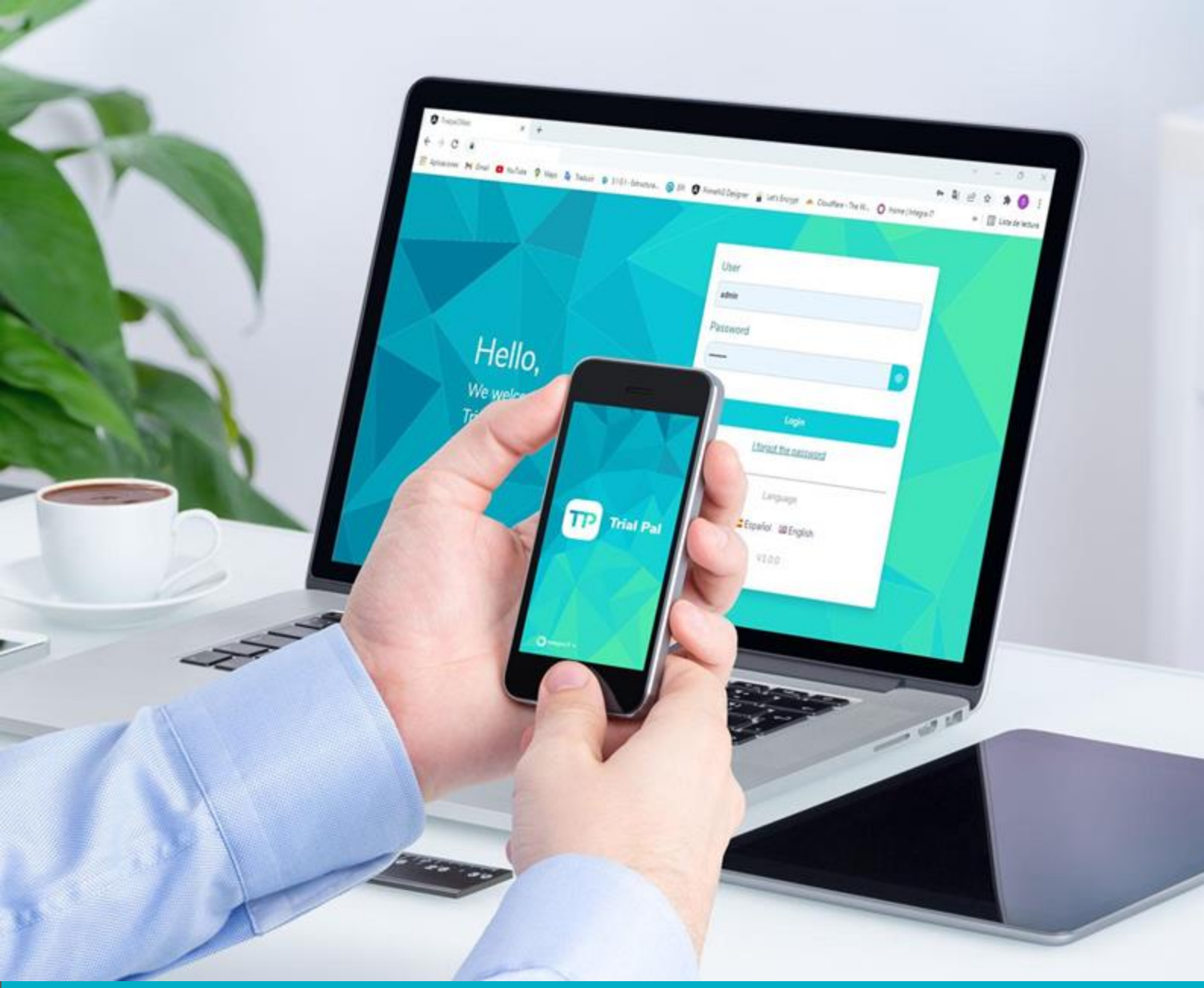


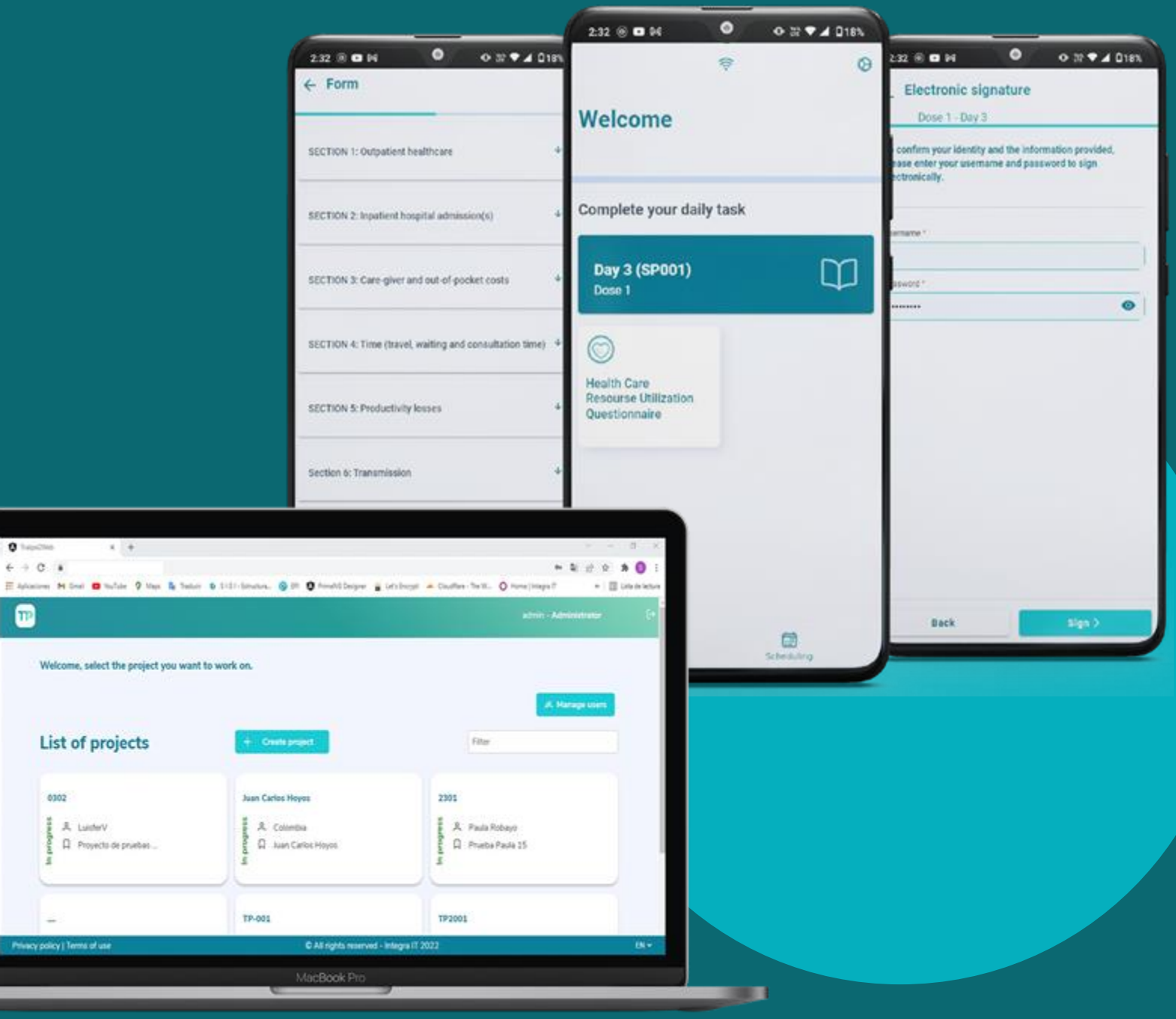
integra IT

TrialPal

Mobile App and Web eCOA/ePRO solution

Patients Pal for Clinical Trials.

