Trial 360 over odoo

A web-based all-in-one business management software for Clinical Research: Recruitment + CTMS + eSource + Finance + Enterprise Resource Planning (ERP) + HR + Analytics, and more.

integra IT

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ODOO is the heart of Trial360

Value: a truly unique platform

66 official apps (=902 modules) + 39,717 community apps

The only management software **complete** enough to run large corporates (>1000 users) and **simple** enough for small companies: 18.583 databases of 1 user (self-employed people).

What makes the difference between Odoo and SAP? Our users are happy… often fans.

Not just a company

A large ecosystem driven by an Open Source community

5,128
Partners

175
Countries with partners

100k
FTEs on Odoo

39,700
Community Apps(*)

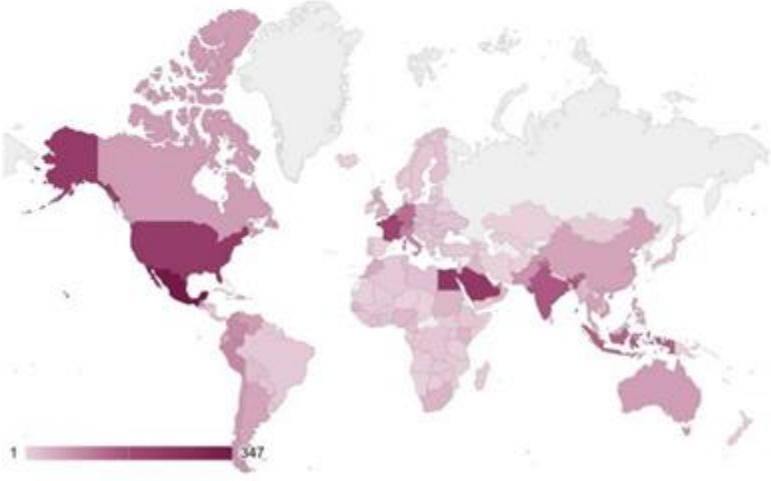
150k
Databases in Production*

10.8M
Users**

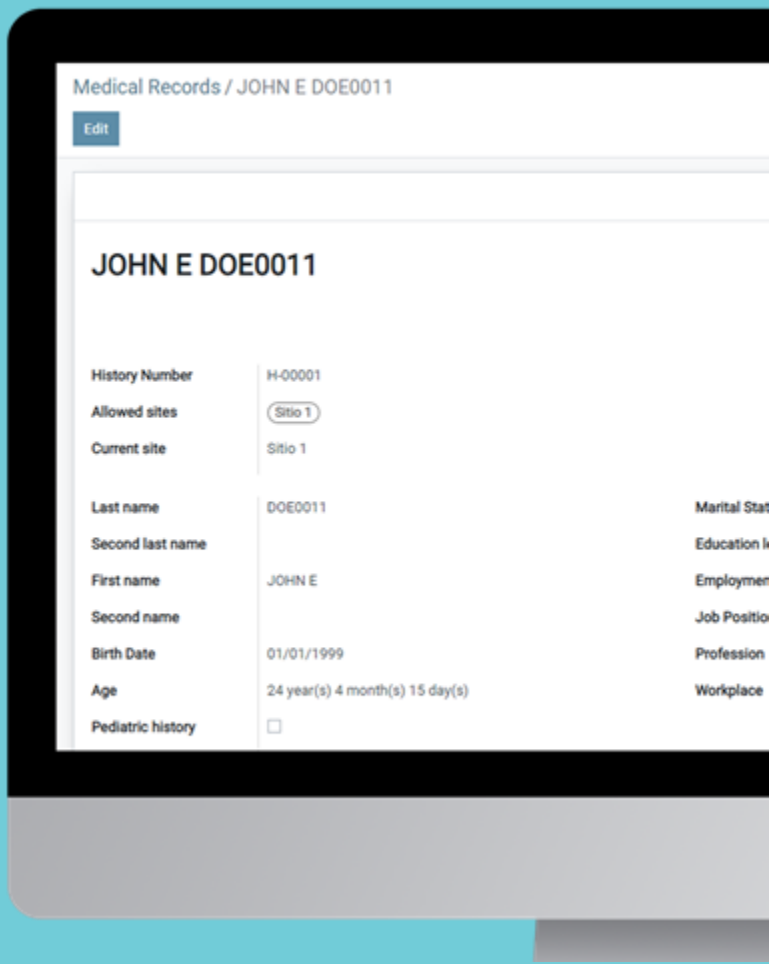
(*) The largest business apps store in the world; the #2 is salesforce AppExchange at 4250 apps.
(**) Paying & free, on databases alive since more than 2 months

 # Partners by Country: Mexico: 348, Egypt: 245, Saudi: 240, U.S.: 232, Belgium: 207, Spain: 200, France: 198, India: 155, Indonesia: 144, Germany: 126

Revenues by Country: U.S. (13%), Belgium (12%), France (10%), Saudi (5%), Germany (5%), Mexico (5%), Switzerland (4%)



