*Category: Investigator-Initiated Trials – Work in Progress*

**Streamlining Data Collection: Implementation of an EDC FHIR Lab Interface**

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**1. Background**

Manual data entry of clinical trial data into electronic data capture (EDC) systems consumes significant time and effort for data and study coordinators. 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. Based on effort monitoring, it is estimated data coordinators spend up to 32 hours per week manually entering data into the EDC system. 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.

**2. Goals**

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) and data review for clinical data management associates (CDMAs)
- Decrease in data latency and reduction in query rate
- Decrease in query response time for CDMAs and DCs

**3. Solutions and Methods**

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 link between Epic and the EDC system. The lab results interface will pull lab results into electronic case report forms (eCRFs) using SMART on Fast Health Interoperability Resource (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. 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.

**4. Outcomes**

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

**5. Lessons Learned 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.