TRIALSTAT

A New Paradigm in Data Management Technology

Toll Free: **866-416-STAT**
Tell: **613-741-9909**
Fax: **613-274-3674**
sales@trialstat.com

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
- ✓ 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
- ✓ Systems Integration
- ✓ System Design & Architecture
- ✓ Regulatory Compliance
- ✓ Systems Validation
- ✓ Master Validation Plans (MVP)
- ✓ Complete Custom Solutions
- ✓ HIPAA & 21 CFR 11 Compliance

JUBILANT LIFESCIENCES

FDA 21 CFR Part 11 Compliant

HIPAA COMPLIANT HIPAA Compliance Solutions

FISMA COMPLIANCE FISMA Compliance Solutions

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Data Without Limitations

Book Your Demo Today

1-888-488-0312

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

JUBILANT LIFESCIENCES

TrialStat Solutions Inc.
www.trialstat.com | 905-999-1957

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The Right Solution To Your Complex Study Needs

Unified eClinical Suite

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