



# TRIAL 360

## ALL-IN-ONE SOLUTION FOR RESEARCH SITES



It is a complete solution in the cloud for sites, a user-friendly system, all-in-one, modular and scalable. Inspired by a site's network, it helps sites comprehensively manage critical processes with high-end technology.

### Trial360 benefits

- Have tailored trials: multi-studies, and multi-sites.
- Reduced study startup timelines in 3 - 4 weeks.
- Swift, cost-effective trial deployment.
- Continuous user-friendly and patient-centered experience.
- Easy-to-use and accessible from any browser, anywhere at any time.
- Automated workflows.
- Integrate with your EDC, IRT, and other systems (RAVE, Integra eCRF).

### Trial360 core modules for clinical trials



#### eSource (Clinical trial set-up)

- Manage clinical trials in one place; the system can conduct multiple types of trials.
- Run multiple sites, in one or different sites, running independently or consolidated data.
- Set up clinical trial protocol within hours, not days.
- Customize visits for data gathering according to protocol.
- Do data management per subject and per visit.
- Access to domain templates for data gathering in adaptable clinical trials.
- Prepared monitoring visits, providing remote access with automatized limited time for detailed data analysis.
- Capture findings and deviations related to your clinical trials and build action plans that the CRAs can optionally view.
- Record explanatory notes.
- Manage all the information from databases of candidates, recruitment, and visits until the end of the clinical trial.
- Get a detailed audit trail of captured data and its modifications (who, what, when, and why).
- Get pre-built domain templates to capture the clinical trial visits information.
- Replace paper, avoid misplacing documents, and save on physical storage and transfers.
- Manage adverse events; classify, detail, and notify.
- Set email notifications for activities, adverse events, and more to one or more specified persons.
- Search, filter, group, and classify all the information by clinical trial, subject, and visit to bind all data records.
- Manage investigative and administrative roles to support processes that arise within clinical trials, maintaining the security principles with restricted user access to role/responsibility.
- Assign subject and randomization numbers.
- Manage delegated participants per visit, for example, to assess the number of visits in which a user participated certain sub-investigator.

- Manage blind and non-blind roles.
- Have role-adjusted views of information.
- Have a status stream in each process that needs to go to the CFRs to prevent them from not loading or updating.
- Verify and ensure that data capture by domain is complete as established by visit.
- Get support for updating protocols and configurations.
- Keep a status stream of the subjects from their acquisition to recruitment until it ends.

#### Recruiting

- Build the possible subjects database for your clinical trial.
- Manage the candidate's interest in participating in the trial.
- Register for each contact, calls, notes, comments, and more effective and trackable leads.
- Get a complete report of subjects and projects databases per clinical trial in real-time.
- Build call scripts per clinical trial or in general.
- Add customizable forms to your recruitment.
- Import external databases.
- Get an Opportunity Score.
- Manage referees and build a relationship with the candidates.
- Use a customizable flow of recruitment stages.
- Manage pre-candidate generation initiatives to maintain the relevant contact database.
- Plan next steps to maintain the candidate's contact and interest.
- Schedule directly and simplify the first visit.
- Get site support on the first visit and measure the effectiveness of your recruitment with the scheduled initial attendance control.
- Get the reasons for drop-outs, analyze why the candidates do not decide to participate in a clinical trial and manage to improve the recruiting effectiveness.

- Manage candidate's duplicates and archives to maintain an optimal and relevant database.
- Run detailed analytics views that let you filter, group, search and organize the candidate's information.

## Scheduling

- Set up clinical trial visits under different dynamic schemes according to the protocol.
- Plan the scheduling of maternal clinical trials.
- Optimize the scheduling per visit of each clinical trial considering each site timetable and staff capacities.
- Schedule the length of your visits by type.
- Prevent overscheduling.
- Keep your visits within the window with intelligent scheduling and real-time control of each visit's status; quickly identify out-of-window visits.
- Do not lose visits; visits scheduled per subject are managed according to protocol.
- Manage unscheduled appointments.
- Schedule follow-up appointments/automatic appointments depending on unscheduled visits.
- Schedule on-site, remote (home and hospital), and virtual appointments.
- Automatic cancellation of visits conditioned to the schedule of another visit.
- According to the clinical trial objectives, recurring visits are adaptable by frequency, including the number of repetitions, date range, and special interest times.
- Make the management and contact records of different kinds, such as visits confirmation, calls, messages, and emails.
- Rescues: Identify subjects in this state to reduce drop-outs.
- During each visit, manage care flows and subject status.
- Record your wait times and total service time during each visit.
- Keep track of the appointment flow status and remote follow-ups.
- Coordinate services and record information during the visits among all the delegates.

