integra IT

Product & Services General Information

The Integra IT Suite for Life Sciences. Solutions for sites, CROs and sponsors.

Content.

integra IT

Executive Summary.

Our perspective

The pharmaceutical industry has many challenges in order to access the information in a quick way. The majority of trials still use paper forms, this practice generates mistakes and create a low level of efficiency. For those reasons Integra IT has developed new solutions to improve the way the data is collected, how the researchers manage the data and how they recognize data inconsistencies. We have created web platforms and mobile applications that allow patients to have a better, in real time, communication with the site; guaranteeing fewer errors on the gathered data while improving Clinical Trial overall operations.

Benefits to our Clients

Integra IT offers you unique solutions combining, adherence, realtime information, new adaptive communication channels, and making the process of identifying any type of local adverse events, Systemic AEs, solicited AEs, serious AEs and AESIs, all available in a single vendor with 12 years of experience in Clinical Trials .

We cover all main processes and operations of Sites and CROs for Sponsor to be efficient in their Clinical Trials Management.

Our Trial 360 solution offer a modular approach towards transforming operations into a paperless automatic one, including electronic clinical record, laboratory and study management to the integration of study milestones and costs with billing and accounting.

Trial Pal App is designed for improving the adherence of the subjects to the study procedures, and to identify possible outcomes in real time, preventing losing cases, that for an efficacy trial are the most important information for the development of the investigational product.

Data is received in real time and the subjects are contacted frequently in a user friendly way through the most used way of communication that are the mobile apps. Site staff are constantly reminded to send the symptoms reports to the site in each home visit. In this way the site is always informed regarding the status (adherence) of any subject.

With the implementation of this solution in your trial, the team will improve the identification of any AEs and AESIs. This identification will occur in real time, allowing the sites and subjects to proceed with the protocol activities within the required window for this important outcome.

Solutions to our Clients

Integra IT will customize the selected solution to support all the processes of the study. Integra IT is in a unique position to support you, thanks to a true perspective of differentiation and collaboration, based on five main characteristics:

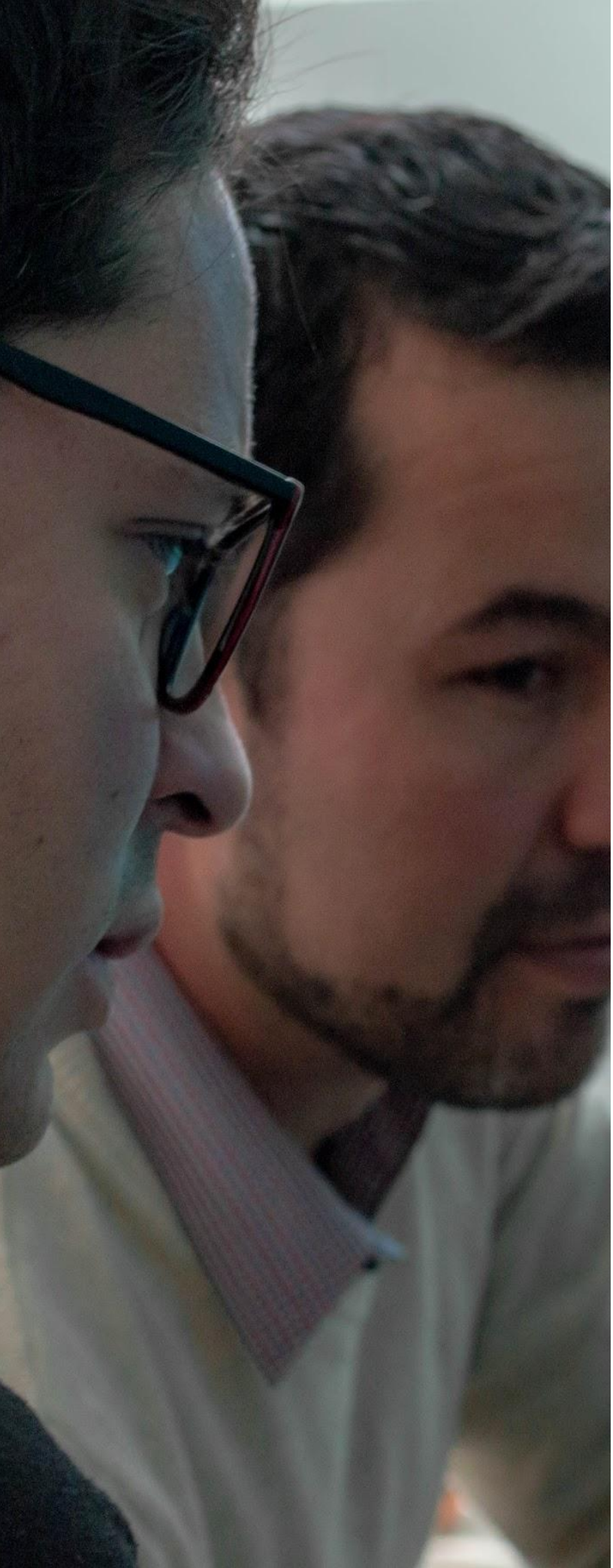
- **Surveillance:** Vigilant-e creates a new way to report any serious AEs and AESIs, or any symptom directly from the information source (subjects), there is nobody who calls subjects or any third-party who is involved in the initial reporting process. We want to avoid possible errors from the call centers. In this way, we can guarantee that the reported information will be accurate, oportune and secure.

- **Adherence:** Improving the subjects' adherence to the study. The research site staff will know in real time what is happening with their subjects. With the planned reporting frequence, the site can confirm which subjects are active and which are not, In this way retention and rescue strategies are focused on those inactive subjects, decreasing the effort of the adherence strategies and maintaining constant communication with the subjects, without limiting to telephone calls.

