

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Work in progress

Elevating Trial Operations: Implementing EHR to EDC Interoperability to Reduce Site Burnout and Data Entry Burden

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1. Background

Cancer research sites face increasing clinical trial complexity amid persistent staffing constraints. Manual transcription of clinical data from Electronic Health Records (EHR) into Electronic Data Capture (EDC) systems remains a major source of operational inefficiency, contributing to data quality issues, delayed timelines, and significant coordinator burnout. As trial demands grow, EHR-to-EDC interoperability has emerged as a promising strategy to streamline workflows and strengthen data integrity. However, successful implementation requires coordinated technical, operational, and organizational change.

2. Goals

This project aims to provide a practical, evidence informed framework for cancer centers seeking to implement EHR-to-EDC interoperability. Specific objectives include:

1. Describing validated strategies for selecting and integrating EHR-to-EDC solutions within complex research environments
2. Identifying best practices for change management, staff training, and sustained adoption
3. Demonstrating approaches for measuring impact using key performance indicators (KPIs) such as data quality, query reduction, workflow efficiency, and staff satisfaction

3. Solutions and Methods

This work-in-progress leverages real-world implementation experiences from cancer research sites that have deployed EHR-to-EDC solutions. Methods include structured case studies and facilitated discussion focusing on:

- **Selection Strategy:** Evaluation criteria, site readiness considerations, and single- versus multi-vendor approaches.
- **Approval and Governance:** Engagement of IT, compliance, research leadership, and operational stakeholders.
- **Implementation and Change Management:** Site preparation, training models, workflow redesign, and ongoing support structures.
- **Measurement:** Collection and analysis of operational metrics related to data quality, staff burden, and trial efficiency.

4. Outcomes

Preliminary outcomes demonstrate meaningful operational improvements, including reduced manual data entry, improved data consistency, and early indicators of decreased site burden. Participants gain a

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replicable framework for implementation, practical insights into overcoming institutional barriers, and a clear understanding of how to measure the operational impact of EHR-to-EDC interoperability.

5. Lessons Learned and Future Directions

Key lessons highlight that interoperability success depends on cross functional collaboration and proactive change management. Automation improves data integrity while simultaneously reducing staff burden. Future directions include expanding interoperability to unstructured data sources, integrating predictive analytics for trial feasibility and prescreening, and connecting EHR/EDC workflows with additional research systems to create a more harmonized research ecosystem.