



# 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.

### Trial 360 Functionalities

- User-friendly.
- Scalable, modular.
- Web-based.
- Multilingual.
- Multisite / multistudy.
- Multicurrency.
- Real-time collaboration.
- Comprehensive user management, according to role and access rights.
- Monitor user creation (enables remote monitoring).
- Eliminates paper usage.

### Core Modules for Clinical Trials



#### Project

- Clinical trial configuration and management.
- Configuration of visits per type (on-site, virtual, home, hospital, follow-up, unscheduled, recurrent), duration, data, laboratories, and images to be captured according to the protocol and their respective invoicing.
- Configuration of automatic cancellation of visits conditioned to another.
- Configuration of recurring visits by date range and special interest periods.
- Management of research and administrative roles, assignment of coordinator and principal investigator.
- Research product configuration.
- Set up adverse events as well as the user who will receive the notification via e-mail.
- Informed consent(s) configuration.
- Configuration of the delegation log of the protocol, users, roles, responsibilities, start and end date of the delegation.
- Get an overview of the project with the status of each of the research subjects.

#### Recruiting

- Customizable recruiting stages.
- Build potential subjects database for clinical trials.
- Upload external databases.
- GeoIP: Automatically detect countries, states, and cities from the candidate IP address.
- Maintained a clean database with duplicate and filed candidates management.
- Manage candidate recruiting previous initiatives.
- Manage referrals.
- Keep initiatives tracking, close opportunities, and get accurate inputs.
- Handle the candidate's interest by giving an opportunity score.

- Register each contact, call, notes, comments, and more for an effective conversion.
- Schedule activities according to processes: calls, meetings, tasks, and sent emails.
- Today's and next day's meetings and activities overview.
- Add customizable forms.
- Call potential candidates directly from the system.
- VoIP: establish a calls line for clients or opportunities; call manually or automatically directly from the browser. Register calls, open forms, and automatize the next steps. Reschedule or send an email for failed calls. Integrated with the Asterisk v13.2 VOIP server.
- Automatize and integrate emails.
- Synchronize your schedule with Trial360 calendar on desktop and mobile.
- Schedule the first visit in a simple way.
- Measure the recruiting effectiveness with the initial assistance control.
- Real-time reports of the initiatives database and candidates per clinical study.
- Get the dropout's reasons and analyze the motives for non-participation to adjust the recruiting strategy.
- Design the overview dashboards for better decision-making.

#### Scheduling

- Plan your scheduling strategy.
- Schedule visits within window time and highlight objective days.
- Optimize scheduling per visit from each clinical study, considering each site's timeframes, visit duration, and staff capacity.
- Plan scheduling for maternity clinical studies.
- Set up clinical trial visits under different schemes according to protocol requirements and dependencies.
- Avoid over-scheduling.
- Keep visits within the window with smart scheduling and each visit real-time status management. Identify out-of-window visits quickly.
- Manage non-schedule visits.

- Schedule follow-up visits automatically, depending on non-scheduled visits.
- Schedule visits on-site, remote (home and inpatient), and virtual.
- Automatically cancel visits conditioned to others.
- Program visits per frequency according to the clinical trial targets, including repetitions, date ranges, and special interest dates.
- Manage the visit assistance with confirmation, calls, messages, and emails.
- Identify the subjects in ransom status to decrease dropouts.
- Get to know the waiting times indicator.
- Identify the entire patient care times.

## Laboratory

- Manage the whole lab samples life cycle, from request until result or shipping to an external central lab.
- Log the sample request into the EMR.
- Register the sample taking into the EMR, including the user in charge, sample type, volume, etc.
- Log and manage the sample processing and shipping to central laboratories.
- Integrate the visit data record with the sample request and lab tracking.
- Upload lab results per sample and visualize them in the EMR visit.
- Lab parameter setting considering sex and age as reference values and sample type.
- Establish lab takes per visit with group, sex, and sample taking way details.