- **Training:** our applications are user friendly and with a couple of "clicks" users can send their symptoms cases reports. Training is simple and it only takes a few minutes to explain subjects how to use our App. Our interface is easy, flexible and has been tested in many trials.

- **Traceability:** All information reported through Vigilant-e and E-diary is managed within our PFS (Patient Follow Up System) platform or our Trial 360 all in one business app which have been validated and audited externally. All data received by our software is audited saving in all cases who, when and from where is someone creating or modifying a record in our database.

- **Support:** We have a complete structure to give support to all sites. If it is necessary we can have an onsite engineer always available as a first contact. The second level of support is given in Colombia with the Integra IT Operations Department. If needed, the third support level will be the Integra IT Software Development Department.



Why Integra IT.

Our company has a huge experience in developing web software and mobile application for the pharmaceutical industry. During 12 years we have done different clinical trials in illnesses like:

- **COVID-19**
- Chikungunya
- Polio
- Dengue
- Herpes Zoster
- Pertussis
- Hepatitis A
- Norovirus
- Meningococcus
- Rotavirus
- RSV
- Diabetes
- Fabry
- Hereditary angioedema

We have performed clinical trials in thousands of patients in 16 countries around the world. We align with our customers goals and help them throughout the process always providing high quality information, dashboards, data management, project management, quality advisory and on site or remote services over our technology.

We not only provide a highly efficient, user-friendly suite of applications, we help site staff make their transition to technology, we help CROs get the information and reports they need and we deliver results as sponsors need them reducing errors in the entire process while integrating data directly to their EDC systems.

Now growing in our Real World Evidence unit and applying our knowledge to AI and Analytics, we are confident in the high value you can get partnering with u.

Our Experience.

Our company was created to develop and operate complex trials for the health and 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.

Diseases

- **COVID-19**
- Chikungunya
- Polio
- Dengue
- Herpes Zoster
- Pertussis
- Hepatitis A
- Norovirus
- Meningococcus
- Rotavirus
- RSV
- Diabetes
- Fabry
- Hereditary angioedema

Some of our Clients

- AstraZeneca
- Oxford University
- OPS
- Takeda
- Vax Trials
- Bill & Melinda Gates Foundation
- MINSA Panama
- FIDEC
- GSK
- JSS Research
- PPD
- University of Colorado
- Asesorías Médicas Integral a los Niños
- ASSIGN
- AJ Vaccines
- CureVac
- Shire

Locations

Vaccine Clinical Trial Stats

1.405.855
Activities Managed

148.972
Visits Managed

524.093
Subject Follow-ups

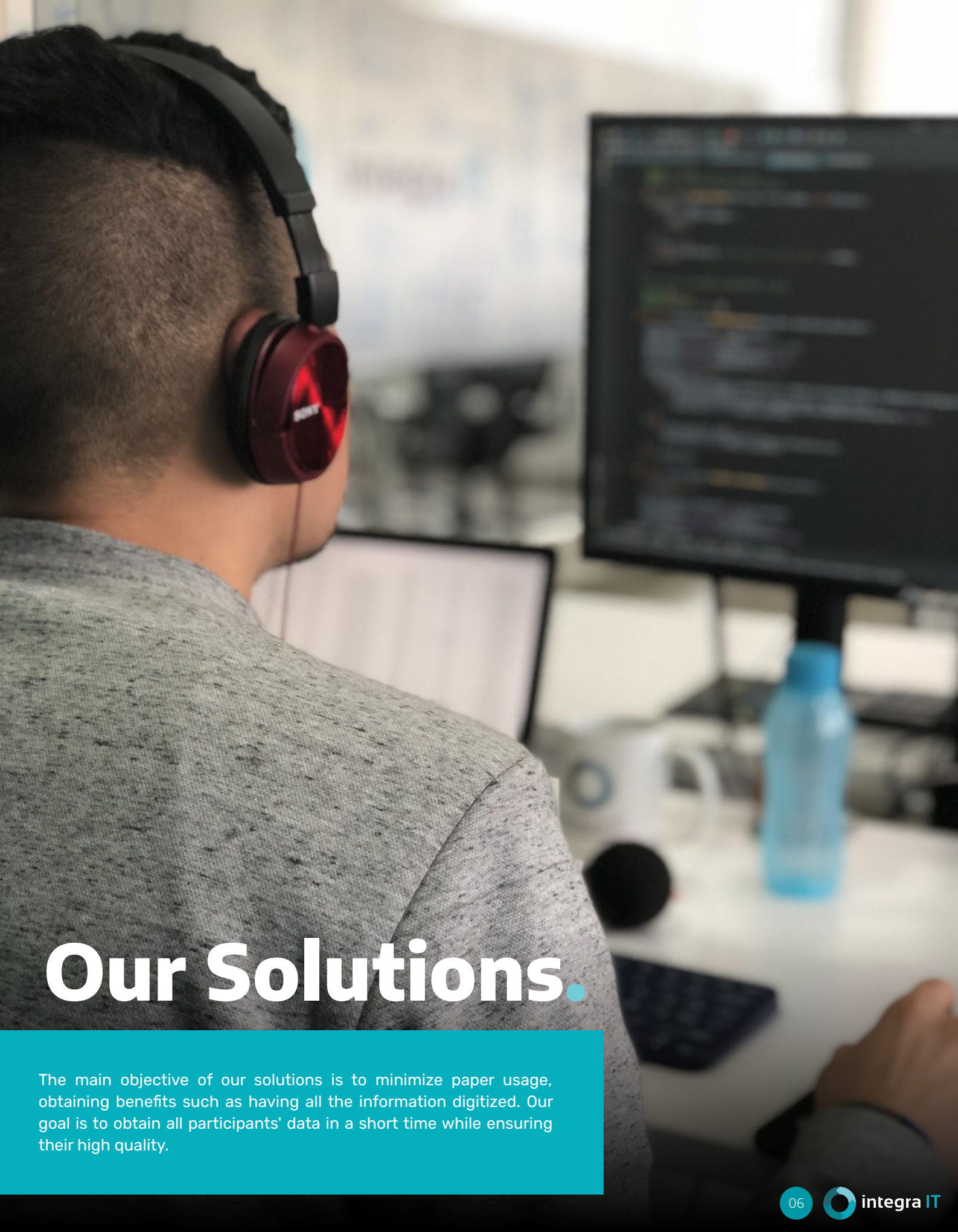
11.498.107
RECEIVED REPORTS.

