PLAYBOOK

# Fast-tracking clinical trials with eSource

Get to market faster and enhance site relationships

OpenClinica

# Overview

Capturing and cleaning patient data for use in clinical trials puts a drag on modern-day research and development. This overwhelmingly manual process takes time, is error-prone, expensive and shifts focus away from higher-value activities.

Thankfully, industry trends are shifting to reduce manual data entry and perhaps even eliminate it in certain scenarios. New tools can integrate directly with site electronic health records (EHRs) to pull out the exact source data required by the trial protocol to auto-populate the trial database and electronic case report forms (eCRFs). Advances in data standards, industry regulations and technology open up data silos and allow us to build a meaningful bridge between healthcare and research.

This playbook covers these developments, discussing what eSource EHR integration is in clinical trials and the potential of this promising capability to reduce the time, cost and effort required to access quality data needed to evaluate new and repurposed therapies.

# Why sponsors should adopt eSource

Few would argue that manually entering data for hours on end is a desirable activity. Yet, that is what sponsors ask of clinical research coordinators (CRCs) every day. CRCs are dedicated, educated professionals who entered the field with the goal of helping patients, many of whom may be in desperate need of treatment options.

In fact, a recent survey found that 60 percent of site staff spend two hours or more per patient per day transcribing data from the EHR into the clinical trial electronic data capture (EDC) system.[1] This is a low-value activity relative to most research coordinators' capabilities and relative to patient needs.

*The plight of the research coordinator*

"

**I love transcribing data.**

– no one ever

# How much time does your clinical team spend per patient per day on manual data transcription?[2]


Clinical research coordinators are the unsung heroes of clinical trials. They make research happen by juggling countless, often thankless, tasks and impart order out of chaos. The burden of data transcription exacerbates the everyday frustrations of site staff. More than 30 percent of research coordinators said they experience stress because of the strict requirements in sponsor contracts.[3] Requirements include an overwhelming number of protocol changes where each change means CRCs must send, update and resend case report forms repeatedly.

Sustained stress leads to job dissatisfaction and high turnover. In fact, the average annual turnover rate for CRCs is approximately 31 percent – nearly double that of physicians.[4] The COVID-19 pandemic seems to have intensified existing trends: 52 percent of site respondents in a 2022 survey reported a higher turnover than before 2020 and a startling 61 percent of all research staff expressed feeling burned out.[5]

These pressures go on to impact study participation. For example, participants are more likely to drop out when the staff member with whom they had the relationship leaves. Like any highly-skilled role, replacing research coordinators is inefficient and costly. Beyond the strain or recruitment and training, novice coordinators typically make more errors than experienced coordinators, which further increases investigator workload.

It's a vicious cycle fed by the tedium and stress of manual data entry.

**61%**

**of research staff say they are completely or somewhat burned out[5]**

# Frustrated sponsors

For sponsors, manual data transcription creates significant delays in two primary ways. One, it may be weeks or months post patient encounter until busy coordinators enter all desired data. Two, manually transcribed data must undergo source data verification (SDV) – a manual data-checking process which adds weeks or months to the clinical trial. SDV is an additional, particularly costly bottleneck, to obtaining finalized data.

Without a doubt, the manual data transcription process used in clinical research today results in **strained site relationships, excessive costs** and **delayed time to market**.

Across the board, sites believe an investment in technology will accelerate clinical research. One innovative solution to this problem is to digitally access source data directly from patient health records (e.g. an EHR system) to automatically populate the trial EDC and eCRFs. eSource delivers:

- **Faster access to finalized data.**
- **Better site relationships as data entry burden lessens.**
- **Lower costs through efficiencies and decrease of SDV.**

**66%**

**of sites believe an investment in technology will accelerate clinical research[6]**

# Market forces making eSource possible

*Historically, various barriers prevented EHR integration. Three new developments pave the way for greater adoption*

**TREND 1** | **THE MOVE TOWARD INTEROPERABILITY**

In the United States, systems integration has become an industry imperative with interoperability mandates under Meaningful Use and the Centers for Medicare & Medicaid Services' Promoting Interoperability Program.[8] While these incentives began well before COVID-19, the pandemic added an accelerant for stakeholders to move toward interoperability as a gold standard.

Globally, similar regulatory and patient-centric forces are driving deeper interoperability. Governments recognize that interoperability can improve healthcare outcomes and save money. For example, Germany's ISiK (Informationstechnische Systeme in Krankenhäusern) federal law means hospitals must have compliant FHIR interfaces in place by June 2023.

