TRIALSTAT

The Most Advanced Connected Suite For Clinical Research

Sponsor
Visualizing Your Trial In Real-Time

Data Management
Real-Time Data Reviewing, Monitoring, Stats SAS Exports, Pharmacovigilance

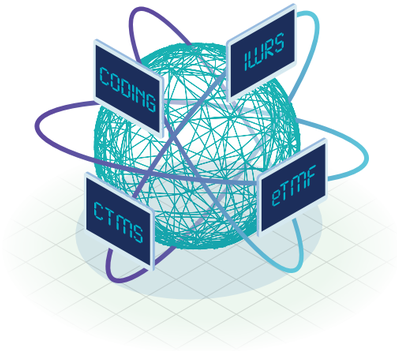
CRO
EDC, Trial Management and Reporting

Site, Coordinator & PI
EDC, Randomization & Supply

Patients
eConsent & ePRO

Toll Free: **1-888-488-0312** Email: **hello@trialstat.com**

Electronic Data Capture (EDC)



You no longer have to compromise on your eClinical Technology. Unleash the power of one of the most flexible, and extensible eClinical Suites for your studies.

With TrialStat's complete set of modules and capabilities you only need one eClinical Suite for your simplest to most complex trials.

Put clear, timely, and actionable insights at your team's fingertips while reducing onboarding time and site issues with one of the most comprehensives platforms available.

- eConsent
- ePRO / eCOA with BYOD
- Randomization
- Supply Management
- Medical Coding
- Robust Reporting & Analytics Portal
- Vendor Neutral Imaging Archive
- Data Exports on Demand
- Analytics across a single study, a program, or entire portfolio
- Named Project Managers and Support team that know your protocol

"The knowledgeable team at TrialStat worked with us to develop a validated custom web application, integrated with both EDC and our internal systems, that streamlines workflow and maximizes our team's productivity. We can collect and manage trial data in a more timely and efficient manner now, which makes our clients happy too."

- Judi Hall, VP Clinical Research at Alimentiv

eConsent

Accelerate clinical trial enrolment and maximize protocol compliance with TrialStat's comprehensive and immersive eConsent platform.

Fully configurable workflows for the best patient experience, including:

- Support for multiple witnesses, Consent and Assent
- Use immersive multimedia content
- Re-consent and the ability for patients to electronically revoke consent
- Email notifications for ease of tracking and management

Integrated with our EDC for optimal performance. TrialStat's eConsent Module also features a flexible API to connect to other EDC platforms.

3000+ TrialStat Users Globally

Executed Studies **1000+** and Growing!

Studies in **20+** Countries

Therapeutic Areas **15+** and Counting!

Study builds in less that **4 Weeks**

ePRO / eCOA

Eliminate the cost of data reconciliation and integration with 3rd party ePRO systems with a fully integrated patient reported outcomes platform that offers:

- Expansive eCRF capabilities for comprehensive data collection including calculations, images, and other complex logic
- Localization of languages for global studies
- Visit notification windows and reminders for improved protocol compliance
- Customizable patient interfaces for a personalized experience
- Visit notification windows for improved protocol compliance

IWRS / Randomization

Maximize the efficiency of your clinical trials with integrated IWRS. Design any degree of randomization complexity, right within EDC.

- Simple to Complex Stratification including support for Minimization Randomization
- Ensure successful patient randomization without complications or delay
- Trigger randomization codes directly within TrialStat, eliminating the added cost of third party tools

Upgrade your randomization solution with TrialStat's IWRS and benefit from the latest technology to ensure successful and compliant patient randomization.

Supply Management Services

Combined with our IWRS / Randomization Module, TrialStat's expert 24 x 7 x 365, Supply Management Services team will ensure your clinical trial sites never miss a potential enrollment again due to lack of supply. Our Supply Management teams are fully trained on your protocol, and offer support in any language to ensure your trial supply is always optimized.

"If you ask the TrialStat team a question, the answer is never "No", but "let's see how we can accomplish that!"