16.269
Lab samples managed

846.193
Forms.

423.848
MOBILE APP RECORDS

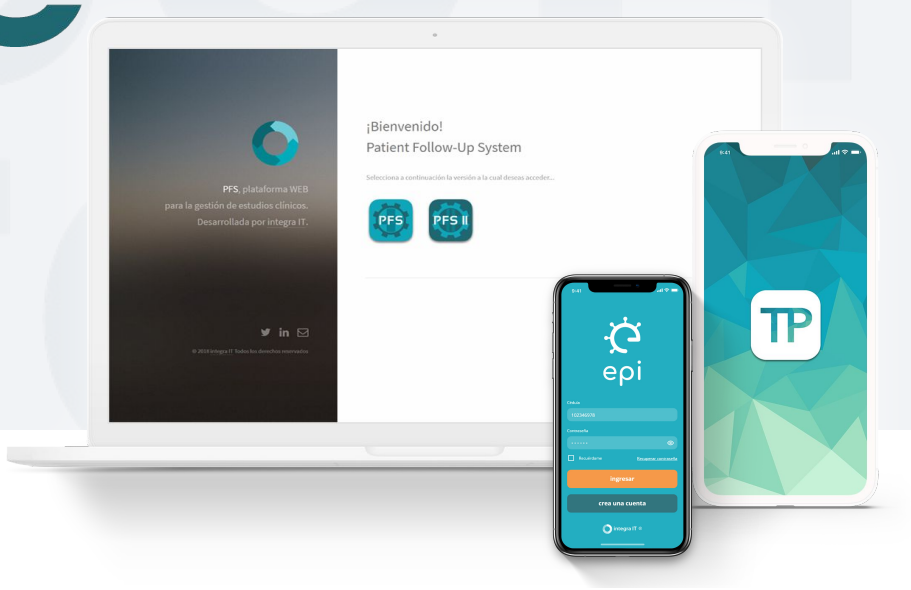
Our clients speak for us



Our Solutions.

The main objective of our solutions is to minimize paper usage, obtaining benefits such as having all the information digitized. Our goal is to obtain all participants' data in a short time while ensuring their high quality.

integra SUITE



Mobile

TRIAL PAL

Modules

- **Vigilant-e**
- **E-Diary**
- **Chat**

EPI

Web

CRF
Case Report Form

PFS II
Patient Follow up System

TRIAL 360
End to End Site EcoSystem

PPM
Patient Program Management

STS
Study Tracking System

CTMS 360
End to End CRO EcoSystem

- eConsent
- eSign
- eDoc
- Timesheet
- eLearning
- WebSite/Recruit

VRT
Vaccine Record Tracker

ECS
Ethics Committee System

Mobile

Integra IT TrialPal Modules

11.5 Million
Reports

58.000
Participants

12 years
Experience

16 Countries

e-Diary

Diaries are used in clinical trials where researchers want to gather information after each vaccination or medication. With this module, the information reported by patients is shared in real-time, in order to enable site staff to know what is happening with each patient

We also improve the information quality creating validations inside the App which allows minimizing typing errors.

Vigilant-e

Vigilant-e module allows clinical trial participants to report actions with information to the research center. It is ideal for surveillance studies where participants must report their health status periodically for long periods of time.

Symptoms

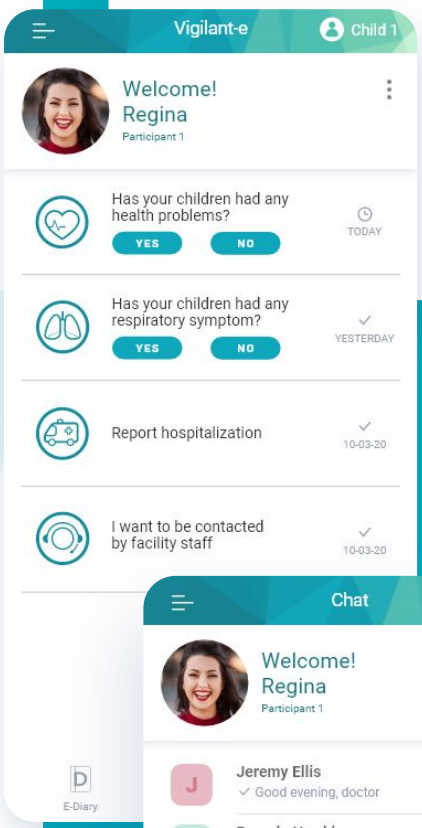
Report symptoms and its severities in one touch.