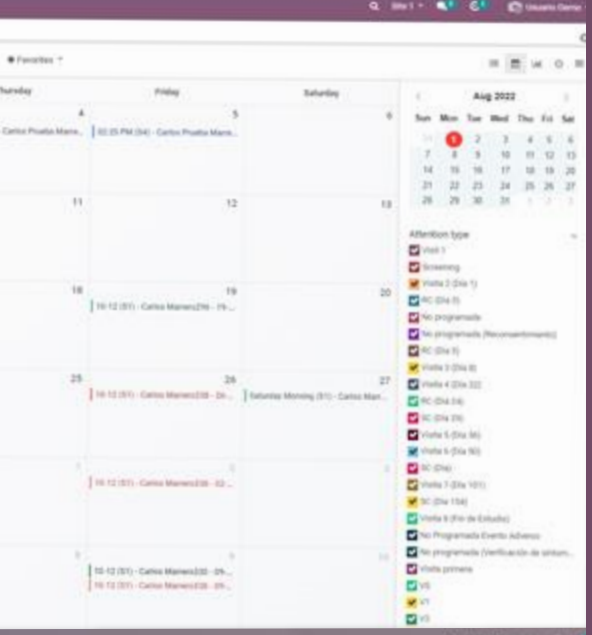
All-in-one solution for Sites

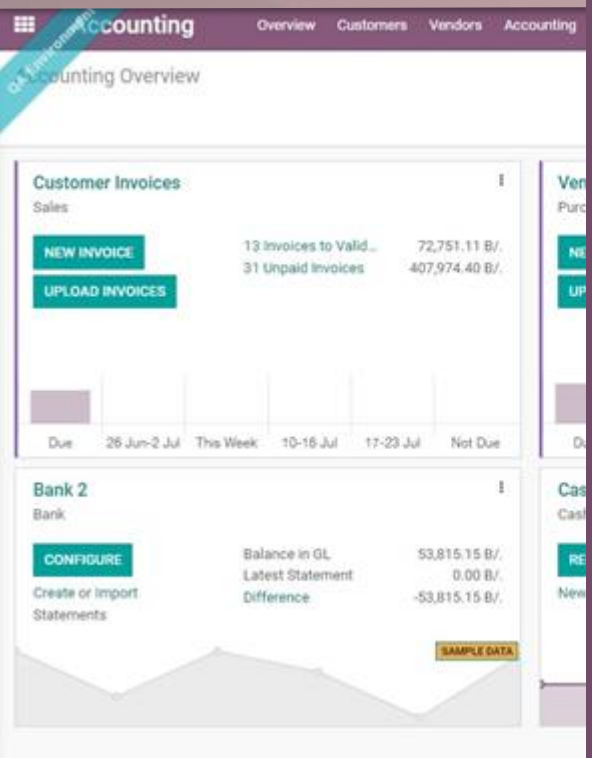


Trial 360 is a web-based platform created for site operations management and clinical trial conduction over Odoo Business Suite Framework designed for Small and Medium Enterprises. This solution is built in compliance with **ICH / Good Clinical Practices and 21 CFR Part 11 from the FDA**, which speed-up and improves quality in research sites processes.

Inspired by real, multi-research site challenges, this modular solution is user-friendly and is flexible for any size, multiple-center, and multi-country sites, under an on-demand and pay-as-you-go model.

We are the only all-in-one solution on the market that integrates an Enterprise Resource Planning (ERP) system like Odoo, with Customer Relationship Management (CRM) and Recruitment, a Clinical Trials Management System (CTMS), System laboratory sample management and eSource or Electronic Medical Record (EMR) over a secure and collaborative solution.





Trial 360, Odoo for Clinical Research

Odoo is a versatile business management software suitable for companies of all sizes. It offers integration, scalability, customizability, cost-effectiveness, a user-friendly interface, and active community support.

- Trial360 in Odoo offers a cost-effective ERP solution for clinical trials, eliminating the need for multiple standalone systems.
- Odoo provides powerful project management tools, enabling you to plan, schedule, and track clinical trial activities.
- Collaborate seamlessly with team members, track progress, and meet deadlines effectively.
- Assign tasks to team members, set deadlines, and receive notifications on the app.
- Ensure adherence to regulatory guidelines by tracking and documenting all necessary compliance data.
- Data accuracy and integrity are crucial in clinical trials, and Odoo offers robust data management tools.
- Capture, store, and analyze trial data in a secure and centralized database.
- Generate comprehensive reports, visualize trends, and make data-driven decisions for successful trials.
- Tailor the system to your needs with customizable modules, workflows, and reports.
- Add new functionalities as required, ensuring Odoo aligns perfectly with your evolving trial requirements.
- Reduce IT infrastructure costs, licensing fees, and training expenses with a comprehensive, all-in-one platform.
- Achieve higher ROI and maximize the value of your clinical trial investments.

Challenges & Issues of Non-digitized Sites.

Lack of 360 visibility and control

From cash flow, expenses and procurement, to HR, resource management, capacity, marketing and more.

Paper usage

Hidden costs associated with storage, shipping, transcription and reconciliation.

Lack of real-time data & clinical trial visibility

Decision-making difficulties, mitigating risks and making timely reports to sponsors.

Recruiting

Delays and gaps in meeting recruitment targets, which cause cost overruns and extend study time, or result revenue losts.

Compliance

Risk of regulatory breaches, protocol deviations due to lack of control.

Kick-backs

Lack of clear and dynamic workflows, unnecessary expenses and loss of competitiveness.

Benefits.

Streamline sites operations and exceed the expected results with Trial 360.

- Reduces study start by 2 – 4 weeks. Implementation in just 4 hours.
- Quick and cost-effective execution of studies.
- Friendly and intuitive tool with a patient-centric approach.
- Easy to use and accessible from any device, any browser, at any time.
- Real-time collaboration.
- Scalable and flexible.
- Automated workflows.
- Allows the recording of the subject number, randomization ID, treatment stage and Date.
- Allows recording and management of adverse events.
- Compliance with standards: 21 CFR 11, ALCOA and GCP.
- Traceability: Audit Trail is part of every activity as called for in FDA's 21 CFR Part 11. You can see who, when, what and why data was changed.
- All subject information is encrypted and complies with all industry guidelines as well as HIPAA.
- Comprehensive user management according to role and permissions granted.
- Creation of monitor-type users (allows remote monitoring).
- It integrates with any EDC, IRT and other systems like RAVE through APIs.

Trial 360 Expertise.

Trial 360 adapts to each site goals, and make possible to reach superior performance indicators for efficient and high-quality clinical studies.

+40
Total clinical trials performed

2 Hours
set-up/startup time record

+10,000
Subjects recruited in just a year

+500.000
Scheduled visits

Trial 360 supports research sites and universities by offering its use at no cost for research protocols with no Sponsor.

92%
Compliance with scheduled visits

99%
99% Invoicing in the same month visits or procedures are completed

+700
Users managed per site

300
Concurrent users

Trial 360 Cross-sectional Features.

