TrialStat EDC

A New Paradigm in Data Management Technology

TrialStat EDC is a scalable, cloud based Electronic Data Capture Suite for pilot / proof of concept studies, Phase I, II, III and IV studies. TrialStat EDC is an excellent choice for the unique requirements of Medical Device studies. It's built on the latest technologies allowing Sites, CROs, Data Management companies, and Sponsors access via any web browser without limiting any system features. Our device agnostic model allows simultaneous access from mobile devices, tablets laptops and desktop computers.

TrialStat integrates important features such as Randomization / IWRS, Inventory Management, Payment Tracking, Medical Coding, ePro, and Imaging directly into the system for seamless trial data collection ensuring site efficiency and facilitating study compliance.

TrialStat EDC is a robust and intuitive Data Management Suite which facilitates accurate and efficient data collection. Intuitive eCRF design and easy to use study configuration tools allow rapid study build times for simple and complex study requirements within 2 to 4 weeks. It provides a single platform to collect and manage all study data, while offering a variety of advanced functionality and integrations with 3rd party systems. Features such as email notifications, data management tools, dynamic skip logic, advanced custom real-time data reporting, source data verification, electronic signatures, on-demand data exports and more are included.

Randomization / IWRS

Save on overall study costs and run your studies more efficiently with our integrated Randomization / IWRS. TrialStat EDC provides integrated IWRS functionality, allowing for varying degrees of randomization complexity. Sites are able to enroll and randomize subjects directly within TrialStat EDC and without the need or added cost of another software system.

A Unified eClinical Suite Delivering Real-Time Data

Advanced Integrated Features

- ✓ Completely Customizable eCRFs
- ✓ CDASH Compliant eCRF 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

ePRO

TrialStat's integrated Electronic Patient Report Outcome (ePRO) module seamlessly combines site data with patient data without the need for a 3rd party system. Using TrialStat ePRO eliminates the added cost of data reconciliation and integration with a 3rd party ePRO system. The ePRO module allows for full eCRF capabilities, localization of languages, customized patient interfaces, visit notification windows and operates on any mobile device, table or computer.

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

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Medical Coding

TrialStat EDC enables Data Managers to utilize WhoDrug, MedDra, and Custom Dictionaries directly within TrialStat EDC to complete their coding activities, quickly and easily. Simply choose the desired dictionary and version and apply it to a field within an eCRF. TrialStat's Coding capabilities satisfy even the most discriminating Data Managers.

Custom Validated Development Services

TrialStat is unique in the industry, providing validated custom development services. As a matter of practice, we regularly include new features based on Sponsor requirements. Our expert Software Architects, Software Developers and Compliance Experts provide complete custom development services to meet your unique requirements while ensuring compliance with all relevant regulatory requirements such as 21 CFR Part 11, HIPAA and Privacy Shield. Whether you need additional features built into TrialStat or a completely separate custom application TrialStat's develop team can design, develop and validate your custom solution.

The TrialStat Advantage

TrialStat is committed to providing Data Management solutions customized to the requirements of each study, offering flexible, cost-effective Data Management solutions across all phases of clinical research. From rapid database build through database lock, we deliver consistent quality on-time and on-budget.

For organizations wishing to configure their own studies, TrialStat provides comprehensive designer training for TrialStat EDC. Included with our training programs are Mentor builds to ensure new Certified Designers follow TrialStat EDC best practices in eCRF design, and study configuration. In addition, TrialStat EDC includes a complete library of CDASH compliant Case Report Forms to bring an unprecedented level of consistency across all of your studies, while reducing study configuration timelines.

Our Data Systems meet Code of Federal Regulations 21 CFR Part 11, and our procedures and controls further ensure data integrity and authenticity. All data is subject to time-stamped audit trails to independently record the date and time of operator entries that create, modify or delete electronic records.

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JUBILANT BIOSYS

FDA 21 CFR Part 11 Compliant

HIPAA COMPLIANT HIPAA Compliance Solutions

FISMA COMPLIANCE FISMA Compliance Solutions

rackspace

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