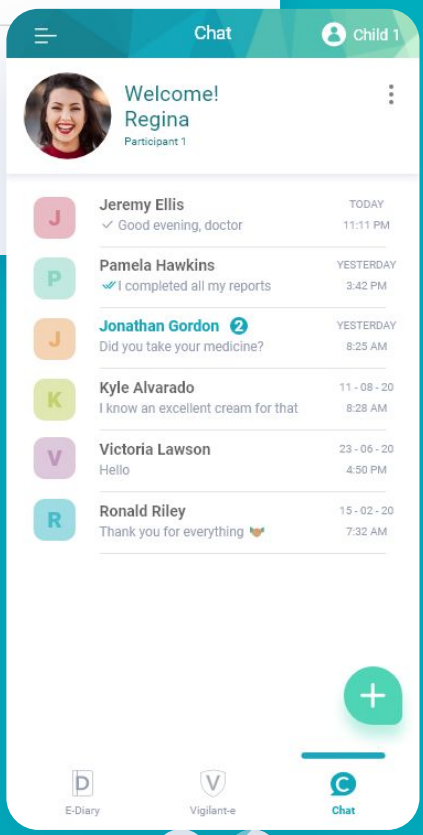
Contact Requests

Notify that a participant wants to receive help or information.

Hospitalizations

Inform that a participant has been to an ER or is hospitalized.





Chat

The Chat module is designed to improve communication between the subjects and the site. It provides all the tools of traceability and safety ensuring that all conversations related to the study remain registered in our databases.

Site users are able to review the conversations related to study subjects or tutors. It is the best way to stay in touch with patients.

Benefits

Reliable

Real-time information

Customizable

User-friendly

Off-line functions

Traceability

Mobile App Requirements

Android

Software

- **Storage:** MicroSD + Internal memory higher than 2GB.
- **GPS:** needed, plus A-GPS support
- **CAMERA:** 1MP or higher.
- **CPU:** 500 MHz or higher.
- **DATA:** WIFI, GPRS, EDGE, 3G o 4G.

Hardware

- Android 4.4.2 or higher.

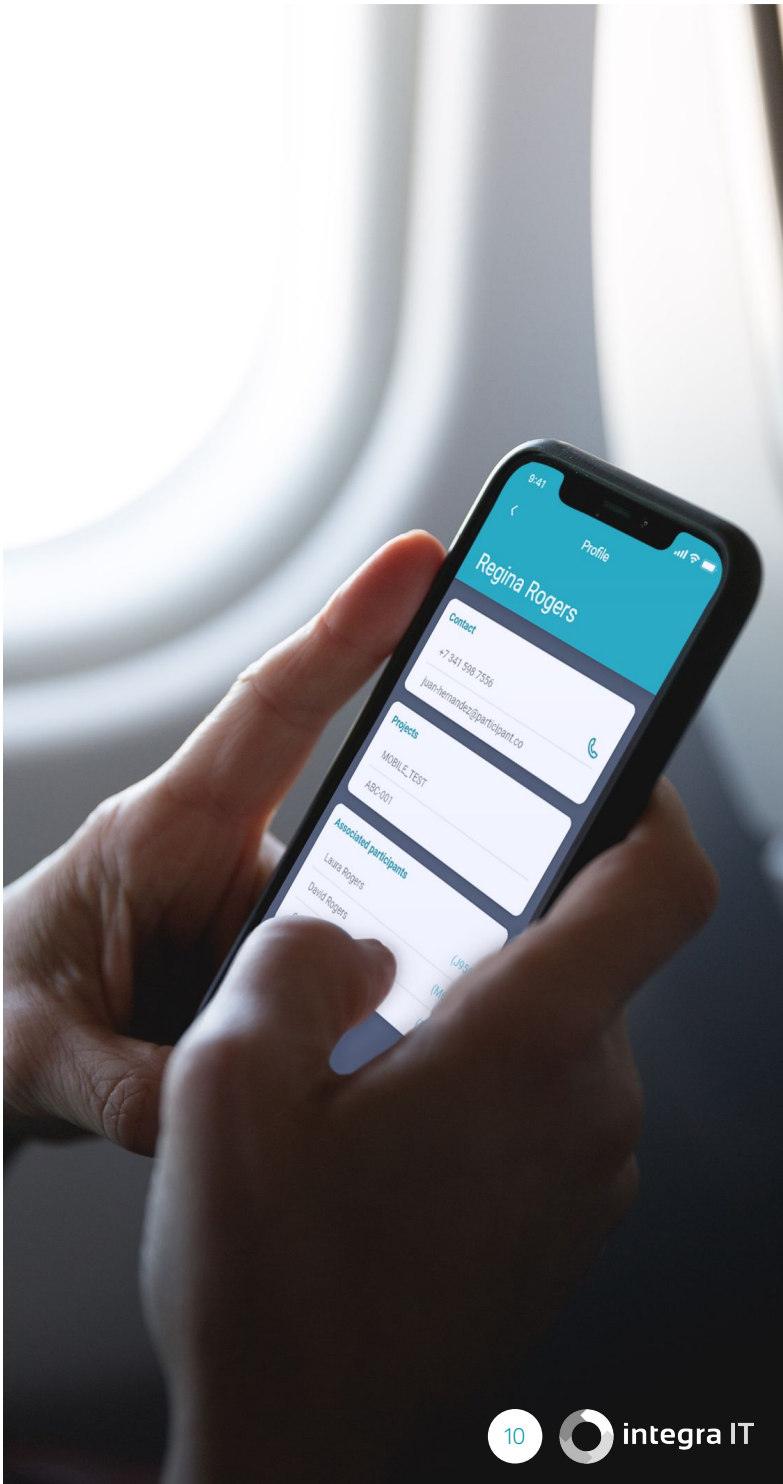
iOS

Software

- iOS 10 or higher.

