Streamlining Data Collection: Building a Bridge between the Source and the Electronic Data Capture System

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

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Erin Crecelius, MA; Mary O'Dwyer, MRP, CCRP; Leilani Barry Logan, MSc; Saianand Balu, MS; Jill Frank, MS; Robin V. Johnson, M.Med.Sc.; Randy Church; Carrie B. Lee, MD, MPH; J. Kaitlin Morrison, PhD

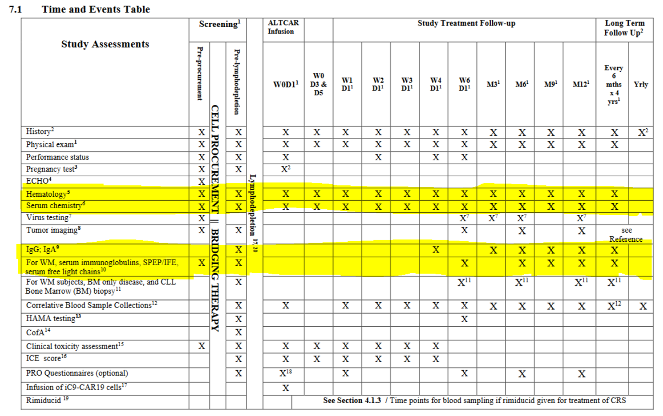
Background & Goals

Manual data entry of clinical trial data into Electronic Data Capture (EDC) systems consumes significant time and effort. A large bulk of the time is spent entering lab result data. A typical investigator-initiated trial includes up to 3 lab eCRFs containing multiple lab assessed at multiple timepoints (figure 1). Lineberger Comprehensive Cancer Center (LCCC) initiated a project with the EDC system vendor, Advarra, to establish a patient information link between source system (Epic) and the Electronic Data Capture System (Advarra EDC) for LCCC sponsored investigator-initiated trial (IIT) laboratory result data. Reducing data entry time can result in effort spent on critical tasks including enrolling and managing research subjects. Manual data entry also introduces the opportunity for transcription errors resulting in an increased risk to data quality.

The goals of this project are to improve data quality by reducing transcription errors and to alleviate a portion of data entry and review burden for staff. Metrics to be used include:

- Decrease in Effort Tracking hours per month dedicated to data entry for Data Coordinators (DCs).
- Decrease in Effort Tracking hours per month dedicated to data review for Clinical Data Management Associates (CDMAs).
- Decrease query rate.
- Decrease in query response time for CDMAs and DCs.

