

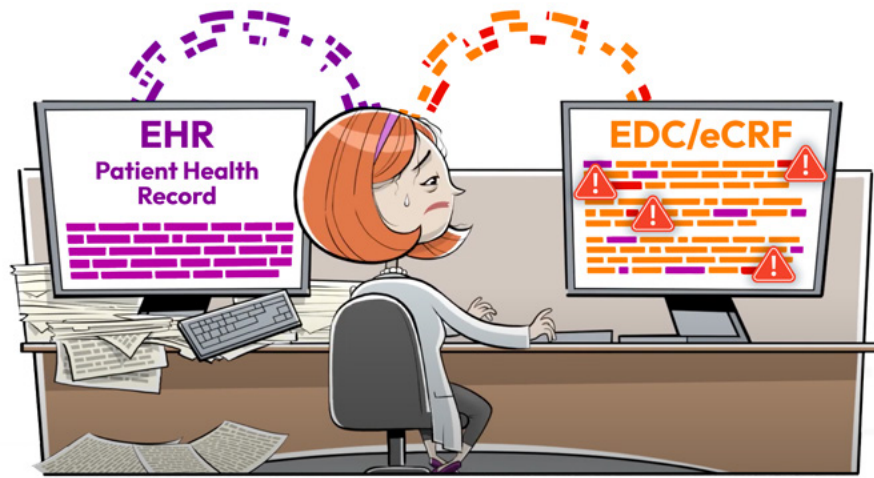
OPENCLINICA CASE STUDY

Data Confidence, Financial Gains: The Business Case for EHR eSource in Clinical Trials



Background

A major bottleneck and expense in clinical trials is the manual collection and abstraction of clinical data from medical records. This expense is further exacerbated by human errors that require additional investments in data cleaning and validation. Further, manual abstraction is a significant source of stress and burnout for many clinical research coordinators (CRCs).



This compromised data not only hinders sponsors' ability to make well-informed decisions, but also leads to valuable time lost while patients await treatments – thereby intensifying the urgency of the clinical trial timeline for both patients and sponsors.

Challenge

The goal of one multicenter phase 2 platform trial – an adaptive platform trial of repurposed therapeutics for patients hospitalized with a severe infectious disease – was to enroll 100 percent of patients hospitalized in intensive care units meeting the study criteria. Since the enrolled patients were hospitalized, CRCs needed to manage data forms, concomitant medications (con-meds) and labs multiple times every day for every patient.

At the point of study activation, a digital link between the EHR and the EDC system did not exist. Absent eSource EHR integration, data generated during the first four months of the trial were completely entered into the study database manually. For clinical research coordinators, the absence of EHR data integration and automated data capture meant “entire Monday mornings and the better part of afternoons – depending on the number of subjects on study that weekend – were dedicated to pulling data for the multiple subjects over multiple days.”



As one CRC observed, “Most of this data already exists in the subject’s EHR but we wind up spending a lot of time to find that data and then copy it in the study’s EDC.”

Solution

The sponsor chose OpenClinica's eSource solution, Unite™, to accelerate the study timeline by eliminating the expense of errors associated with manual abstraction of electronic health record (EHR) data into clinical trial research databases (EDCs) and electronic case report forms (eCRFs). Unite eliminates manual data abstraction through a flexible integration framework; is launched directly within the patient's EHR patient chart; and, automatically populates the exact data required by the trial protocol into eCRFs.

Results

“Once we had that link established between the EDC and the EHR, I was able to enter an entire weekend's worth of data completely and accurately within minutes.”

-Clinical Research Coordinator

After just eight of the eventual 30+ trial site deployments in the multicenter phase 2 platform trial, the team studied the impacts of EHR to EDC integration. In addition to concluding the study ahead of schedule, the use of EHR eSource technology resulted in:

- A 16-minute per form savings for elapsed data entry time on the primary daily eCRF, a 61 percent reduction compared to manual entry;
- For just 52 patients studied at one site with a 15-day treatment course, 208 hours of clinical research coordinator time was saved;
- The elimination of data errors by the automated, validated EHR-loaded data and the downstream costs associated with cleaning, source data verification (SDV) and validation;
- Low implementation costs, and
- Reusability across sites.



