Category: Cross-Cutting Innovation and Collaboration – Work in Progress

Bridging the Resource Gap: Implementing EHR-to-EDC Integration in Investigator-Initiated Oncology Trials

A. Martin[1], L. Snodgrass[1], M. Lieber[2], M. Boyd[2], K. Moore[2], D. Raine[2], D. Binder[1], T. Drumm[1]

[1]University of Colorado Cancer Center; [2]Paradigm Health

1. Background

Investigator-initiated trials (IITs) constitute a significant portion of a cancer center's clinical portfolio. These trials face distinct operational hurdles, including limited funding compared to industry-sponsored studies, while still requiring high-volume, complex data entry. Utilizing electronic health record (EHR) to electronic data capture (EDC) software is an emerging strategy to bridge this gap ensuring data integrity and operational efficiency in resource-constrained environments.

2. Goals

To deploy the clinical pipe (CP) EHR to EDC solution on an IIT utilizing REDCap as the EDC.

3. Solutions and Methods

Our radiation therapy (RT) research and IIT teams partnered with a technology vendor to initiate a pilot to integrate EHR-EDC technology within an activating IIT in our center's research portfolio. Selection criteria included use of REDCap, no required FDA registration, and an early 2026 activation date. We evaluated the feasibility of technology integration, the resources needed, and the time for implementation.

4. Outcomes

Project team. Seven internal staff, spanning the IIT, REDCap, and EHR teams, collaborated with the vendor's management and technical leads to align requirements and workflows.

Trial selection. We selected a Phase II, single-arm rectal cancer IIT for this pilot based on its size, timeline, and strong investigator engagement. The trial evaluates high-dose-rate (HDR) brachytherapy to improve organ preservation following Total Neoadjuvant Therapy.

Execution. Implementation began with REDCap database development and provision of administrative access. The timeline from selection to mapping was three months. We demonstrated technical compatibility for automated transfer of laboratory values, vitals, adverse events, medications, and medical history (21 percent of total fields). As this technology was previously installed at our site, no additional funding was required. Study staff training was offered free of charge.

The RT clinical research team received a 30-minute training on how to use CP, while also providing feedback to make integration more successful. In addition, the research team will receive additional written guidelines on the use of CP after the first patient enrollment.

The pilot successfully resulted in the launch of CP on 03/02/2026, with the first data transfer anticipated concurrent with the first participant enrollment.

5. Lessons Learned and Future Directions

The site-by-site configuration of REDCap presented a potential bottleneck for multi-site rollouts. Privacy and security concerns, along with complex institutional structures, served as the primary implementation hurdle. Additionally, due to the emerging nature of the solution, extensive investigation and foundational infrastructure work were necessary.

This technical pilot successfully demonstrated that applying EHR-EDC technology to an IIT is feasible with minimal resources deployed at a site where the technology is already installed. While the initial application involves numerous procedural steps, future deployments may become more repeatable and efficient. As efficiencies are quantified with increased use of these solutions, the funding necessary to scale the solutions across a site portfolio is likely to be offset by reductions in staff efforts, such as manual data entry and monitoring review of data.