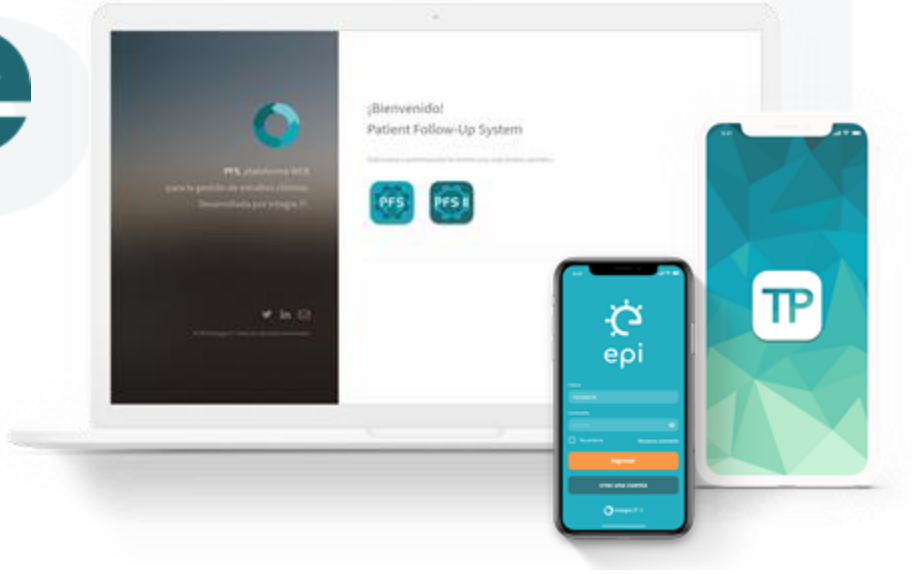
One of Integra IT solutions for the Life Sciences industry.



TrialPal.

Our eCOA/ePRO DCT mobile and web application is subjects clinical trials best friend. A simple to use solution that works even when subjects lose internet connection and contains a differentiating factor for vaccine clinical trials, providing sites with immediate notifications regarding adverse events, sending stakeholders automatic alerts, and giving access to real-time dashboards with subject status, eDiary adherence and reports to improve decision-making.