## Pharmacy

- Establish warehouses.
- Create medicines, vaccines, research products, medical devices, etc.
- Carry out the technical reception of products.
- Add products to warehouse inventory.
- Dispense products.
- Make product return.
- Log and tracking of final product destruction.

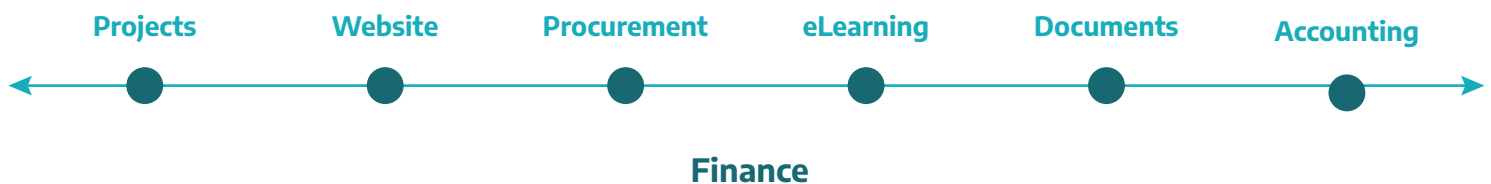
## EMR (Electronic Medical Record)

- Manage and register medical data from end to end.
- Record all the visit information according to protocol through organized and structured fields.
- Coordinate data record activities between staff, thanks to data access per role.
- Establish one medical record per subject.
- Capture and manage findings and protocol deviations related to the study.
- Log explanatory notes related to a visit.
- Log checklists, surveys, questionnaires, and training performed to the subject.
- Register inclusion and exclusion criteria.
- Capture the data from remote patient monitoring.
- Eliminate paper medical records.
- Adverse events report and analysis with automatic notification to the study team or project coordinator.
- Blind and non-blind role management.
- Automatic validation of patient participation in more clinical trials.
- Compliant with local regulations.
- Inform consent upload previously to EMR visualization.
- Track all user's activity and data logging.
- Record and follow-up medical orders within the EMR.
- Record the administration and observation after medicines and vaccine administration.
- Create process status to drop the information into the eCRF.
- Give remote access to auditors.

## Imaging

- Create studies to be set up according to the protocol.
- Set up imaging requirements per visit.
- Manage imaging study requests according to the protocol in the EMR.
- Upload the result (PDF lecture).

## ERP Core (Optional)



## Accounting

- Invoice faster and more reliably: manage the charge of clinical trials per visit and/or activities carried out within them timely.
- Minimizes the difficult task of the administrative team to carry out the collection and expense management by subject, activity, and visit.
- Keep a precise control of each billable item within the study attributable to visit and subject.
- Economic support management to be delivered during the participant's visit.
- Issue invoices under local legislation.
- Manage all the site accounting.
- Obtain income and expenses per clinical trial (Analytical Accounting/Cost Center).
- Issue pro-forma invoices.
- Digitize invoices, upload files in image or PDF format, and the system will create them with Artificial Intelligence to ease loading their details.
- Supports multiple currencies.
- Multi-company scheme to integrate a group of companies in the same system with real-time consolidation reports.
- Tax accounting reports, profit and loss, and more.
- Simple Settlement.
- Accounts payable, suppliers invoices, and expenses control.

## Invoices

- Send corporate invoices directly to customers with just one click.
- Automatically send invoices by email as a PDF attachment or print and mail them.
- Get paid faster with online payments: Accept online payments with PayPal, Ingenico, Buckaroo, Stripe, Authorize.net, Atos Worldline, or Adyen.
- Automated follow-ups: Automated follow-ups are effortless to set up and help streamline billing to get paid quickly and easily.
- Keep movement records of bank accounts and the status of invoices.
- Use the status summary to keep track of invoice drafts, paid and unpaid invoices.
- Automatically register all the transactions of bank accounts by importing and reconciling bank statements.
- Analyze sales: Access detailed data to get a comprehensive overview.
- Access to critical information with dynamic and customizable dashboards. Make your definitions and analyze billing by product, customer, vendor, etc.