User-friendly

Scalable

Web-based

Multi-language

Multi-site / Multi-study

Multi-Country Multi-Currency

Real-time collaboration

User management per role and permits

Monitor-like users for remote monitoring

No more use of paper

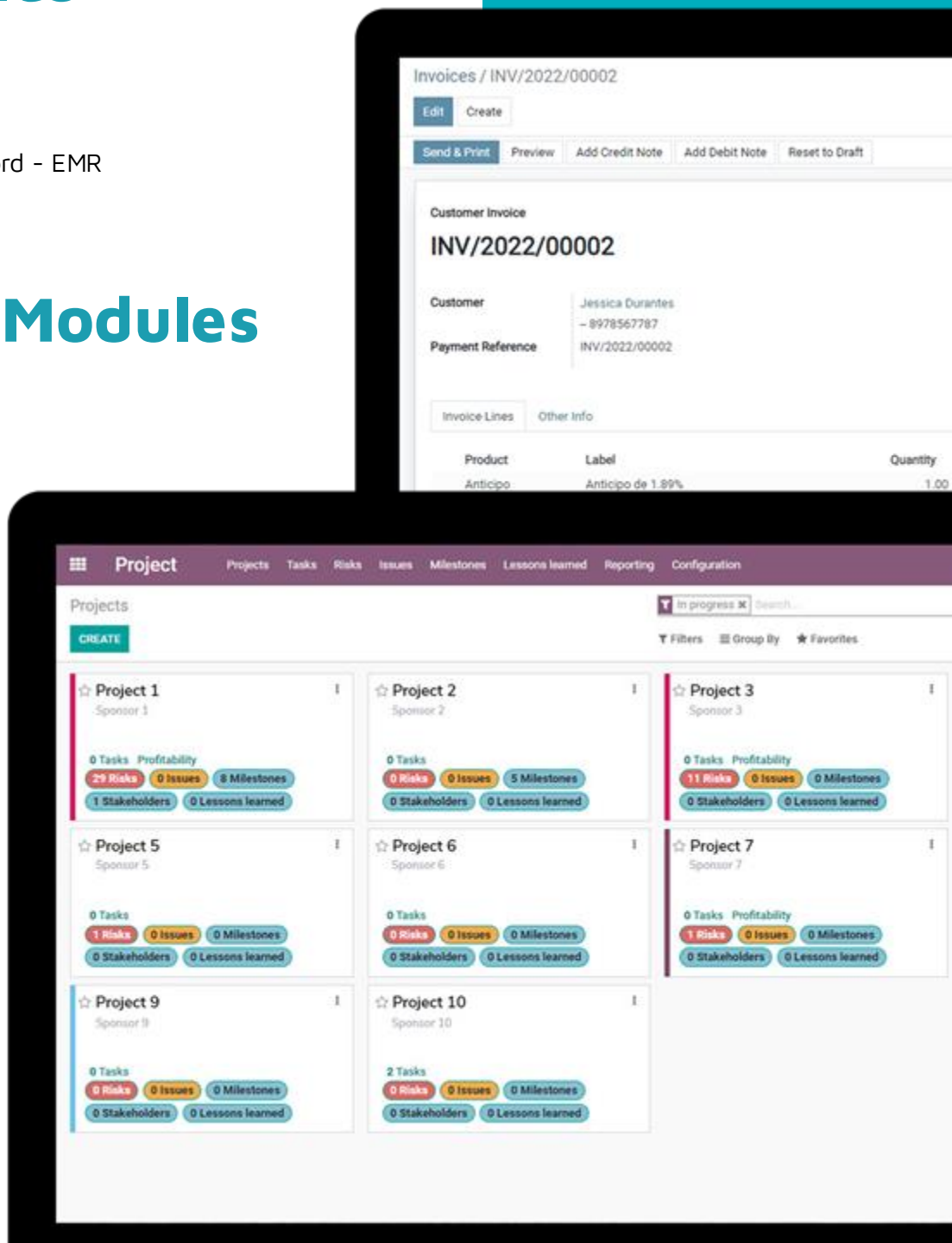
Trial 360 Clinical trial Modules.

Core Modules

- Research Projects
- Recruitment
- Scheduling
- Electronic Medical Record - EMR
- Laboratory
- Finance

Additional Modules

- Imaging
- Pharmacy
- Projects
- Website
- eLearning
- Documents
- Electronic signature
- Human Resources
- Marketing
- Surveys
- Activities
- Notes



Research Projects.

Set-up and manage clinical trials in the Projects module:

- Visits, visit type, duration and data to be captured according to the protocol
- Automatic follow-up appointments dependent on unscheduled visits
- Visits are automatically cancelled if a specific condition is not met
- Delegation record
- Adverse events
- Billing charges per visit
- Management of research and administrative roles
- Research product
- Recurring visits by date range and times of special interest

Efficient process for setting up a project:

Recruiting

Define the recruitment flow and its stages, from the loading or creation of possible subjects to the first visit scheduling:

- Possible subjects database.
- Import external databases.
- Handling duplicate and archiving candidates.
- Manage initiatives prior to lead generation.
- Schedule the first visit in a simplified way.
- Referrals management.
- Follow-up initiatives, opportunities, registration of each contact, calls, notes, and comments.
- Schedule activities: calls, meetings, tasks, sending emails.
- Add customizable recruiting questionnaires.

Recruiting general flow:

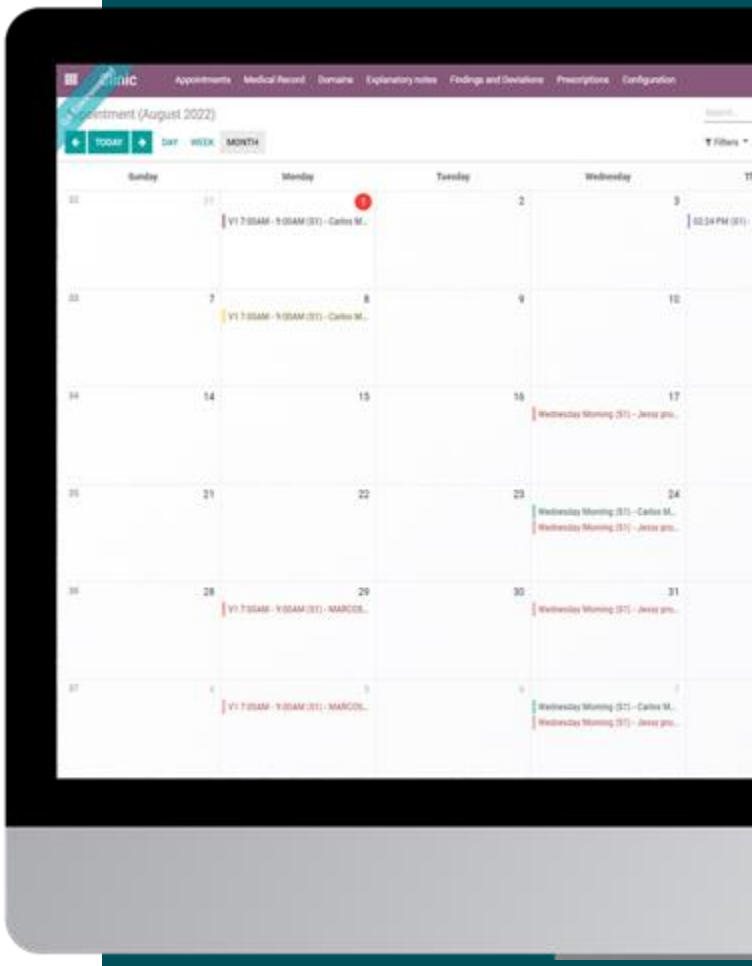
1	2	3	4
Candidate	Call log	Pre-screened	Scheduled

See Recruitment combined with Marketing Modules Brochure

Scheduling

Get a streamline scheduling strategy for an efficient site operation and demand planning:

- Schedule visits within the window, highlight target days.
- Prevents over scheduling.
- Real-time control of each visit status.
- Identifies visits that take place outside the window.
- Manage unscheduled, on-site, remote (home and hospital) and virtual appointments.
- Automatically cancel the visits dependent on one another.
- Program recurring visits adaptable by frequency, including number of repetitions, date range and special interest slots.
- Manage the visit attendance with confirmation, calls, messages and emails.
- Get waiting times, total attention time indicators.



