



The eClinical Suite

An integrated solution for collecting, tracking and reporting clinical trial data

The eClinical suite provides a comprehensive, functionally-rich solution to streamline clinical trial processes. It uses proven workflows that enable clinical operations to effectively plan each stage of a trial. The eClinical suite is able to capture, manage, clean, export and lock trials quickly and cost-effectively. Whether you are a pharmaceutical, device, biotechnology, academic or government institution, the OmniComm eClinical solution is a proven system for large scale global projects or single site Phase I studies.

eClinical Portal: The gateway to the eClinical Suite, the portal is a dashboard for study metrics and reports, as well as a repository for study files. It provides users with access to key metrics and study data, enabling a comprehensive view for ongoing decision making.

eData Capture: A zero footprint, full-service Electronic Data Capture (EDC) system. Monitoring, and data management tools are included, and a powerful configurable workflow.

eData Management: A CDMS system that includes a robust standards-based design tool for eCRF and edit checks, meeting your needs for Double Data Entry and paper based studies. Study and cross-study analysis are enabled in a single data repository.

Ad-Hoc Reporting: A user-friendly tool for creating real-time reports and data listings in Excel and ASCII, as well as providing CDISC ODM exports, and on-demand SAS extracts.

AutoEncoder: A configurable tool for coding of clinical data, e.g. adverse events, medical history, concomitant medications, etc. against commercial and/or user defined dictionaries e.g. MedDRA / WHO Drug, etc.

eStudy Conduct: A CTMS system for project planning and management, study management, monitoring, and accounting.

Adverse Event Reporting: A system for data entry and management related to adverse events and serious adverse events. This module contains a reporting tool for CIOMS, FDA and EMEA.

eHealth Education: A self-paced training tool for sites, monitors, data managers and other clinical trial staff. Includes practice simulations and certification processes.

OmniComm is a global provider of customer-driven eClinical solutions to organizations that conduct life changing clinical trial research. OmniComm's growing base of satisfied customers is a direct result of the company's commitment to deliver products and services that ensure ease of use, faster study build interoperability and better performance.

The eClinical Suite from OmniComm

- Are you a sponsor or CRO in need of a system that supports paper, EDC or hybrid trials?
- Do you have a compound or device you acquired with a mix of data that is paper and electronic?
- Do you need an Adverse Event Reporting System, or a Clinical Trial Management System?
- Do these need to be integrated?

If your answer is yes to any of these questions, consider the **eClinical Suite**, the solution of choice used in more than 85 countries to support thousands of clinical trials over 50,000 investigator sites.

eData Management (CDMS) is integrated and feature-rich, offering local and central laboratory support, an object library for re-use across trials, edit checks that execute when you want them – field, form and in batch, and versioning for delayed site deployment of mid study changes.

eData Capture (EDC) provides a fully-functional and highly-configurable system integrated with the CDMS.

eStudy Conduct (CTMS) helps you define standard operating procedures and checklists, plan and schedule resources,

define international language requirements, and is integrated with the CDMS and EDC modules.

Adverse Event Reporting (AERS) supports global standards and is ICH E2B compliant, with Adverse Event Reconciliation between the CDMS/EDC and safety databases. It is integrated with the CDMS and EDC modules.

This fully-compliant, validated system is 21 CFR Part 11-compliant, with a full audit trail. It also supports eSignatures.

Why have clients used the eClinical Suite for many years, across multiple trial phases and programs? The answer is a comprehensive product suite, a commitment to industry standards, and a robust professional services offering.

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