## Expenses

- Manage employees daily expenses, whether they are per diem, office supplies, or any other concept of expense. Access all the receipts and charges in an Expense dashboard and create, validate or reject them with

just one click—no need to download any specialized software to keep expense records.

- Upload all receipts directly to the expense record: Employees can easily attach copies of their receipts directly to an expense record.
- Add attachments via a mobile device by taking a photo of the receipt and sending it to the designated email address.
- As a manager, easily track spending records across the entire team to stay on top of costs and ensure they stay on target and budget.
- As an accountant, record company and employee expenses by adding them to the books and process payments and invoices.

## Spreadsheet

- Make projections, calculate commissions and analyze additional data with

real-time information.

- Understand the financial situation and discover the earning potential.
- Analyze data: Make well-informed and efficient decisions.
- Model and manipulate data: Insert revenue analysis for sales, purchases, budgets, and subscriptions and get historical, current, and predictive figures views.
- As new data is created within the apps, the spreadsheet is continually updated without having to export or worry about integration.
- Detect critical problems and identify patterns and trends.
- Add filters based on dates, relations, or text.
- Bring data to life: Visual representations help efficiently and quickly understand data. Large volumes of data are represented appropriately, with authority and clarity.

## Human Resources

### Employees

- Centralizes all HR information.
- Restrict visibility of sensitive information to HR managers only, or publish general information to all employees, such as the employee directory.
- Receive alerts about new permit requests, job assignments, applications, evaluations, and more.
- Keep track of hours worked by employees and classify them per project, client, or task.
- Easily access statistics to record and analyze timesheets and check each employee's attendance.
- Integrated accounting automatically publishes reports based on time spent on projects and provides real-time data.
- Easily keep track of vacations and sick leave of your employees:
  - Employees enter their requests (paid personal time, sick leave, etc.).
  - Managers decide whether to approve or reject the requests.
  - The notification is sent to the employee, and their calendar is automatically updated.
- Quickly update and approve expenses: Employees can easily submit and justify expenses. Managers can review all expenses and approve or reject individual requests if needed. Once approved, the expenses are immediately updated in the Accounting module.
- Easily set up and schedule the employee assessment process. Design form-based questionnaires to get feedback from all employees to managers and their self-assessments.
- Streamline the hiring process: Keep track of the received applications. Monitor and manage the candidate's pipeline, integrate with the Surveys application to create automatically an assessment questionnaire associated with each candidate's record.

### Assessments

- Set up multiple employee assessment plans for each department.
- Filter and sort reviews per employee, status, due date, recognition, and plan name to get an overview of reviews.
- Create multiple surveys for each stage of the assessment process.
- Convert any employee evaluation into a PDF form to be printed immediately.

### Hiring

- Handle the onboarding process easier, from recruitment to hiring.
- Post job offers on the website and follows the application process with the kanban view.
- Follow each candidate and create a database of skills and profiles with indexed documents.
- Track job openings, see which channel drives the most applications.
- If candidates contact you via email or online form, receive automatically indexed data (resumes, cover letters, etc.) and reply with just one click, using templates or customized emails.
- Defines stages and interviewers.
- Defines the document management process itself. Find the complete documents in the Documents section. Create an organized and instantly accessible repository with all candidate's resumes.
- Integration with calendars.
- Send offers online, and create links with the offer for the selected candidates. Let them review the offer, upload their personal information, and sign it.

### Time Off

- Manages employee permits.
- Keep track of all employee's vacations: Employees enter requests, and managers approve and validate them. Each employee's schedule is updated accordingly.
- Managers can view the permits of their entire team in a complete view to keep the team organized and easily forecast the distribution of tasks during the absence of its members.
- Set the number of leaves assigned per person to allow employees to record their leaves accordingly.
- Create new permission types for unusual situations.
- Plan and monitor the team's availability for the day, week, and month on a clear calendar.
- Get statistics on the number of permits per person, by department, and per type of permit and export them in PDF in just one click.