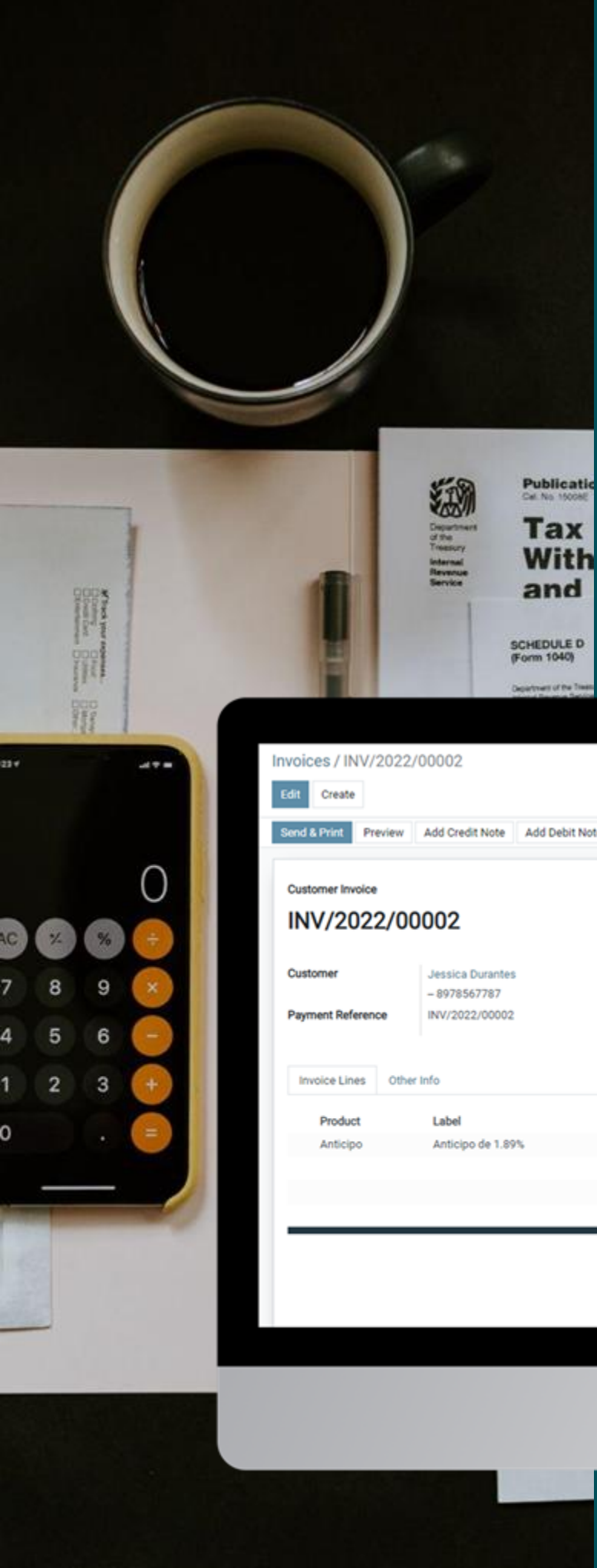
Scheduling general flow:

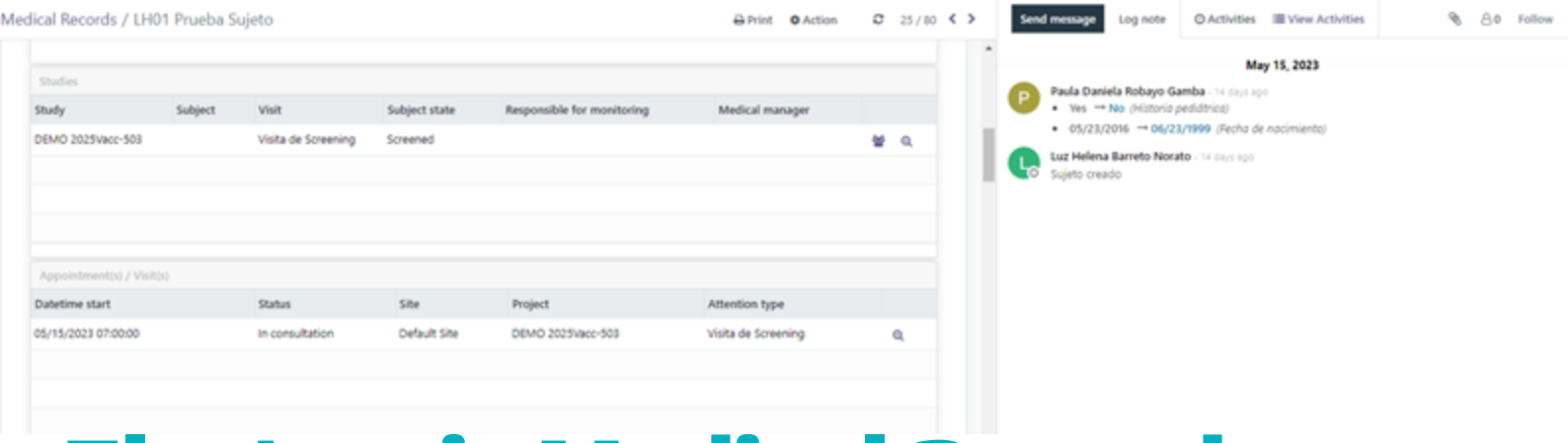
Schedule	Confirm	Waiting evaluation	In evaluation	Closed	Entry CRF
1	2	3	4	5	6

Finance

Reach faster and more reliable billing. Manage the clinical trial charge per visits and/or activities carried out.

- Minimizes collection and expense management tasks per subject, activity and visit.
- Detailed control of each billable item within the study attributable to visit and subject.
- Management the economic support delivered to subjects during visits.
- Invoices issuance under local legislation.
- Complete accounting management.
- Accounts payable, control of supplier invoices and employee expenses.