integra SUITE



Mobile

- TrialPal APP
- TrialPal Site

Modules

- Vigilant-e
- E-Diary
- Chat

EPI

Integration

- TrialPal API

Web

PFS II
Patient Follow up System

TRIAL 360
End to End Site EcoSystem

CTMS 360
End to End CRO EcoSystem

CLINIC 360
End to End Hybrid Site EcoSystem

STS
Study Tracking System

LAB SAMPLES
Site or Central Lab System

VRT
Vaccine Record Tracker

PPM
Patient Program Management

CRF
Case Report Form

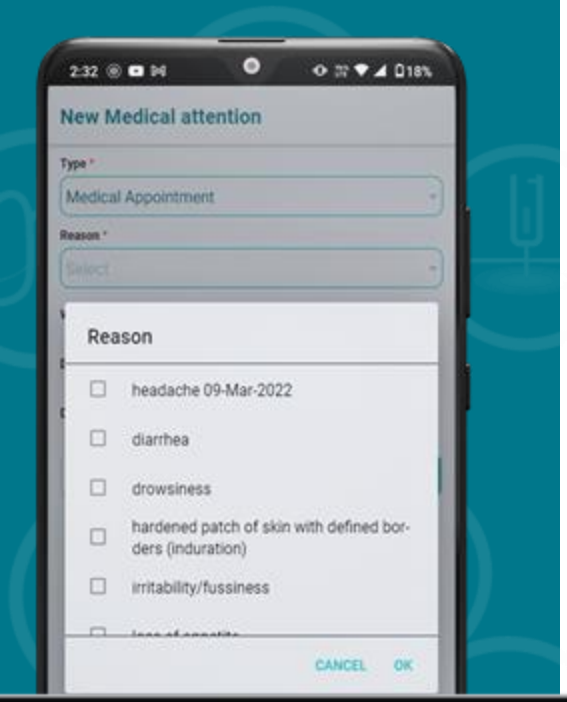
Integra IT TrialPal Statistics

+11.5 Million
Reports

+58.000
Participants

12 years
Experience

18 Countries



TrialPal
New Version

TrialPal APP

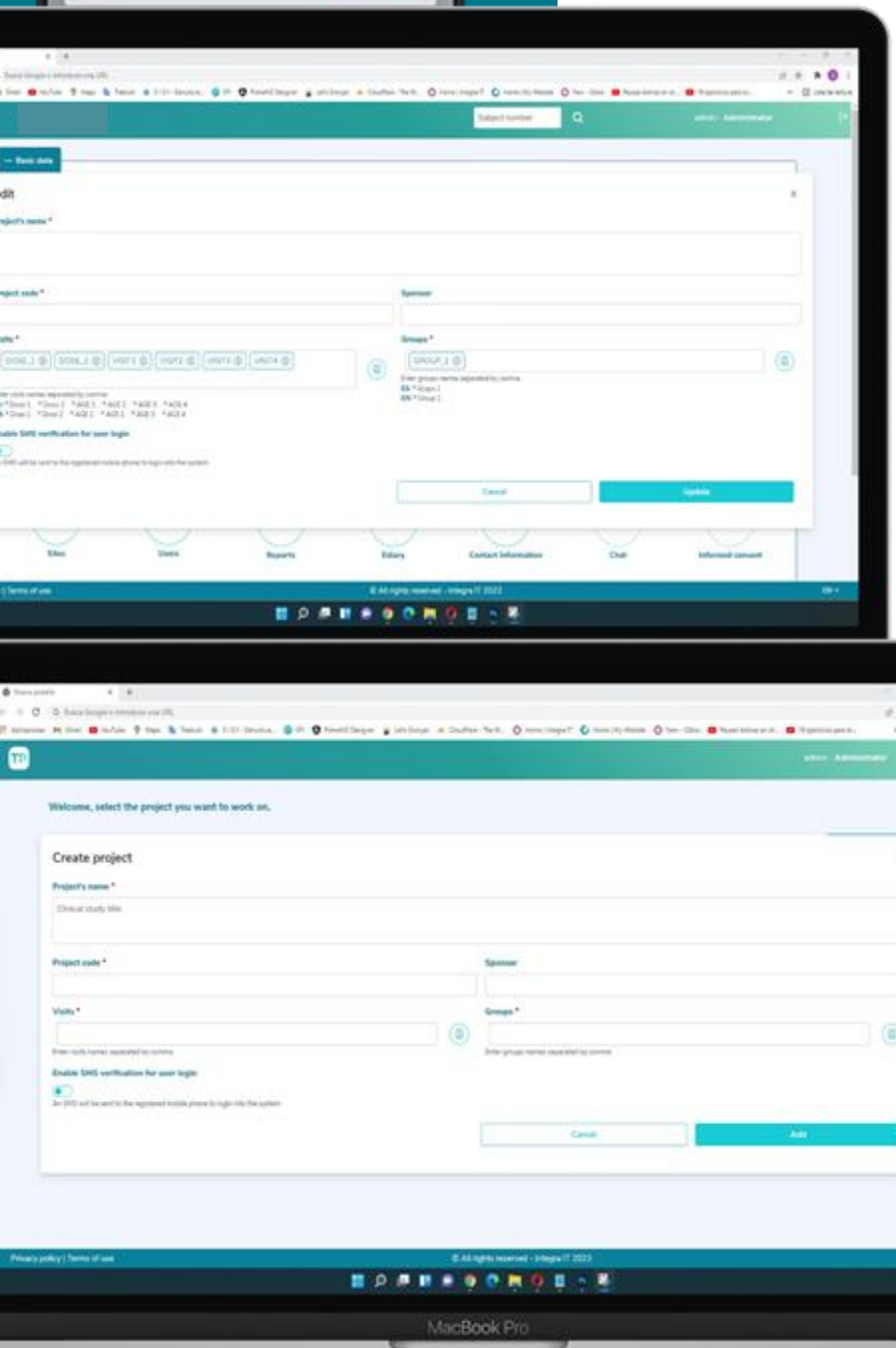
Patients Clinical Trial Best Friend

TrialPal API

Interface with third party software

TrialPal Site

Site Clinical Trial setup and management



What is new?

Trial Pal 2 App and Web version

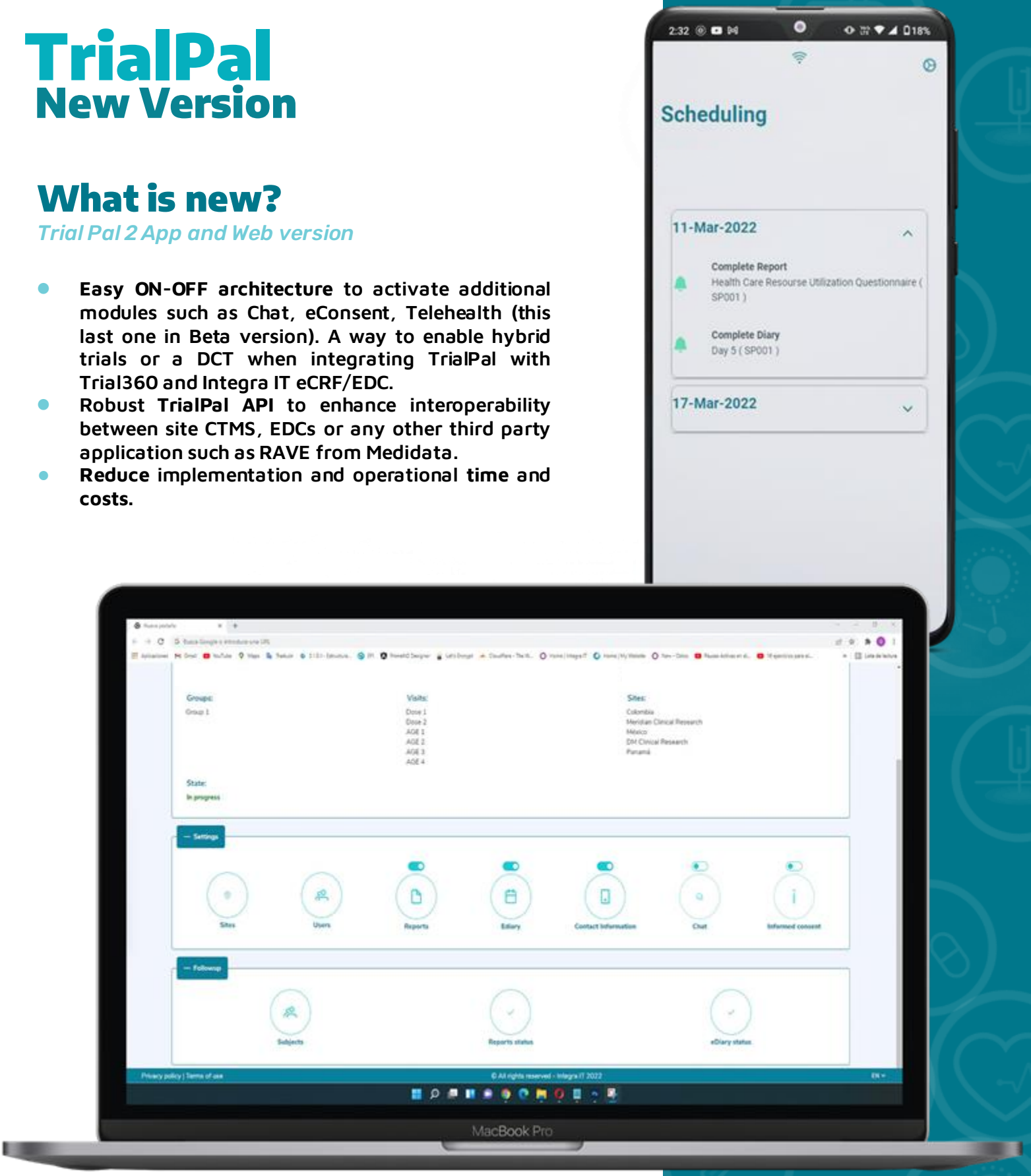
- **Simplifies study setup** and speed up process to have eDiary or any type of form ready in 1 to 2 hours as per protocol specifications.
- **Both web responsive and mobile apps** integrated in the same solution. More options for patients.
- **Notifications and alerts are customized** per study and by you, in order to remind patients when a report is needed without impacting their user experience (UX).

TrialPal
New Version

What is new?

Trial Pal 2 App and Web version

- **Easy ON-OFF architecture** to activate additional modules such as Chat, eConsent, Telehealth (this last one in Beta version). A way to enable hybrid trials or a DCT when integrating TrialPal with Trial360 and Integra IT eCRF/EDC.
- Robust **TrialPal API** to enhance interoperability between site CTMS, EDCs or any other third party application such as RAVE from Medidata.
- **Reduce** implementation and operational **time** and **costs.**

