

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

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

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.

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.

Project Team

Seven internal stakeholders across IIT, REDCap, and EHR teams partnered with vendor management and technical leads to align on requirements and workflows.

Execution

Implementation initiated with REDCap database development and administrative access setup.

Timeline from selection to data mapping:

3 months

Enabled automated transfer of key data:

- Laboratory values
- Vitals
- Adverse events
- Medications
- Medical history

21% of total fields mapped

Study staff training provided at no cost

Existing infrastructure allowed deployment with no additional funding required

Trial Selection

A Phase II, single-arm rectal cancer IIT was selected based on:

- Manageable size and timeline
- Strong investigator engagement
- No required FDA registration

Training & Adoption

- RT clinical research team completed a 30-minute CP training session
- Feedback was incorporated to optimize integration
- Additional written guidelines to be provided after first patient enrollment

Outcome

- CP successfully launched on 03/02/2026
- First automated data transfer expected at initial participant enrollment

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.

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