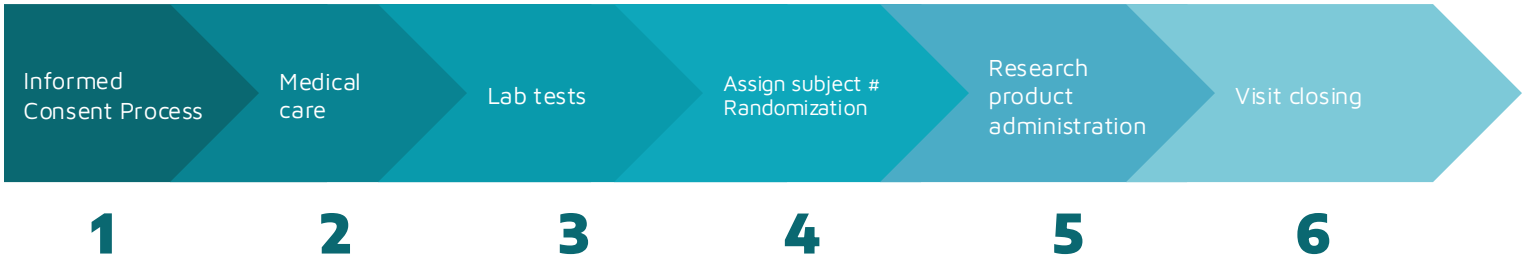


Electronic Medical Record – EMR

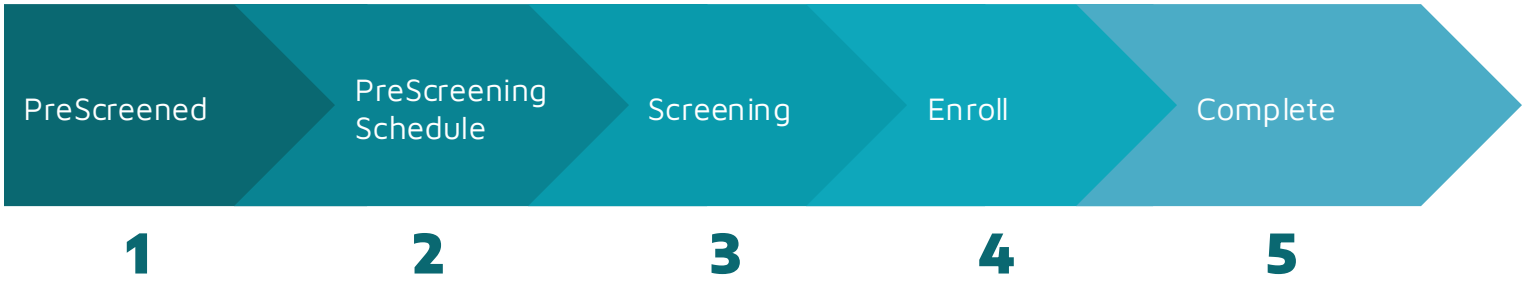
Record the participants data from start to finish; all the visits and diagnostics information through structured data and coordinated between the staff, since it has an data view adjusted per roles:

- Single medical history per subject.
- Capture and management of deviations related to the clinical trial.
- Register the research product administration and post-administration follow-up.
- Record explanatory notes related to each visit.
- Adverse events report and analysis with automatic notifications sent to the project coordinator or any interest user.
- Remote access for auditors.
- Follow-up on the participant status and the progress within the research project.

The general point of care flow and medical record registration:



Track each subject in the clinical trial:

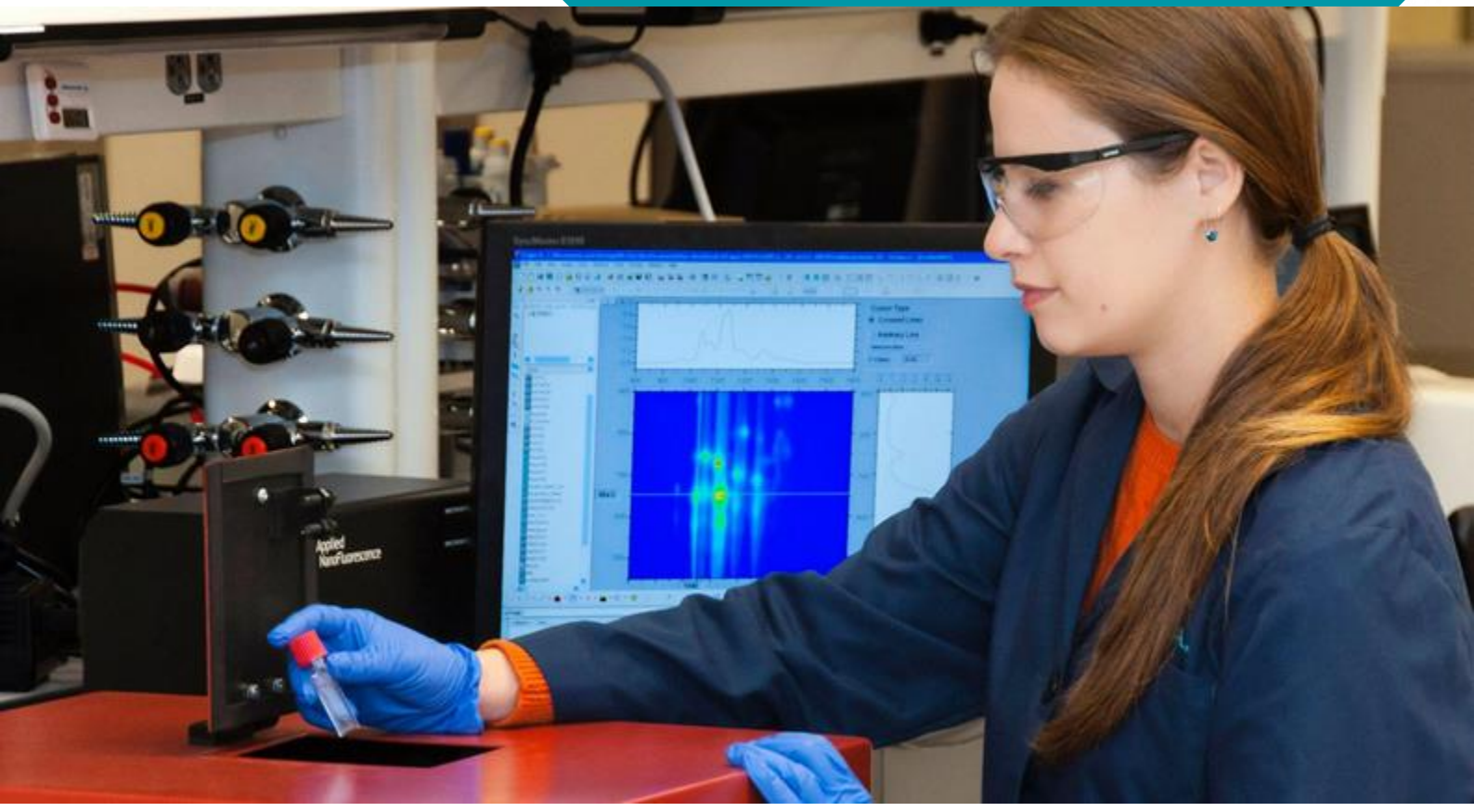


Additionally, follow up the prescreening failure, screening failure, and drop outs.