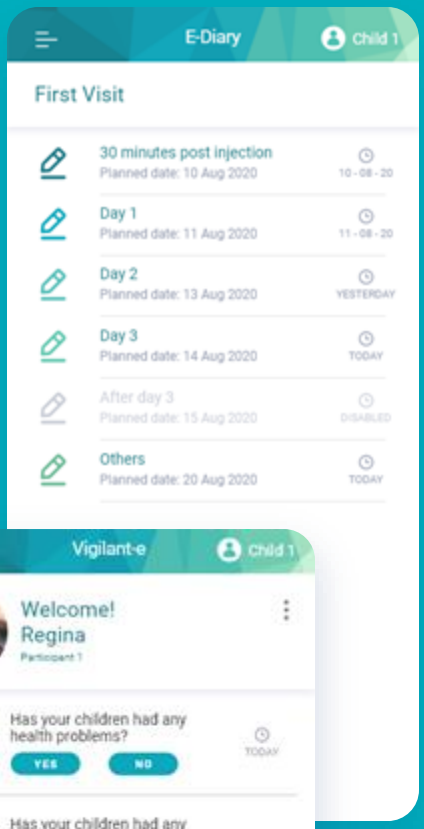


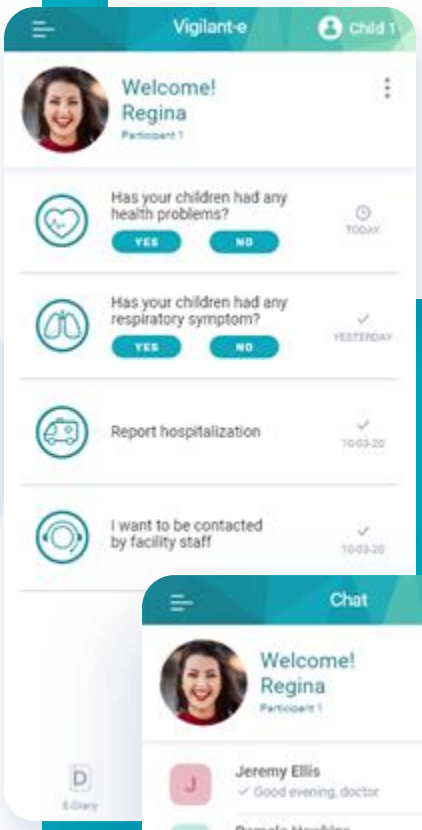
TrialPal Modules

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.





Forms and Surveillance

This 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. It is also used to create any type of form including QoL

Symptoms

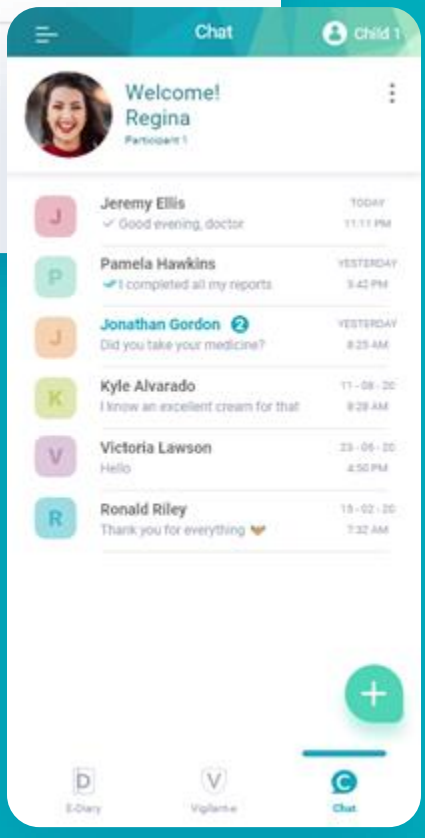
Report symptoms and its severities in one touch.

Contact Requests

Notify that a participant wants to receive help or information.

Hospitalizations

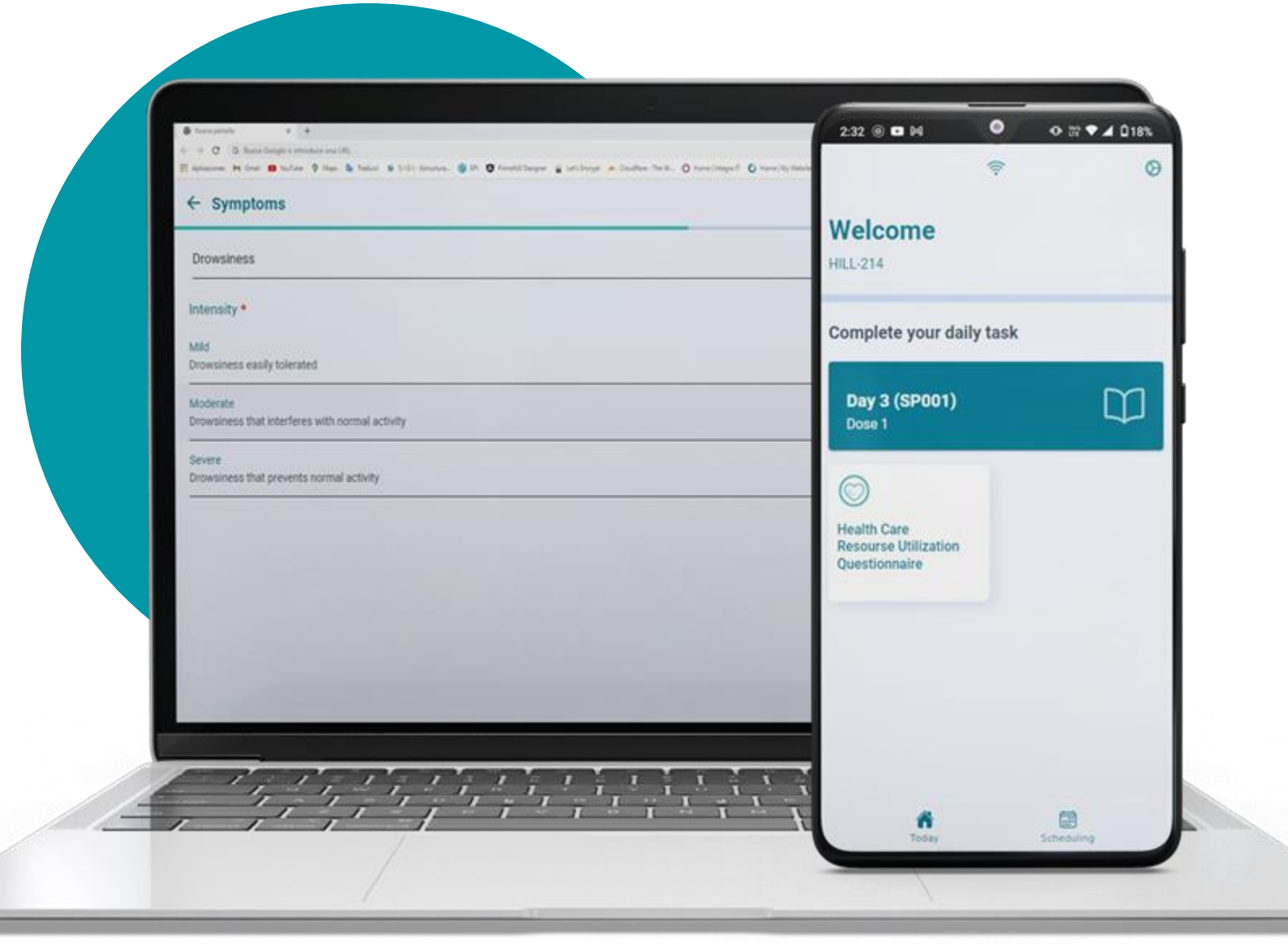
Inform that a participant has been to an ER or is hospitalized.



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.



The Focus of the e-diary

E-Diary is a module of our Trial Pal App which uses technology to improve patient gathering information after each vaccination or medication.

The information reported by patients is shared in real-time though a dashboard making patient follow-up process simple giving knowledge about what happened with each patient.