Hardware

- iPhone 6 or better.



Web Solutions

PFS II
Patient Follow up System

PPM
Patient Program Management

CRF
Case Report Form

STS
Study Tracking System

TRIAL 360
End to End Site EcoSystem

CLINIC 360
End to End Site EcoSystem

CTMS 360
End to End CRO EcoSystem

VRT
Vaccine Record Tracker

PFS II

Patient Follow up System

The PFS Product is a specialized software (WEB Portal) based on high reliability and availability platforms that guarantees an excellent service performance without interruptions, using security standards, and guides such as CRF Part 11 from the FDA. This system is designed mainly for the Sites and will allow managing subjects in a very efficient way.

PFS has a modular architecture that can easily adapt to our customer needs. In particular, the PFS has modules for administration and management of patients (subjects), candidates, households, visits scheduling, samples and window management, CRF forms data capture and monitoring of adverse events.

Through PFS, you can manage interactively and in real time, all the information of the subjects. This is of great value in tracking the subject as it has email alerts indicating any event important for the study. Likewise, it is a key aspect for maintaining high adherence of patients during the study since it has the detailed tracking information where we know what subjects have not made their reports, what was the last visit made and by whom, when is the next visit and call, etc.

Subject Module

This is where all patient information is stored (contact information, parent information, subject number, etc). All information collected is handled with roles, and profiles that will have access according to their privileges to see more or less detail of subjects; always ensuring the confidentiality and integrity of information.

Subject Log Module

This module presents a very simple to use functionality that records the contacts they have had with the study subjects. Thus, a consolidated tracking log for each subject. Team members know who was the last person to contact the subject and when did this happen.

PFS-Lab Sample

This module helps to manage laboratory samples generated during the study as stool and blood samples. You can configure different states in which these samples may be and each of these is used to configure a form containing information on that status change. Similarly, it helps manage the boxes where samples are stored.

We have developed an interface with the CDC lab systems for a more efficient communication between the studies and CDC.

PFS-Schedule

This module allows controlling subject visits agenda. It presents a calendar view to show all study visits. The main feature is that this module helps sites calculating study visit windows and it also has holiday management, for accurate and real planning.

PFS-Candidate

This module allows massive load of information from different sources of potential subjects for a new study. It also allows us to schedule initial study visits. Once a candidate has passed all the enrollment process, they can be promoted as a subject / patient within the system.

PFS-Activities

The activities module allows the user to complete and/or monitor the progress of the various activities associated with a subject that is participating in a project or clinical trial. Within the module you can perform the following actions: Start Activities; List Activities; Assign Activities; View Statistics; Download Activity Reports; Do Activities.

PPM

Patient Program Management

The PPM is a BPM system (Business Process Manager) which allows to configure any patient assigned workflow. Built with a To-Do list where the client defines the best-suited activities flow for its needs.

This system can be safely accessed from any place the client wants. We developed several modules based on our experience that will allow you to manage more efficiently your patients' follow up based on the defined workflow.

Among the main modules you will find:

- Dashboard: a board that indicates the patient's status in real-time.
- Statistics: this module will allow you to have statistics of your collaborators regarding the activities of the assigned patients.

CRF

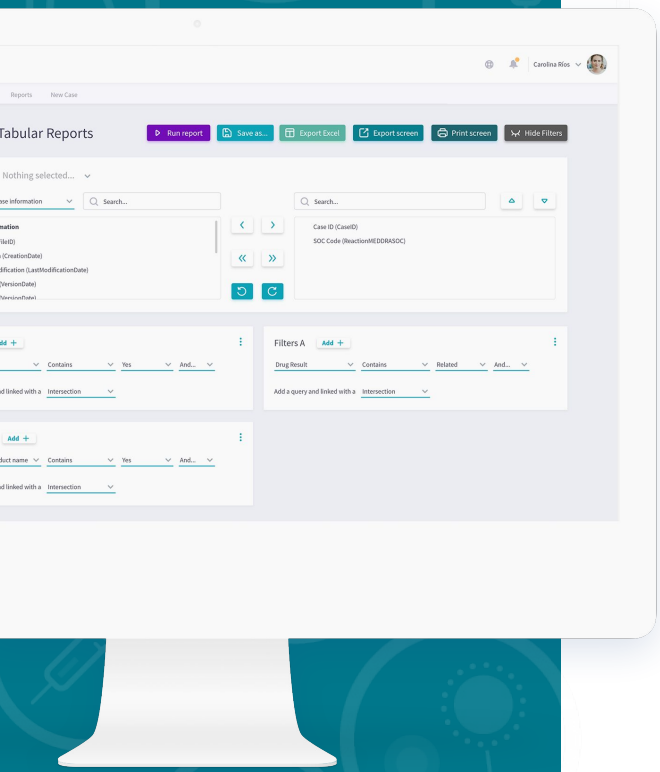
Case Report Form System

The CRF is a WEB system developed in order to allow users to enter, verify, and sign clinical trials information, where the following functionalities are enabled.