Laboratory

Manage the life cycle of laboratory samples from their request, sample collection until their result, or shipment to external central laboratories.

- Upload the results per sample and they will be visible in the medical history visit.
- Parameterize laboratories considering sex and age as reference values and type of sample.
- Define laboratories to be taken per visit with details of group, sex and the way the samples are taken.



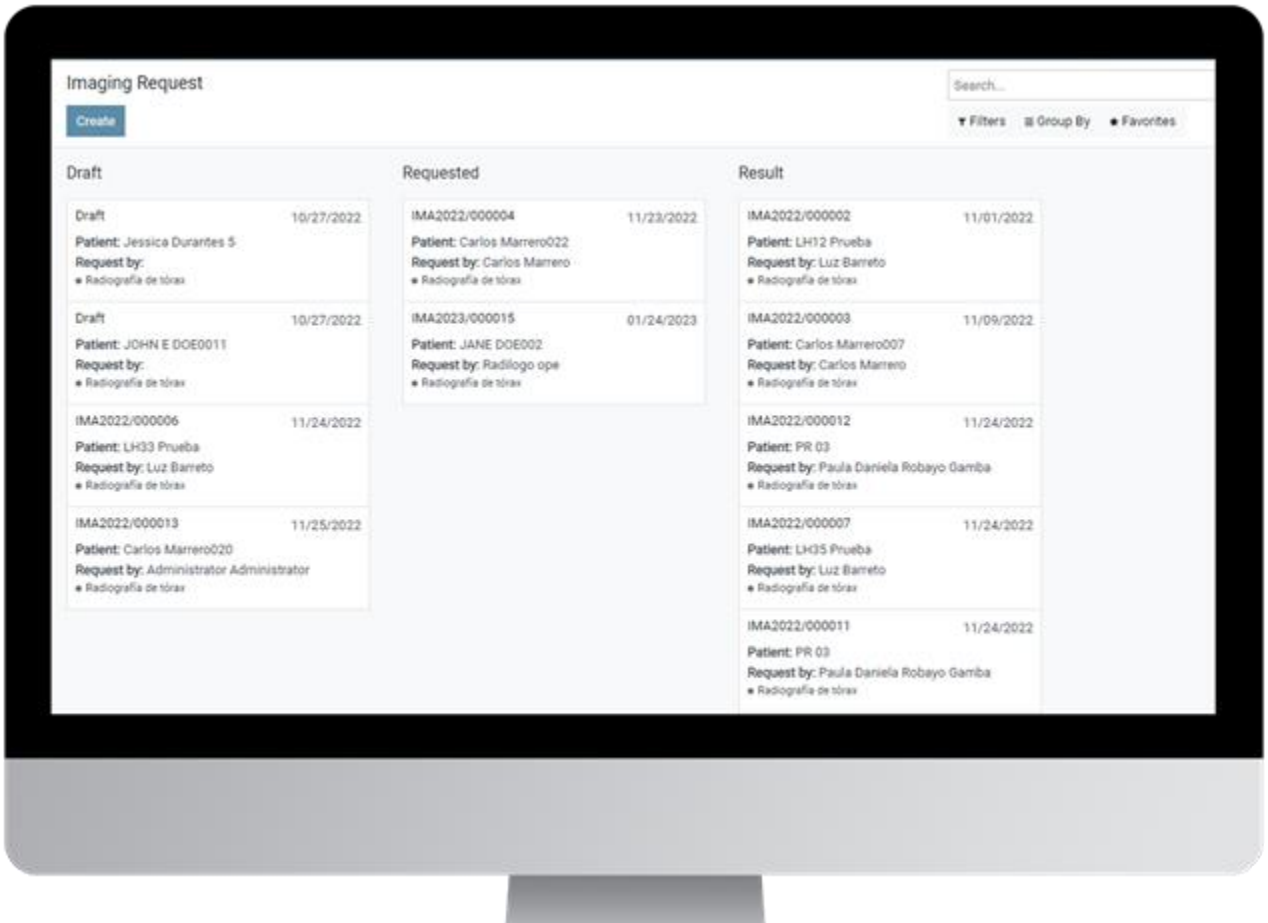
Lab samples flow:

Additional Modules.

Imaging

Register and monitor orders for imaging studies within a research project.

- Create the required studies to be configured according to the research protocol.
- Setup the images required per visit.
- Manage the request for imaging studies defined by the protocol in the clinical history.
- Upload the result (PDF reading) of the study.