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

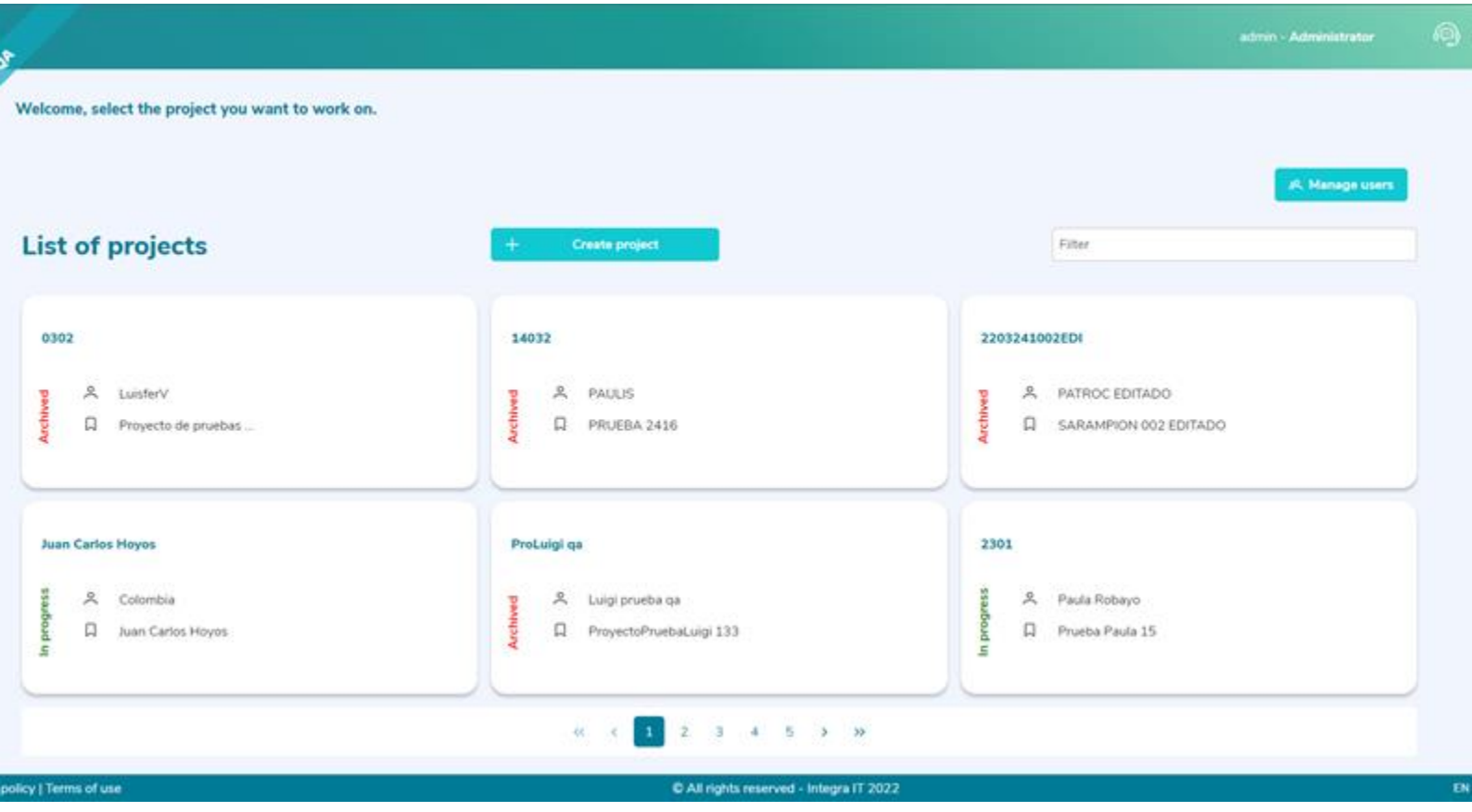
TrialPal Site

The TrialSite management console enables participant enrollment and set-up study protocol, forms, notifications, alerts, and reports. Get multiple views of the eCOA/ePRO data entry status, reporting performance analytics and data precision. Made agile study start-ups with the on-off architecture; this module interface is intuitive and requires low-burden implementation and support time.

- Patient's cards with eDiary information
- eDiary Assesment
- Patient reporting adherence metrics in real-time
- Participants groups customization
- Download the PDF patient card report to add to EMR quickly
- Audit trail
- Set up e-mail notifications for specific symptoms and levels.

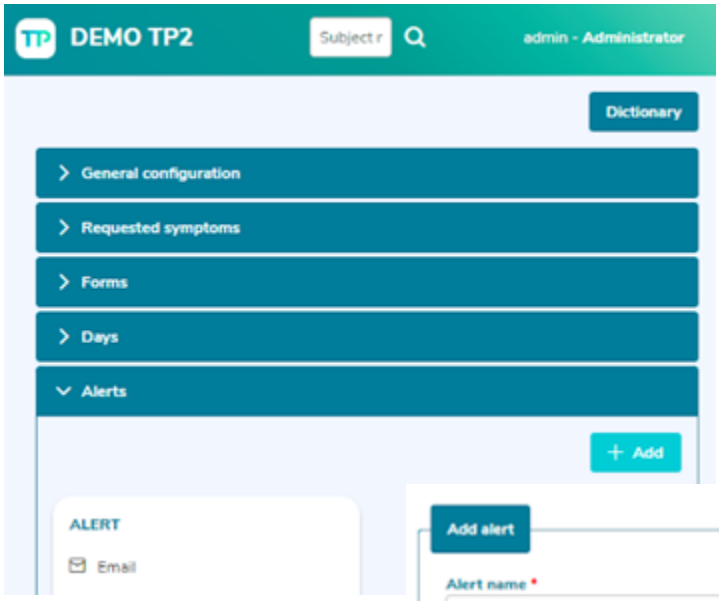
Set-up and remote monitoring of:

- Visits
- Alerts
- Symptomatology
- Surveillance Reports
- Temperature
- Point of care
- Medicines
- Multimedia