## Laboratory

- Manage the life cycle of laboratory samples from request until result or shipping to external central laboratories.
- Get support for preparing external samples, assembling boxes, and shipped to central laboratories with follow-up management.
- Straightforward integration between the laboratory module and visits from your clinical trial.
- Upload results of the processed samples will be reflected immediately in the visit and medical history.
- Parameterize laboratories considering sex and age as reference values and way of taking the samples.
- Define laboratories to take per visit with the detail of group, sex, and the sampling method.

## Finance

- Faster and more reliable billing: manage the clinical trial payments per visit and/or activities carried out in a timely and reliable manner.
- Minimize the administrative task of managing charges and expenses by subject, activity, and visit.
- Keep precise control of each billable item within the trial attributable to visits and subjects.
- Manage financial support delivered to subjects during visits.
- Issue invoices under local legislation.
- Manage your entire accounting.
- Obtain income and expenses data per clinical trial (Accounting / Analytics / Cost Center).
- Issue pro forma invoices.
- Digitalize invoices, upload your files in image or PDF format, and they will be created with Artificial Intelligence to facilitate the correct loading.
- Compatible with multiple currencies.
- The multi-company scheme integrates all the companies in the same system with real-time consolidation reports.
- Accounting reports for taxes, profit and loss, and more.
- Simple conciliation.
- Manage supplier invoices and staff payments.

## EMR (Electronic Medical Record)

- Get an Electronic Medical Record to gather all the information about your medical care and visits in one place.
- Keep a consolidated clinical history for subjects that may participate in more than one clinical trial (not at the same time).
- Get validation for subjects not participating in more than one clinical trial simultaneously.
- The EMR is built in compliance with local regulations.
- Use a single medical record for clinical trials and diagnostic medical care.
- Complete medical record: history, medications, vital signs, and more.
- Get precise and structured data.
- Avoid interpretation of the physician's, participant's, or delegate's handwriting.
- It is designed to improve the work team's experience, oriented towards reducing the complexities of working with paper files.

## Cross-sectional system features

- Multilanguage
- Multisite / Multistudies
- Multicurrency
- Real-time collaboration
- Comprehensive management of users according to role and permissions granted. It includes the creation of monitor-type users (when remote monitoring is enabled).

## ERP Core (Opcional)



## Projects (Optional)

Break down your clinical trials into small, planned tasks, assign them to your team and improve collaboration in the execution of clinical trials or internal site projects.

- Access to a detailed and efficient overview of projects.
- Work on one or multiple projects simultaneously, perform analysis and multi-project searches.
- Monitors the expected hours and task completion.
- Track delivery dates and milestones with a clear calendar view.
- Allocates the necessary time to specific tasks.
- Customize the process of each project, change the name of the stages and alerts based on its activities, program and automatize emails, etc.
- Manage tasks on the timeline with the Gantt workflow diagram view.
- Generate reports and analyze the performance of projects.

## Website (Optional)

- Create a customizable website with templates, colors, and dynamic blocks with business capabilities.
- Recruit subjects with customizable form pages.
- Highly customizable in a simple way.

## Documents (Optional)

- Define workspaces with folders hierarchical organization and use sets of tags and actions.
- We have integrated electronic signatures to avoid wasting time printing and scanning documents.
- Assignment of documents to users.
- Workflow definition for your documents associated with fully integrated approval, control, and validation processes, with activities and rules of action to ensure the right person does everything at the right time.
- Easily customizable access rights per folder.

## Validation standards:

Our software solutions are built in compliance with:

- 21 CFR part 11
- ALCOA
- HIPAA
- GCP
- GDPR

**For more information about  
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## eLearning (Optional)

- Obtain a complete and functional solution for learning management, promote staff training, share knowledge and inspire others.
- Train your employees in their various roles, SOPs, policies, protocols, etc.
- Conduct knowledge assessments through quizzes, points, and badges.
- Manage certifications through questionnaires and do assessments per question with a minimum passing grade. Use different types of questions, retries, time limit, issuance of a certificate to pass, randomization of the questions, order and subset questions by groups to mitigate copying.
- Build engaging content: videos, web pages, presentations, documents, SCORM, etc.
- Each staff member can go at their own pace.

## Procurement (Optional)

- Automation of the procurement flow.
- Improve performance of procurement and inventories with rules of provisioning.
- Supplier price lists and product availability.
- Obtain the best offer with purchase tenders.

## Activities and notes

- Program activities automatically per visit.
- Create and customize different types of activities.
- Define the activity types that can be developed.
- Notification of assignment and resolution of activities via email.
- Centralized dashboard of activities carried out and pending.
- Add quick notes or file attachments to any task, keeping the team connected and informed.