- Randomize Subjects
- Enrol Subjects
- Enter Data
- Verify Information
- Manage Queries
- Add Electronic Signature (PIs)
- Download reports

The mentioned functionalities can be performed by the following roles, depending on the access specified for each one:

- Data entry
- CRA
- Private Investigator



STS

Study Tracking System

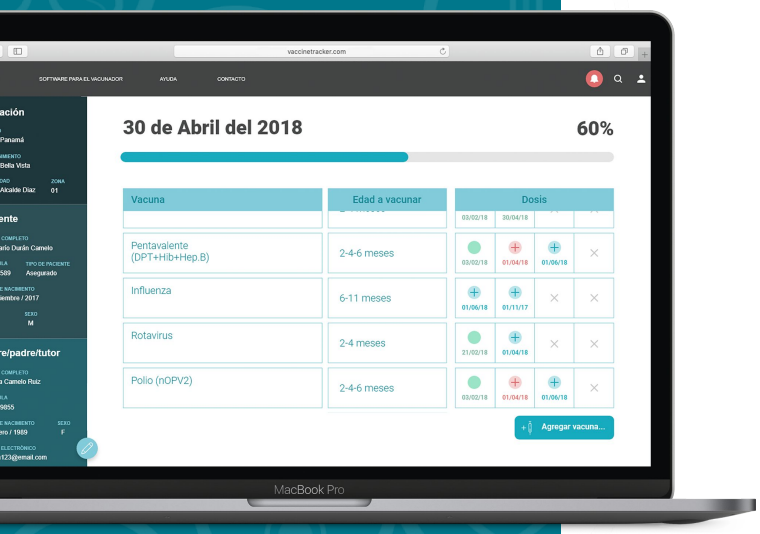
This system is designed so that CROs (Contract Research Organizations) can optimize visits to research centers.

Our STS system allows you to keep a record of the visits of the CRAs (Clinical Research Associate) to each of the sites that develop a clinical study.

Within the STS we have electronic signatures so that monitors and Project Managers can certify that all processes are carried out according to best practices.

Its main characteristics are:

- Creation and approval of reports
- PDF downloads
- Schedule monitor visits
- Register and download reports



VRT

Vaccine Tracker

VRT is a system designed for vaccination management which allows you to have real-time control of all the vaccines that are being supplied and each respective participant vaccination card.

This tool will allow you to collect and centralize all the vaccination centers' information, identify the vaccinator, dose, when and where the vaccine has been supplied.
The system has execution and opportunity reports according to defined vaccination schemes.

SITE CTMS
TRIAL 360 & CLINIC360

TRIAL 360 Ecosystem (All-in-one)

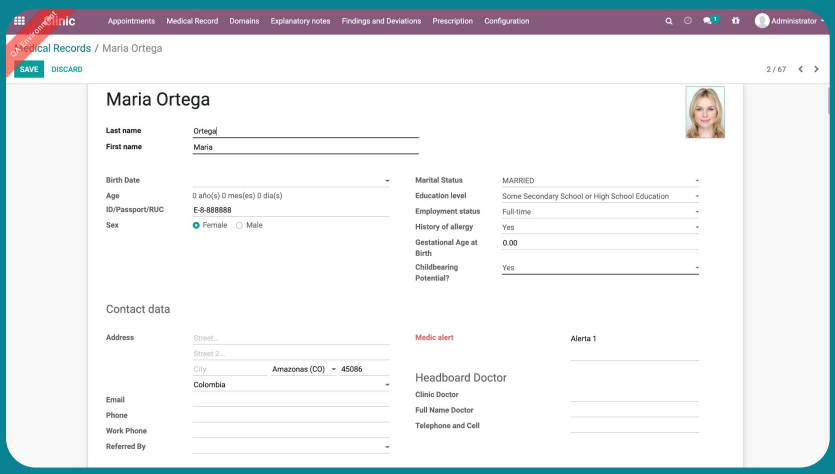
- CTMS - Electronic Health Record - Project - Laboratory- Accounting - Billing - CRM - Website - eLearning - eSignature - Human Resources

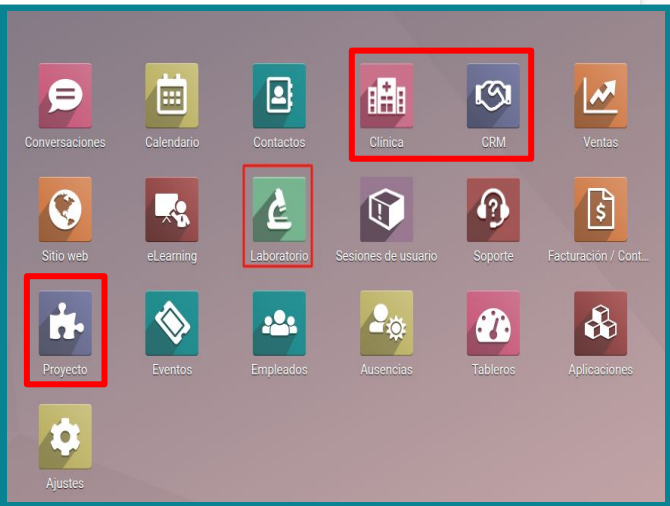
Business Value

- +Agility, Modularity, Flexibility -> At all Levels
- Project: Project flow and life cycle + Invoicing
- 21 CFR 11, ALCOA & GCP Compliant

Benefits

- Value Generation for a Clinical Research Center
- Verticalized solution oriented on how Sites offer speed, quality, security and control to both Sponsors and CROs
- Scalability
- Customized solution
- Clinical Study User Friendly
- Validated Solution compliant with all security and safety requirements.
- Web Based - remote access for reports, monitors, etc.





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Couple of weeks journey.

With Trial 360 Sites have an easy-couple of hours protocol set up system, a validated, user friendly web all-in-one Solution

Quick Project Set Up (By Project) → **Recruitment** (CRM - Website) → **Manage** (Visits & EHR) → **Data Analysis**

Role Based Access setup, including CRAs and CROs PM roles.

Domains.