## Website

### e-learning

- Tool for learning management to promote and manage employee training.
- Create as many courses as needed based on the topics you want to teach.
- Train employees in different roles, SOPs, policies, protocols, and others.
- Build content with videos, web pages, presentations, documents, SCORM.
- Perform knowledge assessments with multiple grading types; per question, minimum passing grade, different kinds of questions, number of attempts, time limit, order randomization, and subset of questions per group.
- Add external links at the end of the content so students can access additional sources.
- Students can check their answers and compare them with the correct ones once they have submitted their exams.
- Manage certifications.
- Track course participation with easy-to-understand progress and completion indicators.
- Each employee can go at their own pace.

## Website Builder

- Create a customizable website with multiple templates, colors, and dynamic blocks with business capabilities.
- The website automatically adapts to mobile devices. Choose to hide or show content on the mobile version.
- Use the dynamic blocks to build a highly customizable portal easily.

- Turn visitors into leads with innovative tools: get visit data based on their IP address, add calls-to-action, design efficient forms, etc.
- Track visitors in real-time and contact the most interesting ones with just one click: push notifications, live chat, SMS, etc.
- Recruit subjects with customizable form pages.
- Chat with visitors instantly with the integrated live chat tool.
- Allow visitors to interact with each other in the forum section.

## Marketing

### Marketing (social, email, SMS)

- Send directly or schedule posts for platforms like Facebook, Twitter, and LinkedIn.
- Send push notifications to potential subjects who visit your website.
- Add social networks like Facebook and Twitter to your dashboard to monitor accounts, engage with the community, and get insights.
- Create fully integrated recruitment campaigns: emails, SMS, push notifications, and social media posts. Get the campaign results overview regarding clicks, revenue, and leads.
- Get an accurate list of the website visitors and communicate with them via email, SMS, push notifications or live chat requests.

- Talk to one or more of your website visitors. They will receive a message on their following action on a crawled page.

### Surveys

- Create engaging online satisfaction surveys, marketing campaigns, and feedback forms in three intuitive steps.
- Use background images to illustrate questions.
- Share and collect data quickly.
- Analyze answers and view results graphs in real-time.
- Compatible with mobile devices. Easily track projects and tasks from anywhere. Stay connected always.

## Add-ons

### Projects (additional)

- Task planning and scheduling for internal site projects or clinical trials.
- Modern user interface designed for project management to get all the information in seconds.
- Search for tasks or issues easily with smart filters. Analyze data with multilevel clustering.
- Customize each project process, change the stages and alerts according to your activities, automate emails, etc.
- Manage tasks on a timeline with the Gantt chart view; the better way to track deadlines and progress over time.
- Use charts to analyze the task's progress: per stages, manager, tag, project, etc.
- Use the tasks calendar view to highlight the project due dates. Just drag and drop activities on the calendar to reschedule them.
- Use the pivot table in tasks to perform detailed statistical analysis on project performance.
- Work on one or multiple projects at the same time. Perform multi-project searches and analyzes.
- Keep track of expected and actual hours to rebuild projections on tasks.
- Enable the sub-areas feature in each project. Create multi-level subtasks to manage the relationship between tasks.
- File completed tasks and get a view of only the ones you still need to work on.
- Each project can have its email address. Emails sent to this address will automatically create new tasks. All the email recipients will be added as followers of the task. Communicate on tasks by sending emails or entering notes.
- Chat online with other users to get answers in real-time. Use chat groups to chat on assignments.
- Follow tasks with just one click and receive alerts based on relevant activities.
- The activity log attached to each task delivers a detailed history of all activities on the document.
- Get the essential project information at a glance: spent time, estimated time, rates, billable hours, etc.
- Use predefined dashboards or create one with the advanced reporting engine—share filters with the team.