"The value of obtaining health records automatically became apparent during COVID-19 when healthcare facilities were limiting access to non-essential staff," explained Michael Keens, a clinical research industry executive and consultant. "During that time, remote access to medical records was very much a driving force of research. It was the first test of the strength and robustness of these medical systems."

## TREND 2 | MATURITY OF FHIR STANDARDS

In tandem with government initiated policies and incentives, the private sector has been working to rapidly evolve a technical standard, known as Fast Healthcare Interoperability Resources (FHIR). FHIR makes it possible for health record systems and research systems to communicate with each other at scale. FHIR unlocks new integration possibilities – making it practical, with precision, to query an EHR system for the exact data required by trial protocols.

As FHIR has advanced, it has taken data transcription one step further by minimizing the need for multiple logins and platforms — a common frustration for site staff typically expected to juggle many portals at once. With the more recent function known as SMART on FHIR apps, validating integrations can happen ahead of time.

This maturity means SMART on FHIR technologies can be implemented in days, not months.

## TREND 3 | DECENTRALIZATION

The pandemic placed a spotlight on the need for greater automation and virtualization in clinical research, with less reliance on the traditional roles sites have historically performed.[9] The need to do more work remotely, with fewer onsite staff, appears to be here to stay. Reducing manual data entry makes it possible for site personnel to work more productively in remote settings.

Using the aforementioned technical approaches, it is also possible to allow study participants to directly share their health record data with a clinical study protocol via a mobile app. This further reduces sponsor reliance on sites. It also expands the pool of potential study participants, increasing both geographic and demographic diversity of patients evaluated.

In addition to functioning as a conduit to medical research, mobile apps help deliver useful data that sits outside of the EHR, such as data from other digital health apps and connected devices.

> **"When you can enable integration — when you can transfer data with a single click straight from the EHR — it opens up a whole new universe of decentralization opportunities for sponsors, sites and patients."**
>
> *Michael Keens,*
> *Clinical research consultant*

# 8 key advantages of eSource

### SPEED
Sponsors can obtain finalized data faster, expediting their path to market.

### REPRESENTATION
Resource-strapped sites can more easily participate in clinical research, helping sponsors embrace the FDA's recent draft guidance around trial diversity.[10]

### PATIENT CENTRICITY
Site staff can reapply their focus to patients, promoting greater engagement and sustained enrollment throughout the study lifecycle.

### DIGITAL INSIGHTS
Sponsors can enrich studies with more insights from digital health, including wearables, mobile health apps and other patient-directed sources.

### HIGH QUALITY DATA
Sponsors can minimize - or eliminate - manual data entry's costly and time-intensive errors, and reduce SDV.

### SITE SATISFACTION
Sites may be more inclined to take on protocols if they offer technology CRCs and investigators know and love.

### MULTIPLE APPLICATIONS
Sponsors can expand data capture beyond limited protocols, using more data for more outputs in a single click.

### COST REDUCTION
With higher quality source data, sponsors can mitigate the costs of SDV and wasted personnel hours, refocusing them on higher-value activities such as patient encounters.

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**"Deployed at eight clinical sites in the multicenter, adaptive phase 2 I-SPY-COVID-19 platform trial, we demonstrated a time savings of 61% over sites using manual data abstraction."**

*Adam Asare,*
*Quantum Leap Healthcare Collaborative*[10]

# How OpenClinica's EHR integration solution works

OpenClinica Unite™ is a ground-breaking technology that delivers on the promises of EHR and EDC integration. It can function either as middleware (the bridge between your EDC and your sites' EHRs) or as an end-to-end eClinical software suite. In both capacities, OpenClinica Unite™ utilizes the study protocol to map directly to the requisite data in the EHR—filtering for just what the protocol requires. Study team members can initiate data transfers in a few simple clicks.

Once auto-populated with data from the EHR, the eCRF becomes a certified and immutable copy of the source data, meeting the FDA requirements for source data. Automated source data capture eliminates the need for SDV because it creates a transparent, traceable and tamperproof path back to the source data originator. The result is lower costs for sponsors, reduced site burden and faster time to market.

# Implementation opportunities across study types

Implementation can flex and scale across multiple use cases. Take decentralized trials. According to Ben Baumann, OpenClinica's COO, "eSource enables decentralization because it doesn't have to involve sites — it can be a patient-directed activity through Apple Health, for instance. Chart review studies, natural history studies, and registries are other examples where this capability really shines because you easily and securely harvest large volumes of pre-existing medical record data."

