OpenClinica Unite™

Bridging the Gap Between Research & Healthcare

Experience the speed and safety of automated, precision source data capture.

OpenClinica

Manually transcribing data is *inefficient, time consuming and error prone.*

Running a clinical trial requires lots of data that already exists in your EHR. This critically important data serves as the source record for clinical trial participants, but must be manually transcribed into the study database. Finally, there is a way to streamline this process.

Introducing OpenClinica Unite™

A powerful and easy way to leverage EHR data for your next study.

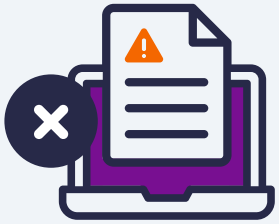
Imagine a world where, with a single click, you could get EHR data into your study database. *Because now you can.*

Sponsors can:

- Obtain higher quality data that is cleaner and more complete
- Get faster access to study data
- Reduce the costly practice of 100% SDV
- Increase site satisfaction and compliance

Don't put your study at risk due to bottlenecked manual data entry from the patient's chart into the eCRF.

Stop wasting precious time and resources. Get back to doing what you do best: improving lives through innovative, transformative research.



Eliminate high-risk manual data entry

Reduce monitoring cost and effort

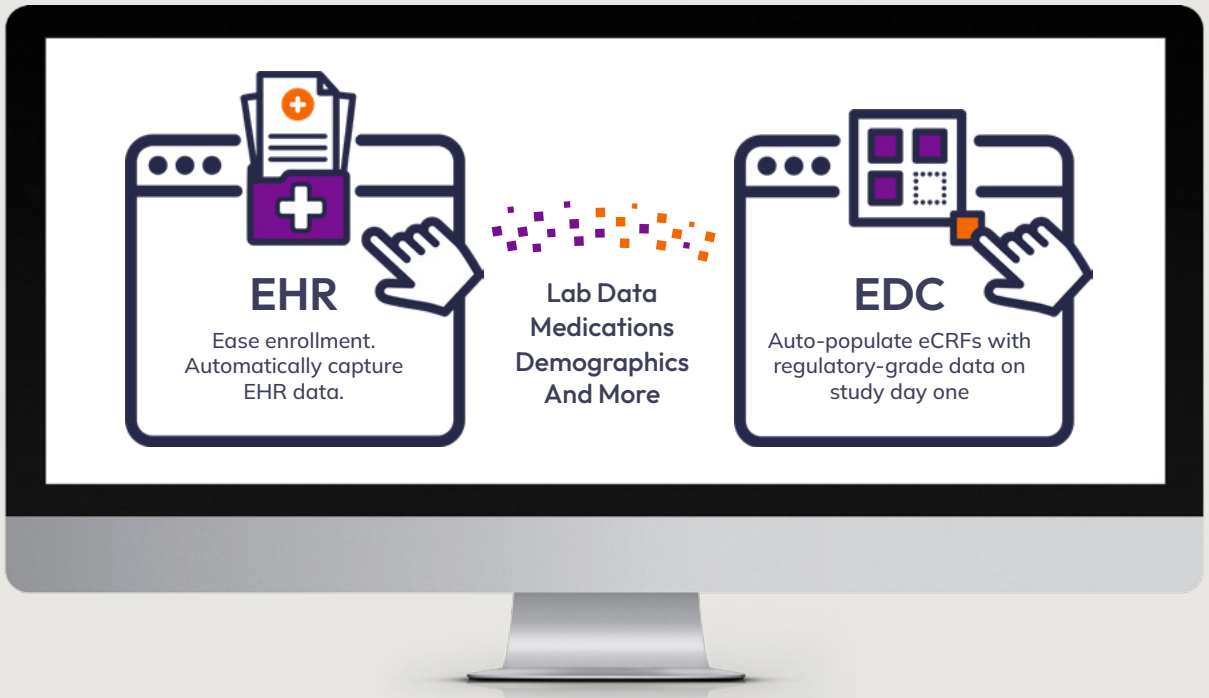
Get faster access to data

Meet OpenClinica Unite™

OpenClinica Unite™ expands the use of electronic health record data in clinical research and greatly reduces the burden of data entry for sites. With OpenClinica Unite, you can securely retrieve data from your EHR to automatically populate trial case report forms.