- Adverse events
- Serious Adverse Event
- Findings and deviations
- Data clarification form / data query
- Comments
- Questionnaires
- Telephone Contact
- Informed consent
- Demographics
- Ethnicity and race
- Medical history
- Allergies
- Concomitant medication
- Anamnesis
- Vital signs
- National Early Warning Score (NEWS2)
- Physical Examination
- Family Planning
- Electrocardiogram (ECG)
- Inclusion and exclusion criteria
- Subject number assignment
- Randomization
- Laboratory
- Medical prescription
- Concomitant vaccines
- Screen Failure
- Baseline Characteristics
- Family History
- External Data Respiratory Illness
- Respiratory Illness
- Respiratory Illness Assessment
- Overdose
- Exposure / Vaccination
- Skin Reaction
- Caregiver burden
- Additional Respiratory Care
- Post exposure observation
- Reactogenicity
- Training
- Dose
- Visit Closure
- Activities
- Symptom Assessment
- End of Study
- Call script
- Statement of Death

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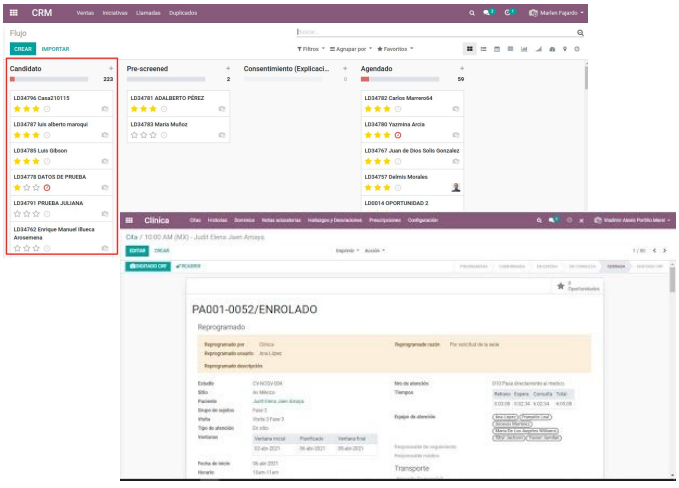


Our modular clinical trial business suite integrates both the clinical operations modules with the site financial and business modules giving site executives a 360 view of the operations, identifying bottlenecks, areas of improvement, taking timely decisiones towards a study key indicators and performance.

Cevaxin Success Story.

Trial 360 has enabled Cevaxin sites to setup up studies in hours, more efficiently recruit, enroll participants and comply with visit scheduling. Cevaxin takes laboratory needs to next level and use Electronic Health Record as source document across their organization allowing CRAs controlled access for remote monitoring. Everything with 100% success in audits.

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 **David** 1

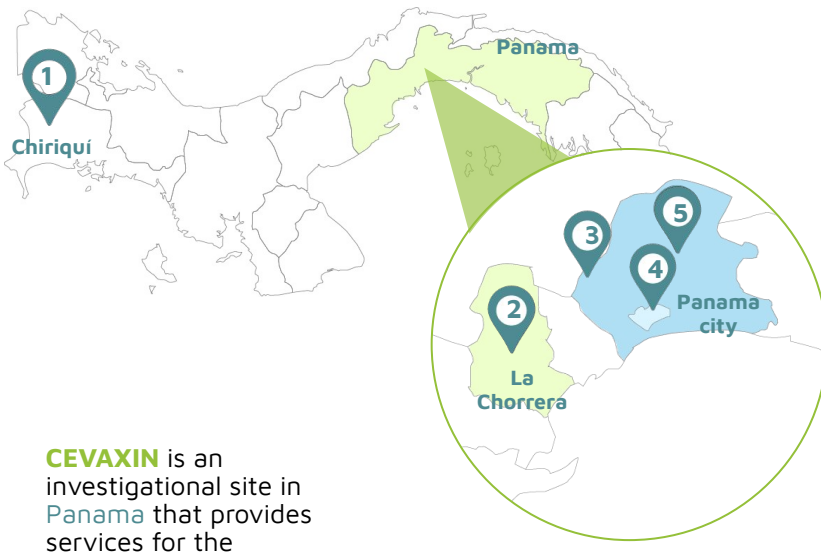
Cevaxin **Chorrera** 2

Cevaxin **Av. México** 3

Cevaxin **Plaza Carolina** 4

Cevaxin **24 de diciembre** 5

Cevaxin **Pacific Center** 6



CEVAXIN is an investigational site in Panama that provides services for the implementation and conduction of clinical, epidemiological and public health studies giving innovative solutions and quality process to achieve high quality data and results for the trials.

+240 employees

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 CRF Part 11, ITIL, ICH and ISO 27001.

Security specifications in systems and platforms of Integra IT.

Integra IT has been audited by several sponsors including by Larix a State Serum Institute CRO in Denmark and by Curevac a German Sponsor, where every process at Integra IT was carefully reviewed and audit, obtaining positive results. Highlights:

1. Databases and infrastructure: Databases used in our infrastructure are guided by ISO 27001, ITIL v3, HIPPA, and FDA 21 CFR part 11.
2. Data validation forms in queries and formats in order to enhance data precision.
3. Databases access using authentication and various access roles.
4. Use of SSL and support of HTTPS in mobile devices, which are supported end to end from mobile to AWS data centers.
5. Databases have security and access 24*7*365. AWS data centers use N+1 on all vital applications that give a great robust.
6. Our database uses Amazon Web Services (AWS), which complies with the highest IT standards in security such as SOC1, SOC2, SOC3 e ISO 27001, is designed to support clinical, medical, and pharmaceutical security standards, and guidance such as HIPPA and Cloud Security Alliance (CSA).
7. Reports and capabilities of exporting data to authorized personnel using CVS, XML and SAS.
8. Information is backed up using AMAZON S3 encrypted platform.
9. We use owned EC2 virtual servers of high availability in Amazon data center, under AWS. S3 is used for advances information storage and managed mechanism.
10. Under EC2, AWS servers employees cannot access server information, only the owners can access the system, under strict passwords and unique private access, and data validations.
11. Firewalls are configured under all deny mode, which means that only inflow data connections are allowed by port, protocol and IP address.
12. Information guards using private keys (RSA - 2048), which prevents massive attacks, or social engineering attempts. AWS monitoring tools identify DoS attacks, including software attacks. When a DoS is identified, a query is initialized using AWS platform, and prevention actions are taken using redundant networks and additional capacities in order to avoid this type of attacks.

Security Standard guidance

1. Follow guidance for ICHs “Guideline for Good Clinical Practice” (GCP E6 R1), having information management and validation within our systems, SOPs, and audit trails in all data flows, with backup contingencies, and disaster recovery designed platforms.
2. Guidance of HIPPA and security principles.
3. Our systems support FDA 21 CFR part 11 guides.

This allows to:

- **Access:** users will have access from any browser to our eCRF, where they will find all the actions that have reported by the subjects, all the information is shown on an environment easy to use, intuitive, complete and save.
- **Scalability:** Our system under-demand allows growth in a fast way and without any investment on platforms or infrastructure. We also have a complete agreement with world-class data centers, that allows us to provide the service and support needed to monitor subjects anywhere in the world and any size operation.
- **Cost Savings:** Our platform will remove the operating cost, such as entering data manually into the system. Also, it will increase the productivity of site staff by giving them the tools to enhance their operation. Similarly, you also have cost savings in specialized servers and IT staff.

¿What is included?

- Integra IT team:
  - Project Management
  - Operations team
  - Support
- Installation and configuration of the platform.
- Continuous improvements (new features).
- Preventive and corrective maintenance.
- Data Backups.
- User Management.
- Our company will provide the support service via email (support@integrait.co) and support ticketing system (http://support.integrait.co) according to SLAs needed by the study.

SaaS Scope

Integra IT will provide the service of attention to failures of Hardware & Software and operating system following the established procedures and following the best practices; with an email box (support@integrait.co) and a ticket support system for incidents (http://support.integrait.co).

Otherwise, we will have Hardware & Software preventive maintenance. Integra IT will periodically perform preventive maintenance of all the equipment in the layers of the entire architecture of the virtualized infrastructure.

The following table shows in more detail the Integra IT Scope:

Activity	Integra IT Scope
User Management	• Access to administrative profiles to the personnel that is designated. These users will be able to control the users that use the platform. • Integra IT will co-manage the users if internally there is no user administrator.
Support	• Standard Support: 8X5 scheme with operating hours from 8 am a 5 pm from Monday to Friday. • Premium Support: 8x6, 8x7, 16x7, 24x7 options per Trial needs (Spanish, Portuguese and English)
Platform administration	• Application, infrastructure, databases and servers monitoring. • Preventive and corrective maintenance in all application components.
Implementation and Software Improvement	• Perform the implementation schedule of the initial requirements. • Installing Servers with the new databases. • Evaluate and implement improvements. • Schedule of activities and dates for improvements deployment into operation.
Service Level Agreement (SLA)	• Guarantee at least 99% of availability every month of the platform(up-time).
Data Retention	• Retention for SaaS time (6 months). At the end of the trial, the databases with the information of the trial will be delivered in any magnetic way.
Smartphone devices (when requested)	• Manage contracts with carriers • Cellphone Inventory management and pre-setup • On-site support Engineer during the enrollment phase.

Our added value

Our solutions offer a high value to clinical trials, we can reduce the deviation in trials Because of the data accuracy. All our apps offer a full fit for each customer, we strive for continuous improvement in order to take all our solutions to another level. Our infrastructure let us be Flexible, so we can grow Quickly, guaranteeing an excellent speed, navigability and timely service from Integra IT team.

SUPPORT

8.5/10 Satisfaction

12 x 5 Global coverage

100% scalable

TRAINING

E-Learning site 24/7

+20 training videos and workshops

USERS

90% consider our apps easy to use

93% would recommend our solutions

Strategic Alliances

Thanks to our strategic alliances we could guarantee quick scalability, the safety to choose in which country will store the information. Besides, we could offer competitive prices based on the dimension of our customer's requirements.

An invitation.

Our services and technology are being used by recognized customers in vaccines, clinical trials, and subject surveillance, which make us a quality reference, service and performance in Latin America and the World..

The Integra IT team has over 14 years of experience in international technical projects, software development and implementation, telecommunication and systems integration, medical and pharma services and other industries applications. We provide design, consulting, tailoring, planning and management of our integrated software and mobile platforms. We design products and services according to health and pharmaceutical standards and procedures.

We use agile methodologies in order to timely respond to your needs and to adapt and align our solutions to market demands. We are an experienced and dynamic team, with the goal to enhance and improve processes in many organizations throughout our information systems, mobile technologies and services. We are based in USA, Colombia, Panama, Brazil, Ecuador, Peru, Dominican Republic and Indonesia.

Contact Information

We are happy to extend an invitation to cooperate and work together as your business technology partner. We will help your business prepare for today's challenges and tomorrow's innovation needs. Feel free to contact our team by email at global@integrait.co . For more information visit www.integrait.co.

Sincerely,

Andrés Rozo
CEO Integra IT

integra IT

www.integrait.co