“

The switch from manual data entry to digital data transfer enabled hours of data collection work on some of the most tedious - and I would argue probably some of the most queried data - to be completely accurate in just minutes, **reducing 60 minutes of manual entry into five minutes of downloading source data.** The subsequent monitoring visits went so much quicker, and the number of queries dropped dramatically.”

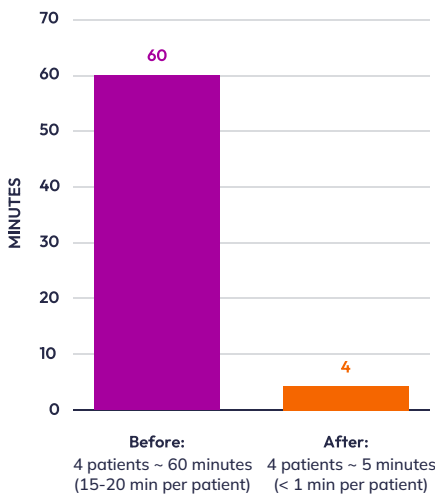
Critical Care Research Coordinator



“Unite significantly accelerated our research, helping us to bring therapies to patients faster than ever before. It’s a vital asset in our mission to deliver life-saving treatments swiftly.”

Study Sponsor

Daily Data Entry Time (minutes) Clinical Trial Results

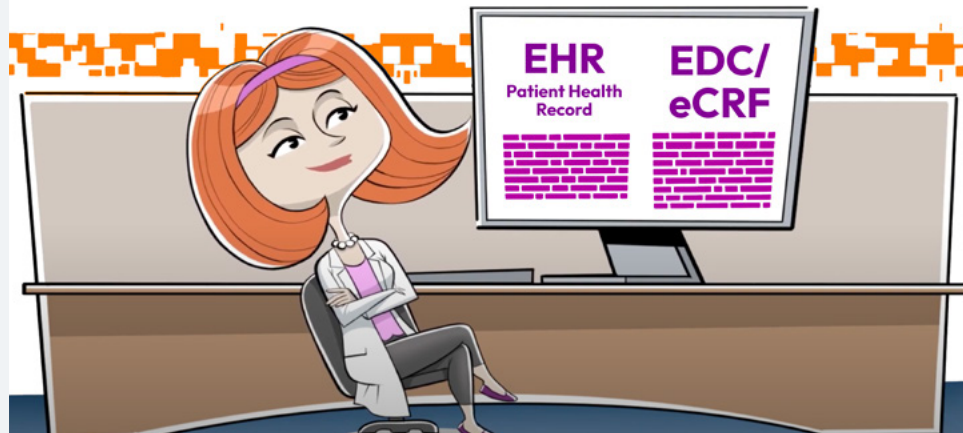


*Data capture efficiencies before and after implementation at one trial site (laboratory data).

Critical Stakeholder Impacts

From a strategic vantage point, the seamless integration of source data directly into the study’s case report forms and database offers a range of compelling advantages:

- 1 Speed:** eSource integration facilitates a consistent inflow of accurate data, empowering swift decision-making in the initial stages and expediting the path to market launch.
- 2 Quality:** Incorporating source data instills confidence among stakeholders in the information they receive. Unite surpasses national and global compliance benchmarks, ensuring the utmost data quality.
- 3 Cost Containment:** Enhancements in the efficiency and accuracy of data capture are important advances in controlling the rising costs of clinical trials.
- 4 Satisfaction:** With reduced data entry tasks, site staff can focus on patient care and scientific research, thereby optimizing their contributions, mitigating burnout and fostering higher job satisfaction.





Since 2006, OpenClinica has advanced clinical trial research by delivering innovative and practical technologies. Our commitment to pushing boundaries continues with our cloud-based platform which streamlines and simplifies source data acquisition and workflows through automation. OpenClinica serves as a secure bridge between healthcare and research, and is the trusted choice for leading life science companies, esteemed academic institutions and government entities worldwide.

We take great pride in supporting a diverse array of organizations ranging from small startups to large institutions across biotechnology, pharmaceutical, academic, device manufacturing and contract research sectors. Our software has supported over 20,000 studies, impacting more than five million patients.

Unlock the potential of your clinical trials: Request a demo or talk to us today!

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