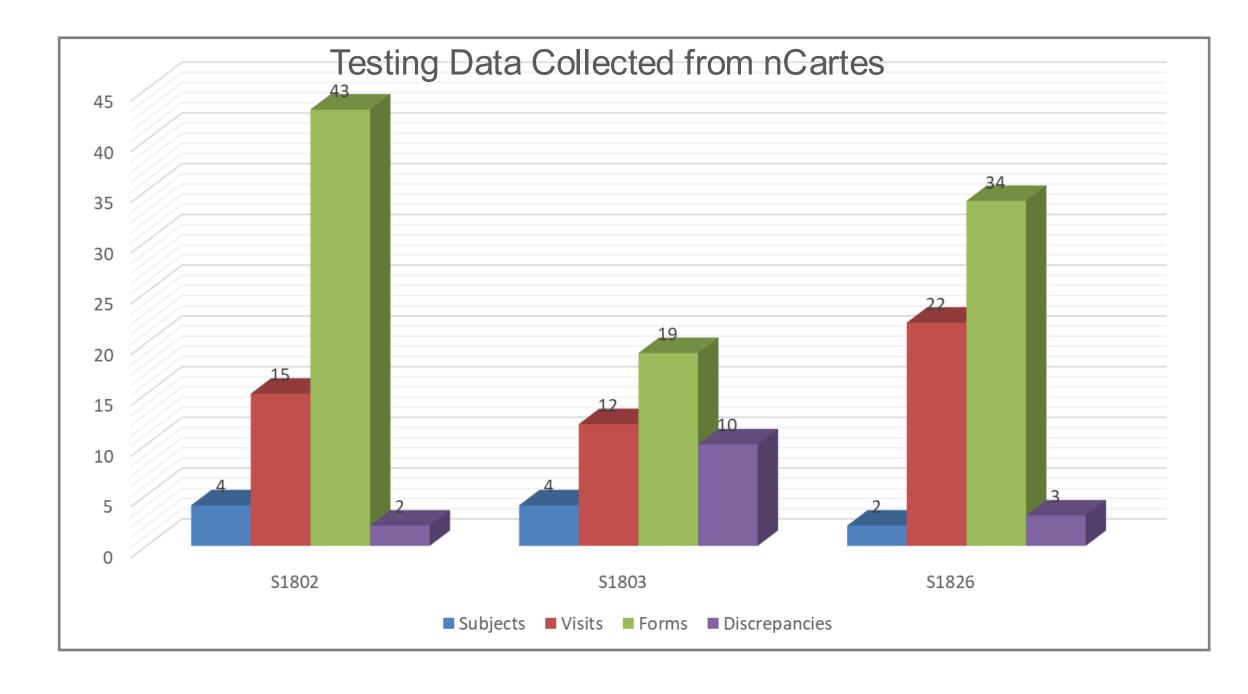

Early Testing Results

In October 2021, testing started on the nCartes system with SWOG forms and data. During the later phases of testing conducted in April 2022, the results of data entry using the nCartes system were compared to those using a traditional EDC entry method. Both time spent doing data entry and accuracy were measured.

To measure time of data entry, an experienced study coordinator was timed entering 43 forms using the nCartes system. It took 100 minutes to complete all forms or 2 minutes and 20 seconds per form. The study coordinator estimated an average time savings of 5-15 minutes on forms that auto populate utilizing nCartes in the future.

To measure accuracy, we compared data that were entered into the nCartes system to already entered EDC data that didn't use nCartes. We looked at 10 patients across three studies (S1802, S1803, and S1826) and 93 form submissions. Fifteen data discrepancies were found out of the 1605 data points between the two methods. The nCartes data entry had approximately 1.5 fewer errors per patient relative to the EDC. Data discrepancies were most common with lab forms. Ten out of the 15 discrepancies were related to lab data. Below are the results broken down by study.

Next Steps

The early results from UAT testing indicate that the nCartes system is capable of both saving study coordinator time and helping reduce data entry error. The early data also indicate, as expected, that these effects are more pronounced on structured forms such as lab forms. Since the data are limited and it's still early in the project, more data will need to be collected to determine a) the degree to which these results are generalizable and b) amount of value that can be achieved through automated capture of structured versus unstructured data.

SWOG plans to launch nCoup into production for three studies in June 2022 and continue to gather more data on the effectiveness of this system. Additionally, four additional studies are currently being planned. It is the hope that many of these benefits will be magnified as more data entry is automated through this system.

Acknowledgements