TrialStat EDC

A Jubilant Life Sciences Company

TrialStat EDC is a scalable, cloud based Electronic Data Capture Suite for pilot / proof of concept studies, Phase I, II, III and IV studies. In additional TrialStat EDC is an excellent choice for the unique requirements of Medical Device studies. TrialStat EDC is built on the latest technologies allowing Sites, CROs, 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 IWRS, Medical Coding, ePro, and Imaging directly into the system for seamless trial data collection ensuring site efficiency and compliance.

TrialStat EDC provides a robust and intuitive system to ensure 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. TrialStat EDC provides a single platform to collect and manage all study data, while offering a variety of advanced functionality. Functions including email notification, data management tools, dynamic skip logic, advanced custom real-time data reporting, source data verification, electronic signatures, on-demand data exports and more.

IWRS

TrialStat EDC provides integrated IWRS functionality, allowing for any degree of randomization complexity. Using TrialStat IWRS will enable sites to trigger randomization codes directly without leaving TrialStat EDC and without the need or added cost of another software system.

A Unified eClinical Suite Delivering Real-Time Data

- ✓ Fully Unified eClinical Suite
- ✓ Completely Customizable eCRFs
- ✓ CDASH Compliant CRF Library
- ✓ IWRS
- ✓ Inventory Management
- ✓ Payment Tracking
- ✓ Patient Report Outcomes (ePRO)
- ✓ CTMS
- ✓ Comprehensive Edit Checks
- ✓ Dynamic Skip Logic
- ✓ AE / SAE tracking
- ✓ Image Management
- ✓ 2-4 Week Build Time
- ✓ Configurable Study Workflow
- ✓ Flexible Data Capture
- ✓ Bar Code Integration
- ✓ Real-Time Monitoring, Reporting & Validation
- ✓ Integrated Real-Time Reporting
- ✓ Multi-Lingual Support
- ✓ Replicate Entire Studies

Medical Coding

TrialStat EDC enables data managers to utilize WhoDrug, MedDra, and Custom dictionaries directly within TrialStat EDC to conduct their coding activities. Simply choose the desired dictionary and version and apply it to a field within an eCRF.

Data Without Limitations

Book Your Demo Today

1-888-488-0312

Corporate Overview

- Delivering Successful Studies since 2001
- Global studies in more than 50 countries & 3000 users
- Subsidiary of Jubilant Life Sciences
- Over 500 completed studies

Professional Services

- EDC Development
- Project Management
- Study Design and 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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ePRO

Using our integrated Electronic Patient Report Outcome (ePRO) module, users can seamlessly combine 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 and visit notification windows.

Custom Development

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.

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 bring eCRF development in house, TrialStat provides comprehensive designer training for TrialStat EDC. We will also provide Mentor builds to ensure new designers follow our best practices in case report form design, and study configuration. We also provide a complete library of CDASH compliant Case Report Forms to bring an unprecedented level of consistency across all of your studies, while reducing database development 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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HIPAA COMPLIANT

HIPAA Compliance Solutions

Comprehensive HIPAA solutions to ensure your patients' protected health information(PHI) stays safe.

PCI DSS COMPLIANT

PCI DSS Compliance Solutions

A difinitive set of PCI security & reporting services for the financial data & payments industry.

SOX

SOX Compliance Solutions

Fully-managed Sox-compliant solutions to keep you at the forefront of the financial data retention compliance.

FISMA COMPLIANCE

FISMA Compliance Solutions

Infrastructure & services that meet the stringent FISMA security standards for government agencies, ISVs, systems integratiors, & VARs.

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