Figure 1. Example Time and Events Table

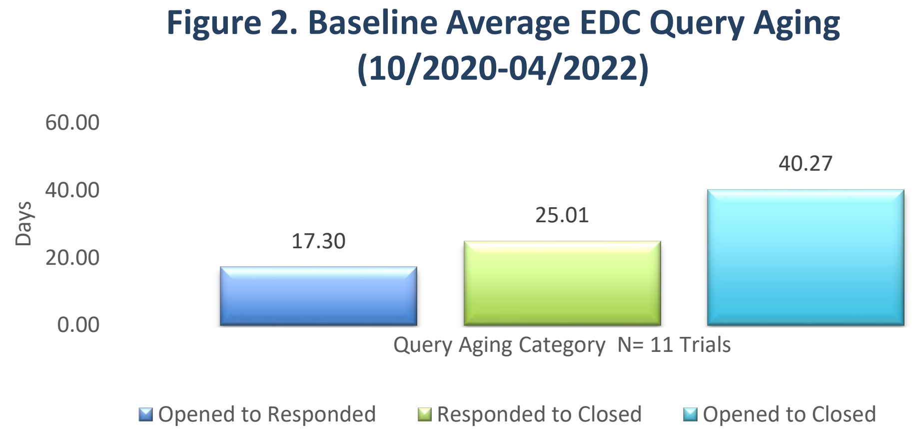


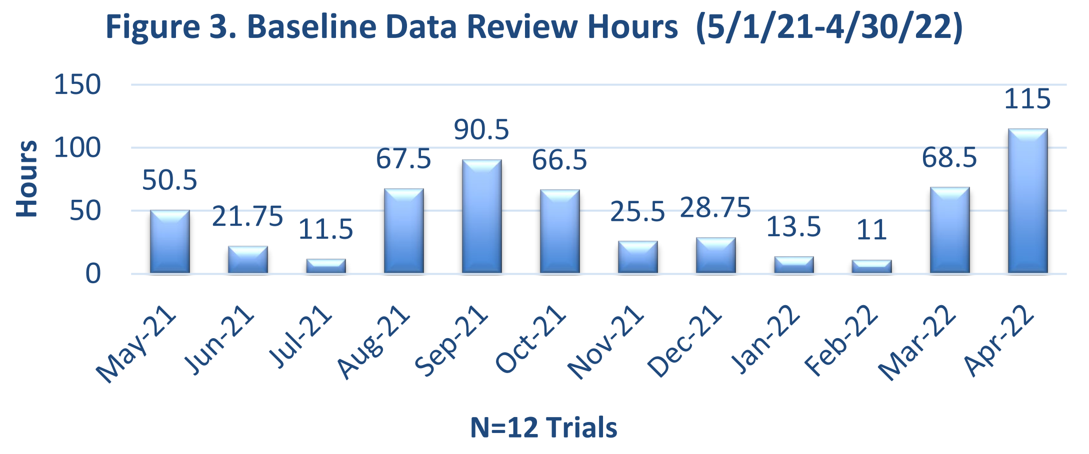
Preliminary Results

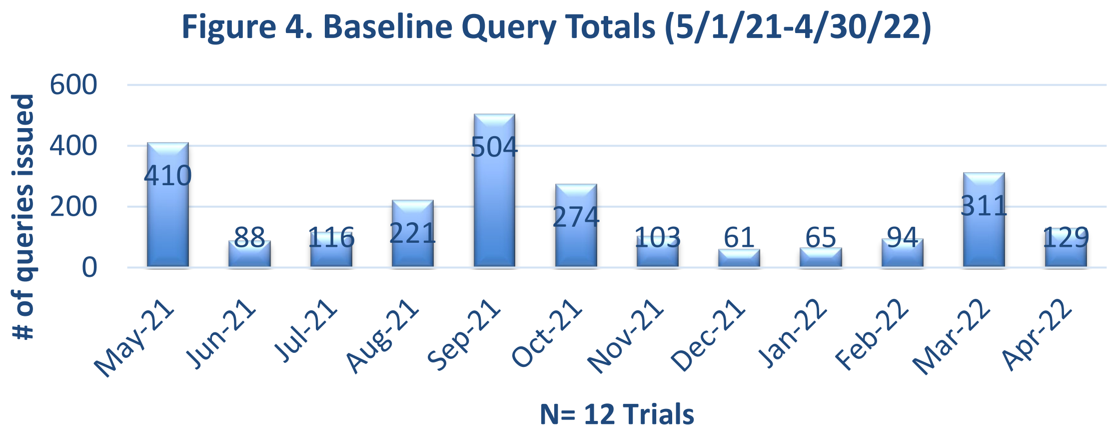
This project is in progress. We will analyze data from protocol data timeliness reports, query metrics, and effort tracking data at baseline and six- and twelve-month post integration to determine the success of project outcomes.

At baseline, data coordinators spend on average 27.5 hours per week manually entering IIT data into the EDC system. Estimates were based on data entry for 11 trials.

The following graphs depict baseline metrics







Conclusions and Future Directions

As the LCCC IIT portfolio grows, there will be an even greater need to assess and streamline data collection. The adoption of CDASH data standards and the growth of a global eCRF library will enable future integrations. This includes additional FHIR mappings for demographic, vital sign, adverse event, and concomitant medication eCRFs published in the FHIR to CDISC Joint Mapping Implementation Guide. There are a large number of trials that remain in the legacy EDC system and, therefore, are not included. Additionally, the data volumes may be less than typical due to rolling accrual holds related to staffing shortages during the measured time period.

Methodology

We established a project team comprised of staff from UNC Health, LCCC Bioinformatics Core, and the EDC vendor (Advarra) to plan the implementation of a patient information interface between Epic and the EDC System.

The lab results interface will pull lab results into electronic Case Report Forms (eCRFs) using SMART on FHIR authentication to the source system. SMART on FHIR together create a standardized way of exchanging data among healthcare systems. The user is temporarily forwarded to the Epic login page to enter their Epic credentials.

Once logged into Epic, access to data will be based on their role and permissions within the source system. When users search for subjects using the medical record number, PHI will be displayed for data selection but not saved in the EDC system (Figure 5). The integration was validated by the vendor in test environments and maps FHIR Observation codes to Advarra EDC lab codes.

Following the UNC FHIR interface build, UNC project team members will validate the integration in the EDC Test instance. The laboratory eCRF will be built using Clinical Data Acquisition Standards Harmonization (CDASH) data standards to enable cross study implementation.

Figure 5. Example search functionality in EDC (provided by vendor, Advarra)