

Captivate® EDC

Flexible, Pre-Validated Electronic Data Capture Built for Real-World Clinical Trials

Product Overview

Captivate EDC is a modern, enterprise-grade Electronic Data Capture system designed for clinical data managers who need flexibility, control, and speed without the overhead of rigid, expensive platforms or the limitations of lightweight tools.

Built for studies ranging from small, fast-moving pilots to complex global programs, Captivate EDC combines intuitive, no-code study build tools with advanced optional customization and powerful live-study capabilities.

Captivate EDC is pre-validated and compliant out of the box, helping teams reduce startup timelines and focus on running the study, not managing infrastructure or validation burden.

Build Studies Your Way

Captivate EDC is designed to support how data managers actually build and manage studies, balancing ease of use with advanced configurability.

Key capabilities include:

- Drag-and-drop CRF and visit design with conditional logic, validations, and calculations Support for complex workflows, adaptive designs, and sub-studies
- Reusable forms, visit schedules, and libraries to standardize across programs
- Optional JavaScript support for advanced functionality Full audit trails for all configuration and build changes

No-Code by Default. Advanced When You Need It.

Most Captivate customers build studies using intuitive, drag-and-drop tools without writing code. For more advanced use cases, Captivate also supports optional scripting and custom functions, giving experienced teams additional flexibility without forcing complexity on everyone.

Faster Study Startup with Pre-Validation

Captivate EDC is pre-validated, meaning the core system has already undergone validation by our team. This significantly reduces the effort required by sponsors and CROs and accelerates time to go-live.

What this means for your team:

- Average study build time of approximately four weeks
 - Some simple studies live in as little as 24 hours
 - No need to perform full system validation, only study-specific UAT
 - Reduced documentation burden while maintaining inspection readiness
-

Seamless Data Flow Across Your Clinical Ecosystem

Captivate EDC is designed to sit at the center of your clinical data stack, supporting clean, controlled data flow across systems and vendors.

Key capabilities include:

- Native integration with Captivate VDC modules such as ePRO and eConsent
 - Secure bulk imports via SFTP for labs and external data sources
 - Configurable datasets for downstream analysis and reporting
 - Consistent audit-ability across integrated data sources
-

Run Live Studies with Confidence

Once a study is live, Captivate EDC provides real-time visibility into study progress and data quality, enabling proactive monitoring and faster issue resolution.

Key capabilities include:

- Real-time dashboards showing enrollment, data completeness, and study health

- Query management with configurable workflows
 - Role-based views for sites, monitors, sponsors, and data managers
 - Automated alerts and reminders to reduce manual follow-up
-

Data Quality, Exports, and Inspection Readiness

Captivate EDC maintains continuous traceability from first data entry through database lock.

Key capabilities include:

- Real-time access to current, clean data
 - Configurable exports including SAS-ready datasets
 - Comprehensive audit trails for subjects, users, roles, and data changes
 - Structured workflows for database lock and study closeout
-

Security, Compliance, and Control

Captivate EDC is compliant out of the box with global regulatory and privacy requirements and is designed to support audits and inspections without disruption.

Key capabilities include:

- Compliance with 21 CFR Part 11, Annex 11, GDPR, and HIPAA
 - Built-in PHI and PII masking features
 - Role-based access controls and authentication
 - Detailed audit trails for data, users, and permissions
-

A Smarter Alternative to Traditional EDCs

Captivate EDC was built to avoid the tradeoffs teams often face when choosing between rigid enterprise platforms and limited low-cost tools.

- More flexible and faster to configure than legacy systems
 - More powerful and scalable than lightweight EDCs
 - Designed to grow with your pipeline without forcing migrations or disruptive upgrades
-

Who Uses Captivate EDC

Captivate EDC is used by sponsors, CROs, academic institutions, diagnostics companies, and medical device organizations running interventional trials and registries.

Common use cases include:

- Phase I–IV clinical trials
 - Post-market and observational studies
 - Disease and product registries
 - Multi-study programs requiring reuse and standardization
-

Why Data Management Teams Choose Captivate

- Faster study builds without sacrificing flexibility
- Intuitive tools that reduce reliance on programming
- Advanced customization when needed
- Continuous inspection readiness
- Responsive support from clinical data experts