Seamless user experience

- Single-sign-on: Launch from either EHR or EDC
- Available anytime, anywhere, from any device
- EHR patient - EDC participant linkage automatically maintained
- Enable patient-direct EHR data share. No site needed.
- Real-time data visualization for use at the point-of-care (track key metrics)
- Puts ERH data, eCRF, eCOD and ePRO data at fingertips
- Enable patient-directed EHR data share. No site needed.



Rigorous compliance

- Compliant with 21 CFR Part 11 standards and ICH GCP
- Compliant with HIPAA and GDPR
- Traceability to the source (data originator, data element identifiers per FDA 2018 EHR guidance)
- Comprehensive information security program
- Compliance and security artifacts available for customer review

Easy to implement

- Implementation in days, not months.
- Secure, standards-based tech widely accepted by IT departments and back by major EHR vendors
- Intelligent filtering ensures you get the data your protocol needs.
- Reuse implementation across multiple trials and sponsors
- Supports all trial types (DCT, registry, Phase I - IV, observational)

Highly customizable

- Visualize data with embedded reporting. View participant records at-a-glance. Easily monitor key trends to enhance safety, data quality and clinical care.
- Unite your data with highly-configurable design options for mapping data elements across lab results, medications, demographics, ontologies in your EHR (LOINC, RxNorm, SNOMED, FHIR ID, CDISC, UTC-00, etc.)

Curious?

Unite, the OpenClinica eSource solution, automates precision source data acquisition from patient medical record systems (EHRs and EMRs) to clinical trial research databases (EDCs) and case report forms (eCRFs) to eliminate the inefficiencies, inaccuracies and manual transcription burdens that plague traditional processes. With Unite, the eCRF can be launched from the patient chart with a single click. Structured data from the EHR automatically populates the eCRF and workflows for user review/validation. Mobile support enables direct data capture at the point of care. Unite delivers regulatory-grade evidence of data integrity and meets or exceeds global compliance standards. Unite's impact on clinical trials extends across a rapidly expanding network of more than 450 physical clinical trial sites, serving millions of patients.

Request a Demo

OpenClinica

www.openclinica.com

Unified Platform of Best-In-Class Solutions

EHR eSource

OpenClinica Unite™
Auto-populate eCRFs/EDC with source data on study day one. Proven, scalable integration frees site staff for higher value research, reduces SDV, incorporates RWE and delivers real-time study outcomes.

Electronic Data Capture

OpenClinica Core™
Speed up study start with intuitive form builder. Maintain momentum with automated workflows & notifications, smart eCRFs and dynamic scheduling.

Randomization & Supply Chain

OpenClinica Randomize™
Create easy, automated workflows for total randomization and supply chain management right within eCRFs.

Patient-Level Data Capture

OpenClinia Share™
Deliver next-level ease – enable study participants to transfer health record data directly to eCRFs with secure, single-click mobile sharing.

ePRO / eCOA

OpenClinica Participate™
Keep participants engaged, ease clinician burden and get higher-quality results earlier with anytime, anywhere, any device outcome reporting.

eConsent

OpenClinica Consent™
Deliver an engaging consent experience to boost recruitment, retention and onboarding with total electronic consent management.

Dashboards & Reporting

OpenClinica Insight™
Visualize, analyze and share key trial insights in real-time with out-of-the-box library of reports. Easily build customized reports and dashboards to meet unique trials needs.

Success begins with a conversation

Let's Talk

OpenClinica

OpenClinica has been delivering innovative and practical solutions for clinical trials since 2006. We continue to push the envelope by automating source data acquisition and workflows through our cloud-based platform. Offering a secure bridge between healthcare and research, OpenClinica is trusted by the world's foremost life science companies, academic institutions and government entities and has been used in more than 20,000 studies involving over five million patients worldwide.

We are proud to support thousands of small, midsize and large research organizations spanning biotech, pharma, academia, medical device manufacturing and contract research organizations.

For more information, visit us at www.openclinica.com

Isn't it time you received a steady stream of early, trusted data in your clinical trials?