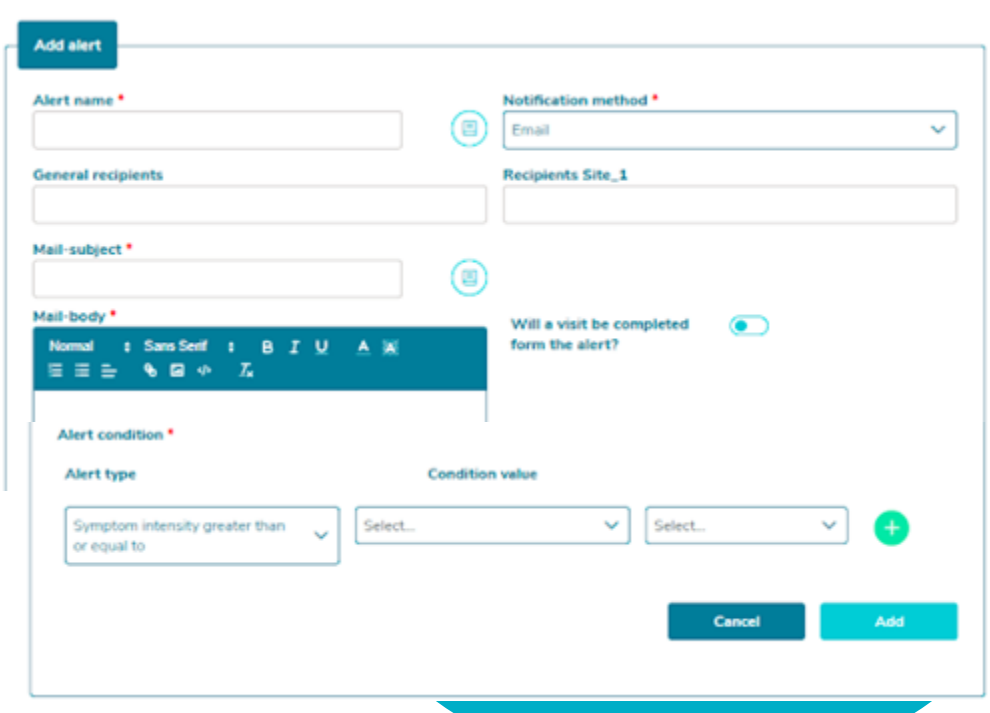
Notifications, Alerts and Forms for Surveillance

- Easy create surveillance reports or forms for symptoms monitoring.
- Pre setup subject notifications types and frequency
- Define alerts that would need to be send to sites, CRO/Sponsor stakeholders, that would be interested in getting real-time alerts over email or sms for grade 3 symptoms or any specific data or response to be monitored.



Alert Types

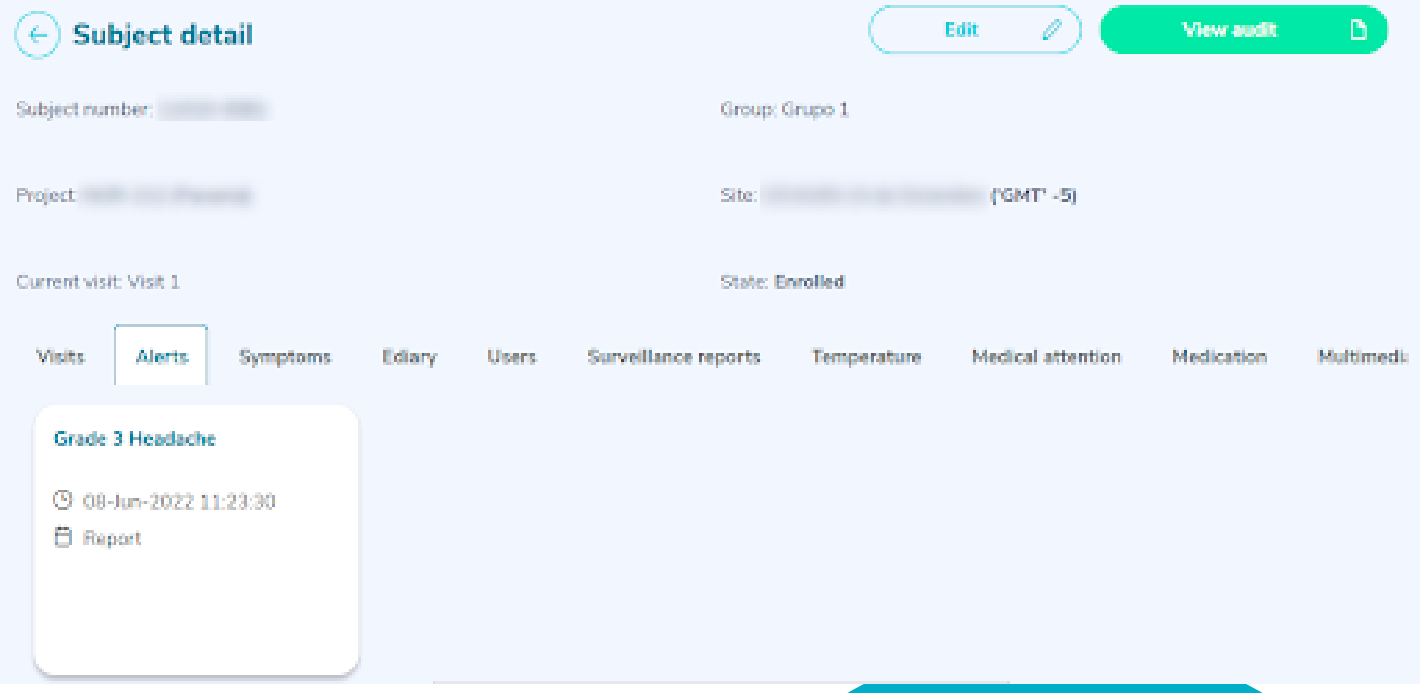
- Temperature greater than or equal to
- Symptom intensity greater than or equal to
- Medical attention / Hospitalization
- Symptom value greater than or equal to
- Symptom value less than or equal
- Symptom value equal to



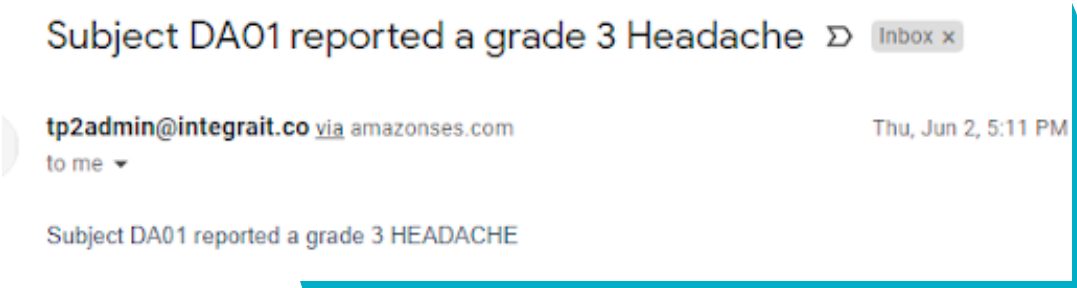
Easy setup your alerts via SMS or email

Notifications, Alerts and Forms for Surveillance

Alerts will be send to stakeholders SMS or email and will also be shown into the Subject detail tap inside the TrialPal Site.