Many of these advantages apply universally across trial types, particularly ones marked by more repetitive data entry requirements. Not all trial data comes from the EHR. However, the savings across time and accuracy for the data from EHR is well worth the investment.

"Even where you have coordinators who are checking in with patients on a daily basis, you still see a significant and quantifiable benefit from just being able to capture routine labs and meds automatically," said Lynsey Bentley, Senior Project Manager at OpenClinica. "For example, we've worked with clients who were running a study in the ICU that required them to check in on COVID-19 daily during their time in the ICU. Without integration, that would have been a lot to transcribe — maybe too much to transcribe for the urgency of those early COVID trials. You can quickly start to see the impact this integration makes when scaled to an entire study."

An implementation approach to EHR-EDC integration can also be thought of on a site-by-site, and even patient-by-patient basis. It's not mandatory for all sites to use the integration to reap the benefits. If just a handful of sites in a multi-site study use it, the payback is still substantial.

# A new reality for modern-day research

*Quality, safety and speed are the lifeblood of clinical development.*
*Capitalizing on eSource EHR integration helps sponsors:*

- **Accelerate decision making and time to market**
- **Obtain finalized data faster**
- **Acquire more precise, fine-grained data**
- **See potential safety signals sooner**
- **Cut down on costly cycles of SDV**

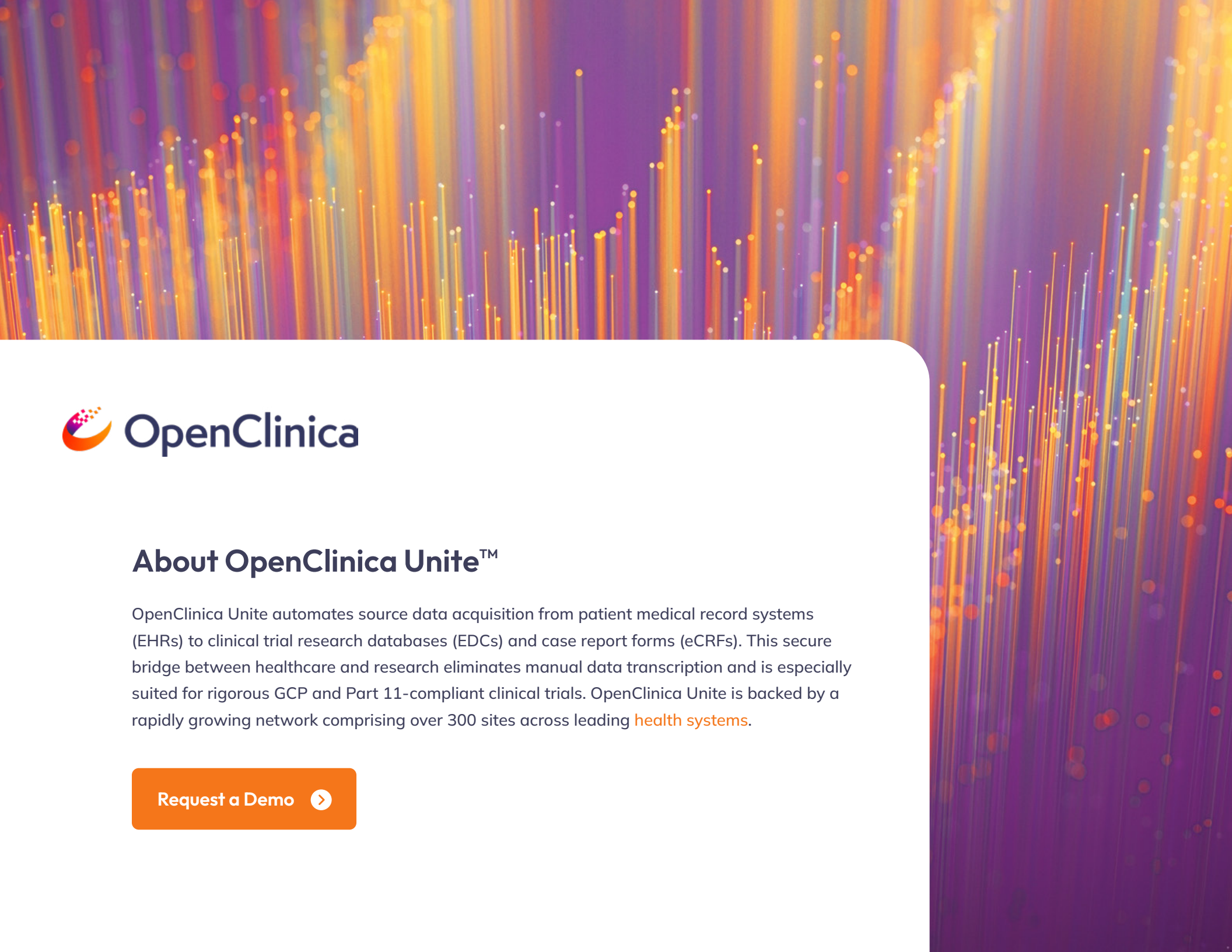
eSource lowers the burden for sites to participate in research, potentially increasing their enthusiasm to join studies and recruit patients. Automated data acquisition from electronic records is now practical for use in clinical trials, promising benefits to both sponsors and sites. Digital first will become the new norm in clinical research as it has in many other aspects of our lives.