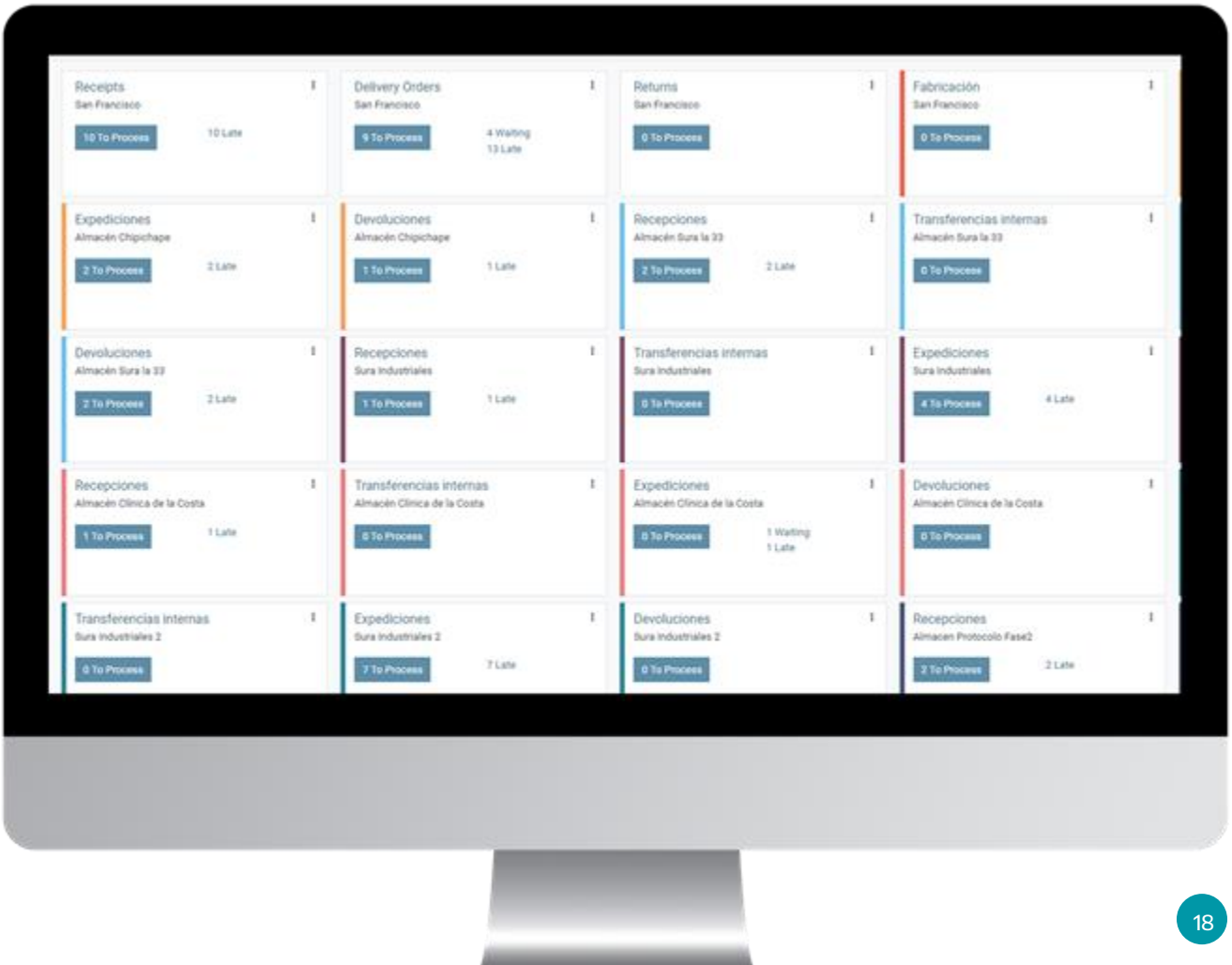


Additional Modules.

Pharmacy

Management and monitor research products, drugs and devices used within the research site; register the technical reception of products, inventory control, dispensing, return, and registration and monitoring products final destruction.

Pharmacy flow:



Additional Modules.

Project

Allows project management, Gantt charts and task views, lists, risk monitoring, incidents, milestones, stakeholders, and lessons learned from additional research site projects.

WebSite

Design a web page with business capabilities, manage recruitment forms, use digital channels, and Chat with visitors instantly with the integrated live chat tool.

eLearning

Complete solution for learning management. Online training and education: make programs, content creation, execution, evaluation, certification, and participation monitoring with completion and progress indicators.

Documents

Structure documents, add tags, actions, assign users, and setup workflows.

Timesheets

Record and track assigned tasks per project, record work time, perform employee performance monitoring by project or by task, manage performance statistics, and integrate with the permissions section.

Electronic sign

Eliminates the need to print and scan.

Human Resources

Centralized human resources information; hiring, permit management, vacations, applications, and evaluations.

Marketing

Design different automated marketing strategies in multiple channels such as email and social networks.

Surveys

Create satisfaction surveys, marketing campaigns, and feedback forms, use images in the background to illustrate questions, share and collect data quickly, analyze responses, and view graphs of results in real-time.

Activities & Notes

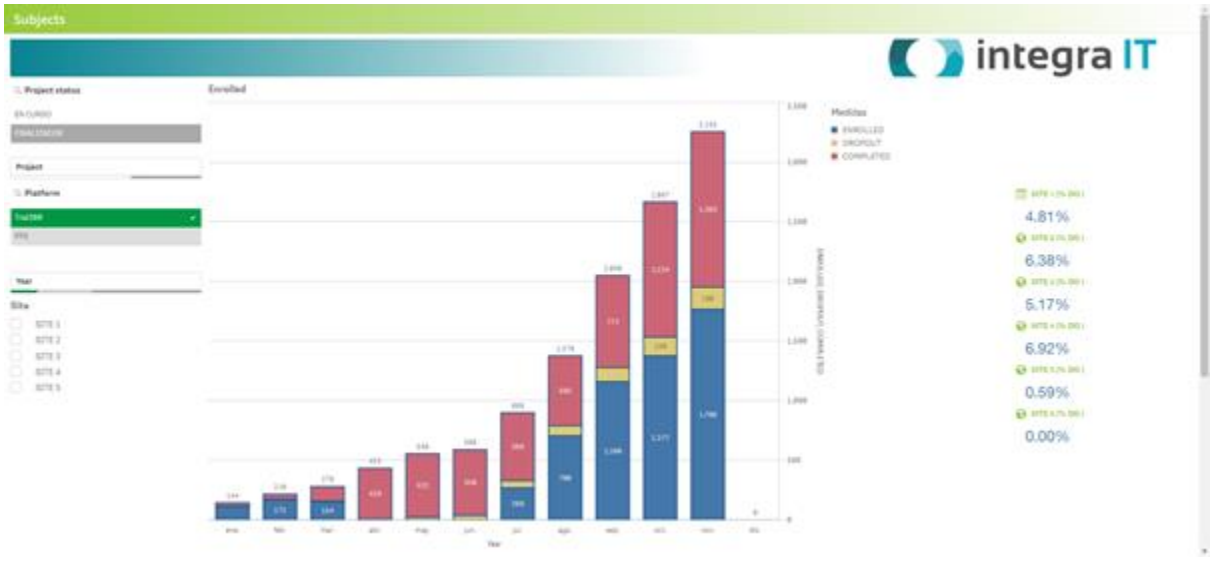
Access to activity boards, adding notes, sending email notifications, and monitor task execution. Add quick notes or attachments to any task, keeping the team connected and informed.

Decision-Making.

Trial360 allows the creation of customizable control panels and the setup of Key Performance Indicators with real-time monitoring: make timely decision-making at all levels.

Analytics.