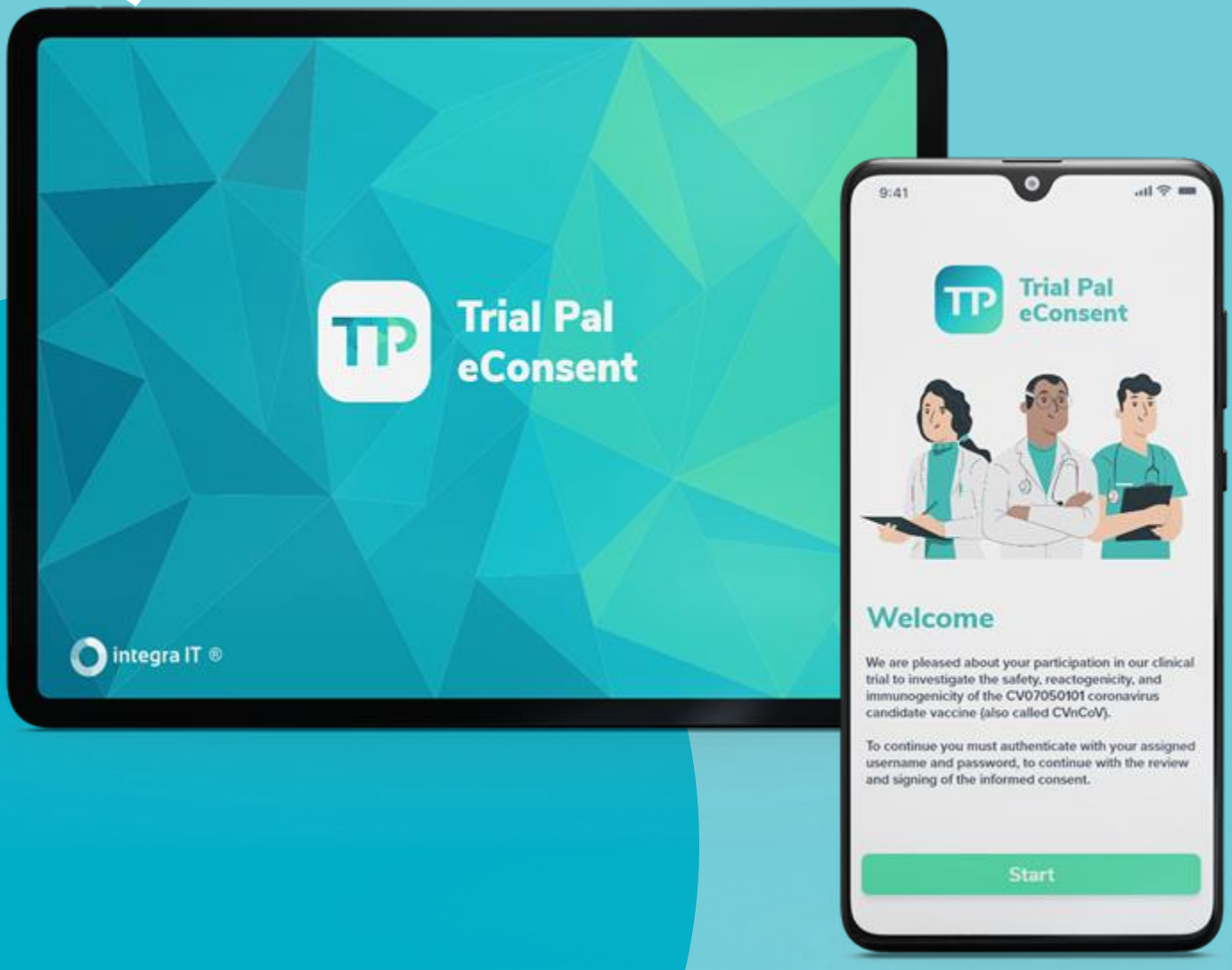


Email example



Trial Pal eConsent

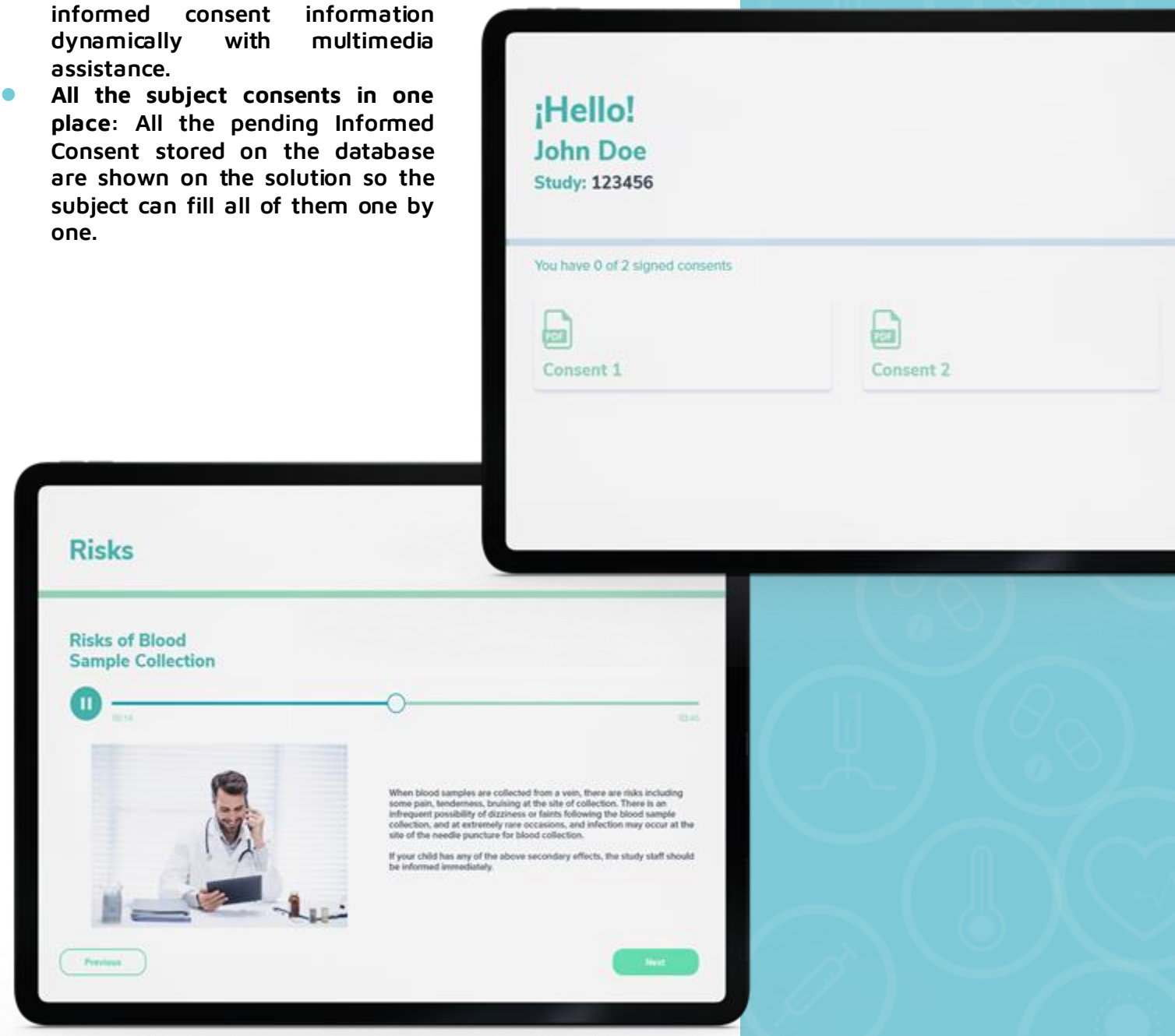
Digital informed consent responsive solution for subjects.



