TrialOne®

The Global Leader in eSource Technologies

TrialOne is the leading proactive eSource and site automation solution for your early phase clinical sites. TrialOne is a comprehensive set of modules that drive efficiencies, reduce timelines and reduce costs through faster and more directed volunteer recruitment, easy to build schedule based workflows, real-time bedside data collection, direct data capture from devices, sample processing automation and modern data processing. The browser-based, tablet compatible system provides an advanced platform for automating your clinic operations, complies with FDA 21 CFR part 11, and supports data standards such as CDISC for faster and easier exporting and reporting of data.

TrialOne is designed and developed by early phase experts for early phase experts to deliver the technology that works the way you work.

eSource Data Collection

Study Data Collection. Real time, browser based data collection from anywhere in the world. TrialOne's compliant eSource tools significantly increases data quality and availability by providing a proactive, schedule driven data collection module. The responsive and user friendly interface drives the timely collection of the information that is most important for your clinical trial and business.

Device Direct Data Capture. A multitude of integrations for smarter data collection. TrialOne integrates with various devices such telemetry systems, ECG machines, vital sign machines, scales and balances. Data is seamlessly transferred from the devices into the TrialOne data collection fields, eliminating transcription errors and automatically alerting staff of out of range data.

Laboratory Integration. Seamlessly send lab orders and receive results. Through an integration with laboratory information management systems (LIMS), TrialOne is able to send out lab panel orders and import results back in for review and signing, ensuring all clinical study data are stored and maintained in one location.

Sample Tracking

Simple or Complex Processing. Complete collection to dispatch management. Process and track barcoded samples of all types (PK, PD, genomic, safety, urine, saliva, etc.) per protocol or sample type instructions, including divergent pathways and multiple transfers. Touch screen compatible, user friendly interface provides lab staff with specific task instructions and alerts users of critical timings. Batch and un-batch samples at any time for bulk processing, storage and/or shipment.

Subject Recruitment

Configurable Database. Collect data relevant to empowering your business. TrialOne's configurable recruitment module allows sites to capture the data they need whether it is a healthy normal, patient population or both. Basic recruitment data to complex medical and medication histories.

Powerful Search Tools. Ensuring the right subjects are recruited on to the right studies. TrialOne's Criteria tool enables sites to quickly and easily search any information including recruitment database information and study data (lab results, etc.) to provide a closer match to study criteria.

Subject Communications. Increased subject compliance, retention and satisfaction. TrialOne has the ability to send automatic appointment reminders to subjects, email blasts, mail merge letters and SMS messages ensuring your population is properly informed and engaged.

Self-Registration. Web based recruitment portal. TrialOne's self-registration feature allows subjects to enter themselves into the database, express interest in specific studies or answer study specific

OmniComm®
eClinical Solutions for Life™

Data Management

Data Review. Real time access. Real time review. Real time adaptability. Source data can be directly accessed and reviewed in real time through TrialOne's browser based data collection and review module. This allows sites to decrease timelines and costs associated with transcription and onsite monitoring. Data queries can also be managed directly within TrialOne. This comprehensive system allows sites to quickly identify issues or risks and adapt accordingly.

Data Exports and Reporting. Cleaner data faster. TrialOne's robust reporting and exporting tools give sites and sponsors the information they need, when they need it. TrialOne's global library, which is built to industry standards (CDISC, CDASH and/or SDTM) prior to data collection, enables sites to provide data exports in a variety of formats as soon as the data is collected including: SAS datasets, PIPE, TAB and CSV files. TrialOne comes with standard reports built in such as blank and completed CRFs, annotated CRFs, sample shipment manifests, subject schedules, etc. Powerful Ad Hoc reports, including cross study reports, can be created and scheduled to auto-run and distribute to appropriate recipients.

Data Imports. Centralized data. TrialOne has an automated file import utility which will monitor a drop location such as a folder on a shared drive or FTP/SFTP site. The import utility will then process the data (laboratory, ECG, subject diary, etc.) into the TrialOne database for immediate display against the appropriate data point on the study schedule.

End to End Clinic Automation

Faster Study Builds. Reusable global library built to CDASH/SDTM standards. TrialOne's QuickStart library allows elements (answers, events, questions, entire study protocols) to be copied or reused, significantly reducing the study build time. Customize events and schedules to exactly match protocol, SOP or site requirements.

Custom Labeling. Efficiency and quality gains using a multitude of barcoded labels. Quickly and easily design labels for subjects, samples, batches, users, equipment., doses and other events. All labels print directly from within TrialOne. As well as system generated barcodes, TrialOne also supports external barcode labels, such as sampling kits, allowing the site to accommodate sponsor needs.

TrialOne. Proven. Faster. Smarter.

- Stats:
  - 20 global sites
  - >1650 beds
  - >500 studies/year
  - >2400 users
- State of the art hosting or local installations
- 24/7/365 multilingual, actual employees CustomerCare team
- Constant innovation and client driven development
- World class implementation and support team
- Collaborative user community

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