- Record work time, at the beginning of the day, on the go, or once the job is done.
- Activate tasks by clicking "Start" to begin your assignments.
- As a manager, get a full view of who is working on what.
- Tasks will continue no matter where you are, even if the Internet connection is unavailable.
- Offline hours are synced to your account once you're back online.
- Organize the employee's workload by assigning them tasks and projects.
- Trigger a periodic email reminder for timesheet users to create a timesheet or for managers to approve it.
- Managers can allow or promote their employees' access.
- Monitor employee performance by project or by task.
- Get an overview and approve the employee timesheets.
- Limit the timesheet visibility to other employees.
- Get statistics on billable hours, billable imports, unbilled amounts, etc.
- Review employee performance by measuring the profitability of their projects.
- Permits can be automatically integrated with timesheets to control the time better.

### Documents

- Save time recording invoices, scanning contracts, and approving documents and become a paperless research site.
- Share, send, categorize and file scanned documents easily. Generate business documents such as supplier invoices and tasks.
- Streamline the workflow by leveraging a fully integrated approval, control, and validation process, with activities, chat, and action rules to ensure the right person does everything at the right time.
- Integration with the Signature app: assign the documents to the right person and have them sign and send them electronically.
- Batch Document Processing: Work in batches and request approvals, change folders, label, and assign multiple files simultaneously instead of one by one.
- Hierarchical folder organization helps to define workspaces that have their own sets of tags and actions.
- Assign documents to users.
- Customizable access rights per folder.
- Integration with other Trial360 modules.

### Timesheet

- Use the timer to monitor the exact time spent on tasks.

## Activities

- Schedule activities, reminders, send messages and internal notes.
- Create the activities that can be done and find them in the messaging section.
- Define activities to be carried out, expiration date, summary, and assign the activity to another user.
- Track activities: Planning, Mark as Done, Done!, Discard. Trial360 will indicate the delayed activities.
- Notify the activities request and resolution by email.
- Classify the pending activities per color scheme.
- Centralized dashboard of carried out and pending activities.

## Signs

- Send, sign and approve documents online.
- Upload PDFs and drag and drop fields for parties to fill out.
- Keep track of the sent documents status.
- Reduce hidden costs like printing, copying, faxing, scanning, deleting, and posting—access to everything online from any device.
- Save time by avoiding waiting days or weeks for all parties to sign documents.
- Eliminate manual operations and improve the quality of completed and signed documents.
- Safe identification: All documents are encrypted to ensure that only authorized people can access the content and document.
- Document Integrity: Trial360 keeps the authorized document under control at all times. Any activity on the document (reading, signing, etc.) is encrypted to guarantee the document's unalterability. An audit trail report is available to all parties at any time.
- The application is validated according to the EU regulation 910/2014 (eIDAS) and the United States ESIGN decree.

## Notes

- Add quick notes or attach files to any task, keep your team connected and informed.
- Break down to-do lists into customizable stages that will turn into columns on the board.
- Add notes to your stages. Each note is a mini-project that will change from one stage to another as the project progresses.
- Drag and drop notes from one stage to another in the kanban view.
- Insert text styles like headings, bold, italics, and lists.
- Group your notes per color to categorize tasks. There are nine colors to choose from and a colorless option.
- Attach text, images, or document files to the notes.
- Upload any text file or document to the notes.
- Export the notes.
- Add coworkers to notes so they can follow discussions and get notifications.
- Choose what others can do with your notes by changing access to view or edit.
- Each author who writes a note can have a different background color to show who writes what. You can link a name with a color.
- Chat to have real-time discussions with those who follow the notes.
- View the changes history of the notes chronologically.
- Check who is connected to your notes in real time.
- Share notes with colleagues by sending them a link or an embedded URL.

## Dashboard

Analyze the business status at a glance:

- Collect reports.
- Generate graphics.
- Filter results.
- Track data.

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