- Colin Miller, CEO, The Bracken Group

The Most Advanced Connected Suite For Clinical Research

Integrated Modules

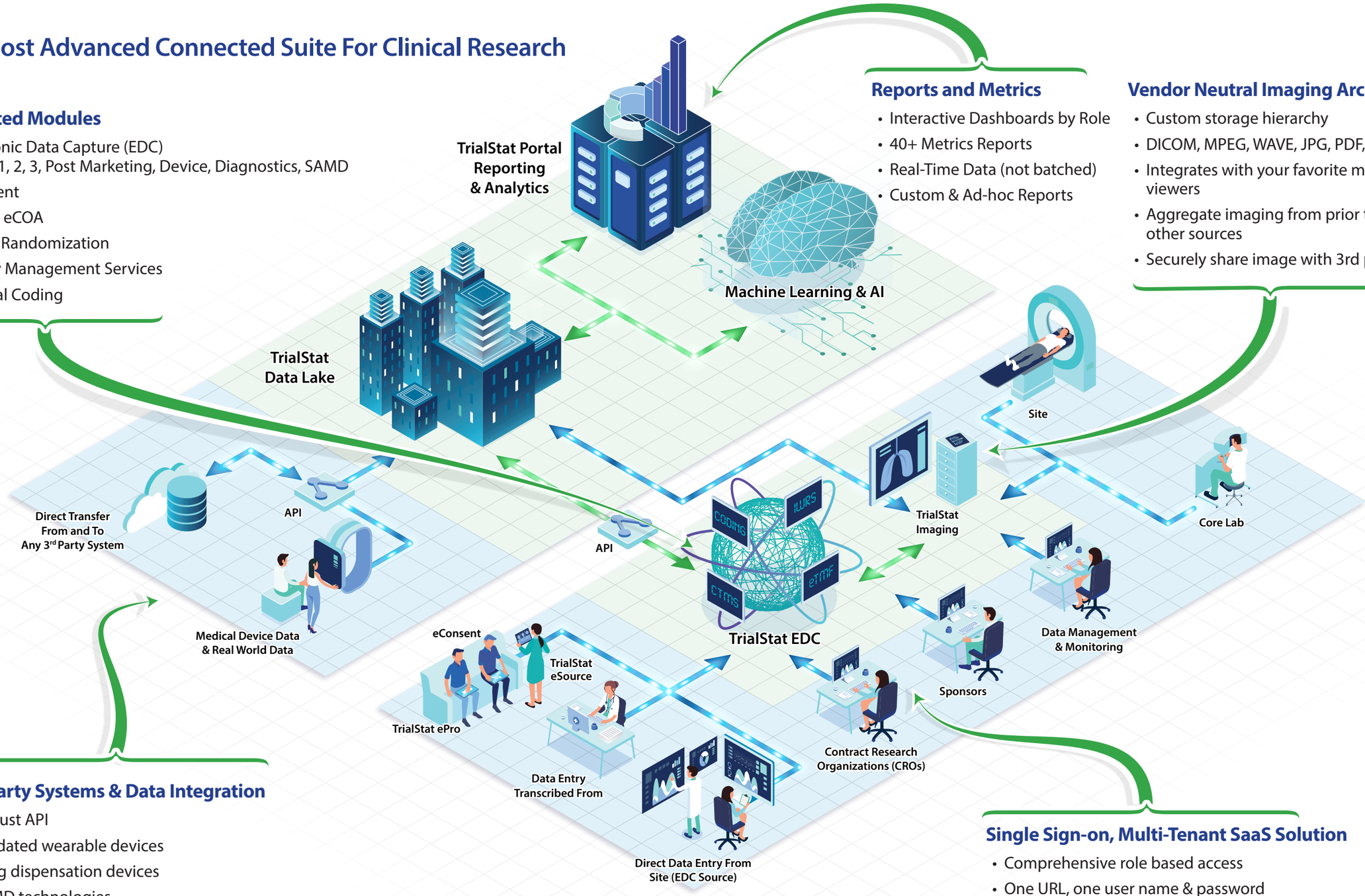
- Electronic Data Capture (EDC)
  Phase 1, 2, 3, Post Marketing, Device, Diagnostics, SAMD
- eConsent
- ePRO / eCOA
- IWRS / Randomization
- Supply Management Services
- Medical Coding