We have advanced analytical data through data integration with Qlik to create visual analysis dashboards; this allows decision-making based on data, improving processes, exploring new market niches, getting to know internal and external customers better, and improving services.



Cevaxin Success Study Case.

Trial 360 have enabled the Cevaxin Site Network to set up studies in hours, recruit and enroll participants more efficiently, and meet visit schedules. Cevaxin takes the laboratory's needs to the next level and uses the electronic medical record (EMR) as a source document throughout the organization, allowing controlled access by CRAs for remote monitoring. All with 100% success in audits.

Cevaxin **David** 1

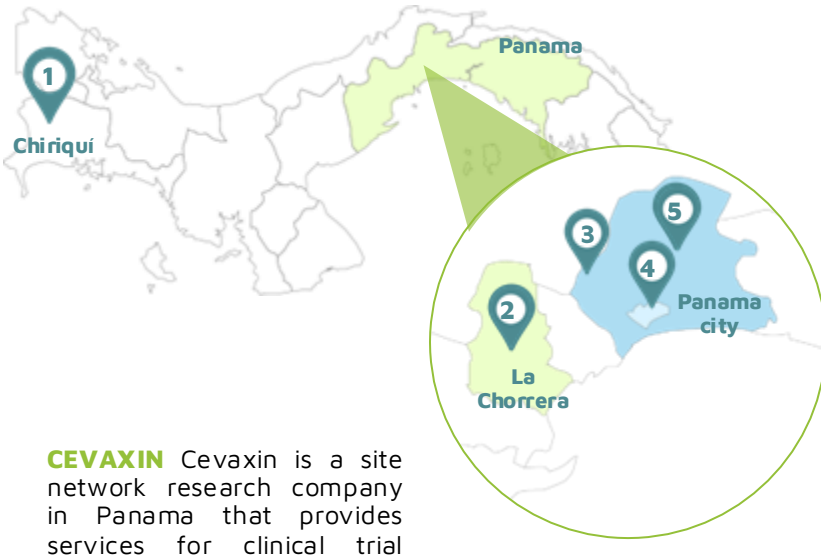
Cevaxin **Plaza Carolina** 4

Cevaxin **Chorrera** 2

Cevaxin **24 de diciembre** 5

Cevaxin **Av. México** 3

Cevaxin **Pacific Center** 6



Research Center

- Key Opinion Leaders network in different medical areas
- **Regulatory** services
- Sponsor for local studies
- **Recruitment and** Adherence Unit
- **Quality Assurance** Unit
- **Contact** Center
- **Project Management** Unit
- **Technology** Embedded

Milestones

2021: 22 projects & >8.000 participants

2020: 16 projects & >6.000 participants

2019: 11 projects & >6.000 participants

2018: 11 projects & >6.300 participants

Cold chain

- Temperature control for samples and vaccines
- Alarm control

CEVAXIN Cevaxin is a site network research company in Panama that provides services for clinical trial implementation and conduction, epidemiological services, and public health studies. The site delivers innovative approaches and quality processes to achieve high-quality data and results for trials.

+250 employees

Our software solutions are build-in compliance with:

HIPAA COMPLIANCE

GDPR

GCP COMPLIANT

21 CFR PART 11 FDA COMPLIANCE

EU ANNEX 11

ALCOA

Security in Software as a Service.

Our solutions are offered under a Software as a Service (SaaS) secure model. This means that your data is hosted on a private server with the latest technology and safety, following the highest industry standards such as HIPAA, FDA 21 CFR Part 11, ANNEX 11, ITIL, ICH and ISO 27001.

Trial 360 allows the research site to define, according to its needs, the following security policies:

1. User and role management.
2. Session expiration time.
3. Simultaneous session.
4. Failed login setup and temporary account lockout.
5. Duration and passwords forced change.
6. Email notifications for unable to log in or suspicious sessions.
7. Password strength with uppercase, lowercase, numeric and special case, number of characters.
8. Double authentication.

Why Integra IT.

At Integra IT, we use innovation in technology for data gathering, access, and surveillance in life science studies across all phases in a time-reliable manner. **We offer a complete portfolio of 100% cloud solutions in compliance with GCP, FDA 21 CFR Part 11, Annex 11 and HIPAA regulations**, aiming to make our partner's work easier and more effective. We develop tailored solutions for pharmaceutical companies, CROs, and sites.

- 100% Web-based solutions.
- Cost-convenient for sponsors, CROs and small and medium research sites.
- Real-time information for data-driven decision making.
- Studies with quick start ups.
- Interoperable solutions within each other and integrable with third-party system.
- Solutions validated in ICH Good Clinical Practices and in compliance with international regulations.
- On-off on-demand scalable architecture (It allows activate /deactivate the modules)
- Experience in low- and middle-income countries.
- Special functionalities for vaccine studies.

Our Experience.

Our company was created to develop and operate complex trials for the health and clinical research industries. Our team, processes and strategy are focused in helping clinical trials sites and CROs implementing technology solutions such as mobile Apps and web platforms.

Our main goal as a company is to support our customers in improving their data collection processes, reduce the communication gaps with their subjects and improve their clinical trials operations from subjects recruitment (CRM) to billing according to Study milestones.

+61.000 participants

Diseases

- COVID-19
- Chikungunya
- Polio
- Dengue
- Herpes Zoster
- Pertussis
- Hepatitis A
- Norovirus
- Meningococo
- Rotavirus
- RSV
- Diabetes
- Fabry's disease
- Hereditary angioedema
- Prostate Cancer (RWE)
- Flu
- Breast Cancer (RWE)
- Sexual Arousal Disorder
- Asthma (RWE)

Some of our Clients

Sponsors

- AstraZeneca
- Oxford University
- OPS
- Takeda
- Bill & Melinda Gates Foundation
- FIDEC
- GSK
- University of Colorado
- AJ Vaccines
- Shire
- Mainz University
- p95
- Valneva
- Clover
- Medigen
- HilleVax
- CureVac
- Ciudad de Botucatu en Brasil

CROs

- Vax Trials
- JSS Research
- PPD
- ASSIGN

Others

- Afidro
- Minsa Panamá
- Instituto de Investigaciones Clínicas Mar de Plata

Locations


Colombia


United States


Chile


Panama


Dominican Republic


Lithuania


Guatemala


Germany


Philippines


Honduras


Turkey


Peru


Brazil


Persian Gulf


Saudi Arabia


India


Argentina


Thailand


Paraguay


Puerto Rico


Mexico

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Talk with us about your research site necessities and **learn more about our flexible and tailor-made payment models!**

Schedule a Demo or contact our experts

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