# BioIT World names Quantum Leap Healthcare Collaborative/ OpenClinica 2022 Innovative Practices grand prize winner.

A major expense in clinical trials is the collection and abstraction of clinical data. This expense is further compounded by human errors that require additional investments in data cleaning/validation. Enhancements in the efficiency and accuracy of data capture are important advances in controlling the rising costs of clinical trials.

We have established a flexible framework for integration and completion of Electronic Case Report Forms (eCRFs) through automated, direct capture from Electronic Health Record (EHR) systems. OneSource (OpenClinica Unite), launched within a participant's EHR patient chart, automatically populates structured eCRFs by extracting data directly from the EHR, without need of manual abstraction.

Deployed at eight clinical sites in the multicenter, adaptive phase 2 I-SPY-COVID-19 platform trial, we demonstrated a time savings of 61% over sites using manual data abstraction. Furthermore, at sites using EHR-EDC integration, data errors were eliminated, leading to additional downstream cost savings in cleaning/validation costs. OneSource/Unite has the additional benefits of low implementation costs and reusability across sites.



OpenClinica

## About OpenClinica Unite™

OpenClinica Unite automates source data acquisition from patient medical record systems (EHRs) to clinical trial research databases (EDCs) and case report forms (eCRFs). This secure bridge between healthcare and research eliminates manual data transcription and is especially suited for rigorous GCP and Part 11-compliant clinical trials. OpenClinica Unite is backed by a rapidly growing network comprising over 300 sites across leading health systems.

Request a Demo

# Sources


1. Internal Study, OpenClinica (2022). Impact of Satisfaction and Burnout Among Clinical Researchers.
2. Internal Study, OpenClinica (2022). Impact of Satisfaction and Burnout Among Clinical Researchers.
3. Cagnazzo, C., Filippi, R., Zucchetti, G., Cenna, R., Taverniti, C., Guarrera, A. S. E., Stabile, S., Federici, I., Monti, M., Pirondi, S., Testoni, S., & Fagioli, F. (2021, March 12). *Clinical research and burnout syndrome in Italy – only a physicians' affair? - trials*. BioMed Central. Retrieved from Clinical research and burnout syndrome in Italy – only a physicians' affair? - Trials
4. Stroo, M., Asfaw, K., Deeter, C., Freel, S. A., Brouwer, R. J. N., Hames, B., & Snyder, D. C. (2020, March 11). *Impact of implementing a competency-based job framework for Clinical Research Professionals on employee turnover: Journal of Clinical and Translational Science.* Cambridge Core. Retrieved from https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/impact-of-implementing-a-competency based-job-framework-for-clinical-research-professionals-on-employee-turnover/799377B6FEF2AACA926AB7B9D6CDAC29
5. Internal Study, OpenClinica (2022). Impact of Satisfaction and Burnout Among Clinical Researchers.
6. Internal Study, OpenClinica (2022). Impact of Satisfaction and Burnout Among Clinical Researchers.
7. Internal Study, OpenClinica (2022). Impact of Satisfaction and Burnout Among Clinical Researchers.
8. What is meaningful use? HealthIT.gov. (2013, June 1). Retrieved from What is meaningful use? | HealthIT.gov
9. *2022 forecast: Decentralised trials to reach new heights with 28% jump.* Clinical Trials Arena. (2022, July 11). Retrieved from 2022 forecast: decentralised trials to reach new heights with 28% jump
10. *Diversity plans to improve enrollment of participants from ...* (n.d.). Retrieved from https://www.fda.gov/media/157635/download
11. *IT world names 2022 innovative practices awards winners.* Bio. (n.d.). Retrieved from Bio-IT World Names 2022 Innovative Practices Awards Winners