

TRIALSTAT

A New Paradigm in Data Management Technology

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A new paradigm in Data Management technology is upon us with TrialStat EDC, Portal and CTMS. TrialStat is a multi-tenant solution, with integrated randomization, payment tracking, inventory management, ePRO, eSource, multi-lingual support, completely configurable eCRFs, user roles, workflows and CDASH compliant eCRF libraries, real-time study reporting and data extracts, cross study reporting, APIs for 3rd party integration into other EDC systems, CTMS platforms, Safety Systems, etc., support for all study phases as well as the unique requirements of medical device studies and the option for completely custom validated features and functionality. Sponsors and CRO's need not look further for their next Data Management platform.

A Unified eClinical Suite Delivering Real-Time Data

Comprehensive Features

- ✓ Completely Customizable eCRFs
- ✓ CDASH Compliant CRF Library
- ✓ Comprehensive Edit Checks
- ✓ Common Forms
- ✓ AE / SAE Tracking
- ✓ Image Management
- ✓ 2-4 Week Build Time
- ✓ Configurable Study Workflow
- ✓ Flexible Data Capture
- ✓ Bar Code Integration
- ✓ Real-time Monitoring, Reporting & Validation
- ✓ Complete Multi-Lingual Support
- ✓ Replicate All or Portions of Entire Studies
- ✓ Powerful Data Management Tools
- ✓ eSource Compliant

Premium Features

- ✓ Randomization / IWRS
- ✓ Inventory Management
- ✓ Payment Tracking
- ✓ Patient Reported Outcomes (ePRO)
- ✓ CTMS
- ✓ Medical Coding

TrialStat Portal – Real-Time Data & Decisions

- ✓ Real-Time Data Visualization
- ✓ 40+ Standard Reports
- ✓ Browser Based & Mobile Responsive
- ✓ Configurable Reports & Dashboards
- ✓ Data Drill-Downs
- ✓ Make Critical Decisions Quickly

TrialStat CTMS – Complete Study Management

- ✓ Seamlessly Report Study Conduct & Data Management Activities
- ✓ Comprehensive Reporting
- ✓ Configurable Dashboards
- ✓ Manage Study Documentation
- ✓ Manage Study Financials
- ✓ Manage Study Budgeting
- ✓ Subject Visit Management

TrialStat – Custom Development & Validation

- ✓ Custom Features for EDC
- ✓ 3rd Party Systems Integration
- ✓ System Design & Architecture
- ✓ Regulatory Compliance
- ✓ Master Validation Plans (MVP)
- ✓ Complete Custom Solutions
- ✓ HIPAA & 21 CFR 11 Compliance

Data Without Limitations

**Book Your
Demo Today**
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Corporate Overview

- ✓ Delivering Successful Studies since 2003
- ✓ Global studies in more than 50 countries & 3000 users
- ✓ Subsidiary of Jubilant Life Sciences
- ✓ Over 500 completed studies

Professional Services

- ✓ Study Development - Case Report Form Design
- ✓ Project Management
- ✓ Complete eCRF Validation
- ✓ Custom Programming & Systems Integration

Regulatory Compliance

- ✓ 21 CFR Part 11 Compliant
- ✓ HIPAA Compliant
- ✓ SSAE 16 SOC 1 data centers
- ✓ SAS 70 Type II

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The Right Solution For Your Complex Study Needs

EDC				
Subject Randomization	Payment Tracking	ePro	Medical Coding	Inventory Tracking
Portal				
Real-Time Data Reporting	Globally Manage Study Conduct	Report Across Multiple Studies	Integrate 3rd party systems - CTMS, EDC, Safety Systems	Custom Development & Reporting

Key Features

Single Sign On + Multiple Customizable Roles	eCRF Library (CDASH Compliant)	eSource	Web Based Drag & Drop Design	Comprehensive Real-Time Edit Checks
Configurable Work Flows	Configurable Roles and Security	Custom Report Designer	TrialStat Portal	Real-Time Reporting Across All Studies
Datasets On Demand – Export Live Data Anytime	Intuitive User Interface	HIPAA & 21 CFR Part 11 Compliant	FDA Compliant Case Book Exports with Bookmarks	Role Specific Dashboards and To Do Lists
CTMS	40+ Standard & Configurable Reports	Simplified Flat Pricing	Enterprise Pricing Models	High Speed Low Latency User Experience
Risk Based Monitoring Module	Protocol Amendments With Multiple Versions	Electronic Signatures	Dynamic Skip Logic	Soft Locks

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