Reports and Metrics

- Interactive Dashboards by Role
- 40+ Metrics Reports
- Real-Time Data (not batched)
- Custom & Ad-hoc Reports

Vendor Neutral Imaging Archive

- Custom storage hierarchy
- DICOM, MPEG, WAVE, JPG, PDF, etc.
- Integrates with your favorite medical viewers
- Aggregate imaging from prior trials & other sources
- Securely share image with 3rd parties



3rd Party Systems & Data Integration

- Robust API
- Validated wearable devices
- Drug dispensation devices
- SAMD technologies
- CTMS and eTMF integrations

Single Sign-on, Multi-Tenant SaaS Solution

- Comprehensive role based access
- One URL, one user name & password
- Can integrate with your SSO technology

Custom Validated Development

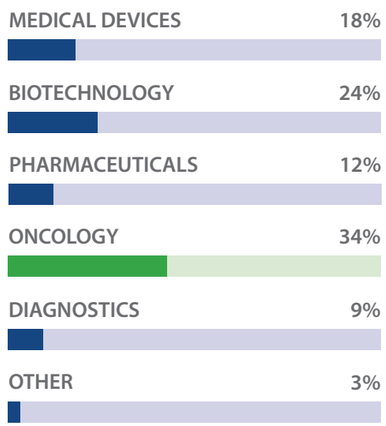
With full service, flexible, and cost-effective Study Development services across all phases of clinical research, as well as custom technology implementations, integrations and custom features, TrialStat is your trusted partner in custom development and integration projects.

- Experienced developers to extend your team's capacity and provide collaborative support on your specific technology needs
- Compliant with all regulatory requirements such as 21 CFR Part 11, HIPAA, GDPR, and including Master Validation Packages / Plans
- Detailed knowledge of technology advancements and system integration requirements ensures no wasted time or effort at scoping or during execution, reducing overall project costs

Experience and Therapeutic Areas

Offering proven reliability, efficient start up and study execution, and 20 years of experience working with clients ranging from diagnostic start-ups to medical device sponsors to international pharmaceuticals, TrialStat is the right choice for life sciences companies and CROs looking to modernize, optimize, or expand their clinical study management technology suite.

- Tools developed and enhanced hand-in-hand with sponsors, sites, and partners—your feedback matters and drives our innovation
- Services and technology solutions for new studies and rescue scenarios
- Proven reliability and quick execution (4-6 week EDC builds)
- 20 years of experience, global reach, translation, and a fully extendible and customizable platform designed to flex as needed for each of your trials



21 CFR Part 11 Compliant

HIPAA Compliance Solutions

FISMA Compliance Solutions

GDPR COMPLIANT

What do you wish your eClinical Suite could do?

Write down your top features or capabilities below and share with our team. If we don't already support, we can build it for you!

1

2

3

4

5

Regulatory Compliance

- 21CFR Part 11 Compliant
- GDPR / HIPAA Compliant
- SSAE 16 SOC 1 Data Centers
- Electronic Signatures
- Quality Management Systems
- Change Control Procedures

"Plus Therapeutics found a reliable, scalable partner in TrialStat Solutions as we transition from manual processes. Their unified eClinical suite simplifies data collection, provides real-time insights, and offers modular features and functions that will allow us to expand into their cost-effective system as we grow. Their dedication to innovation and customer satisfaction is crucial to our success and we highly recommend them."

- Norman LaFrance, Chief Medical Officer, SVP, Plus Therapeutics

TrialStat

Capitalize on the benefits of upgrading your eClinical technology today!

Would you like to:

- Increase visibility into all aspects of study progress
- Improve data management speed and efficiency
- Enhance compliance and data quality
- Reduce start up times, leading to faster study execution overall
- Improve security while adding more robust, flexible, future-friendly features and BYOD capabilities

Take the first step towards improvement and book your demo now. Modernize your eClinical technology and take your organization to the next level.

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