TrialPal eConsent
Our Newest Solution

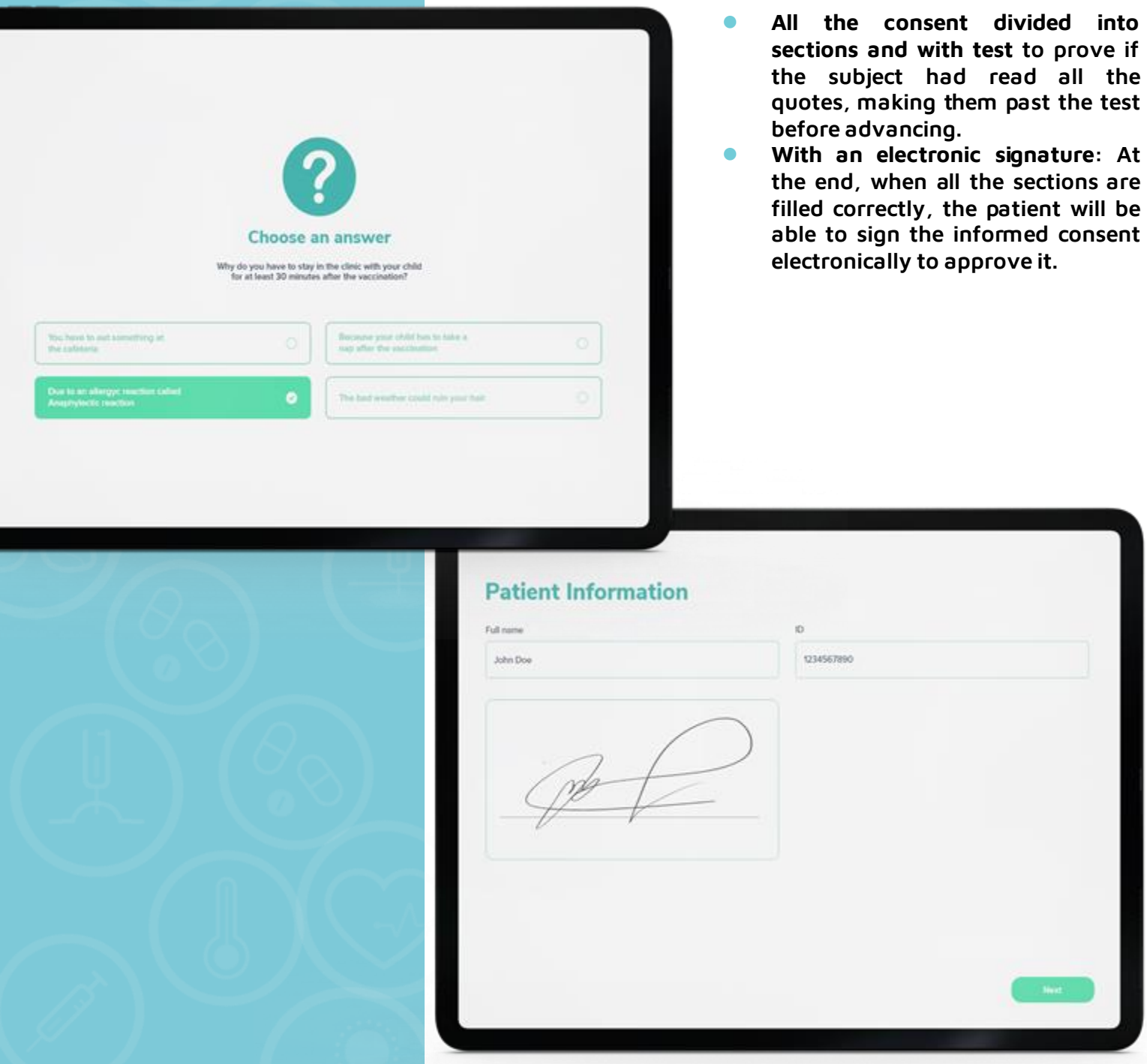
What do we offer?

- **Interactive multimedia electronic consent**: Presenting all the informed consent information dynamically with multimedia assistance.
- **All the subject consents in one place**: All the pending Informed Consent stored on the database are shown on the solution so the subject can fill all of them one by one.



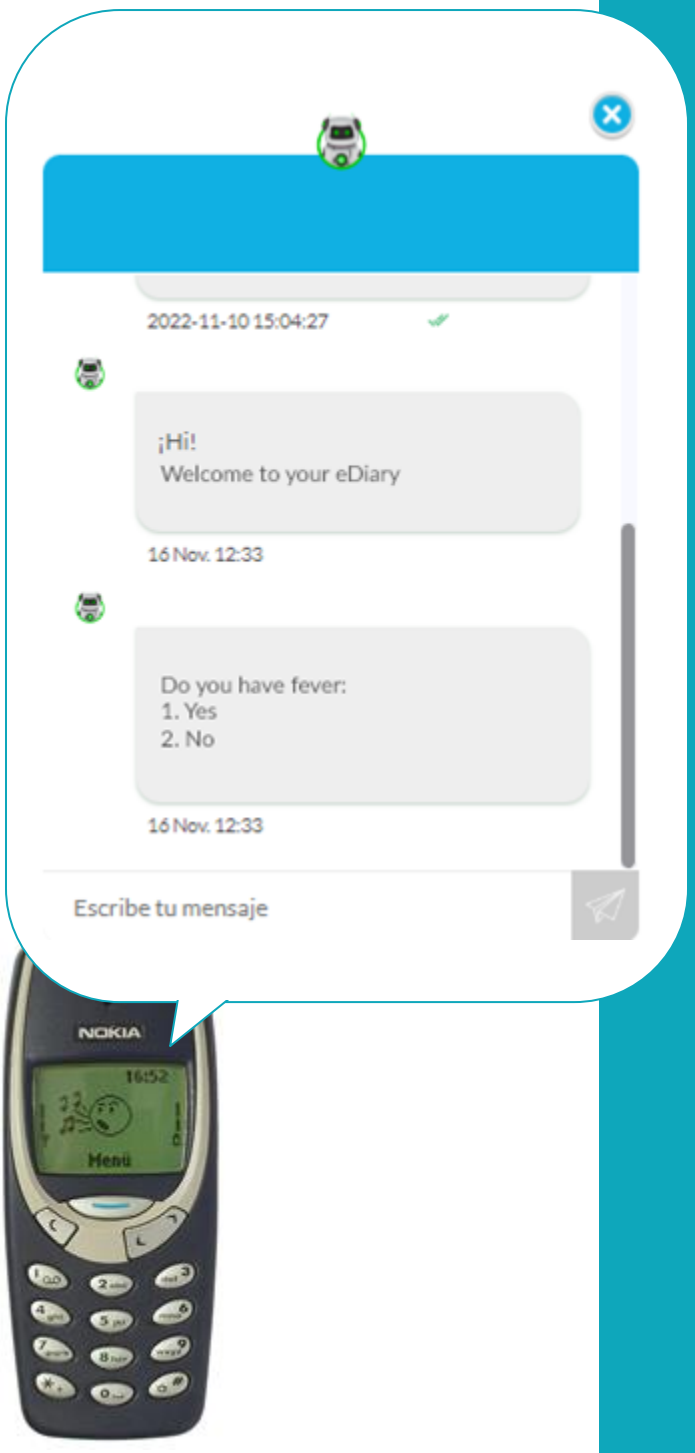
TrialPal eConsent
Our Newest Solution

What do we offer?



- **All the consent divided into sections and with test** to prove if the subject had read all the quotes, making them past the test before advancing.
- **With an electronic signature**: At the end, when all the sections are filled correctly, the patient will be able to sign the informed consent electronically to approve it.

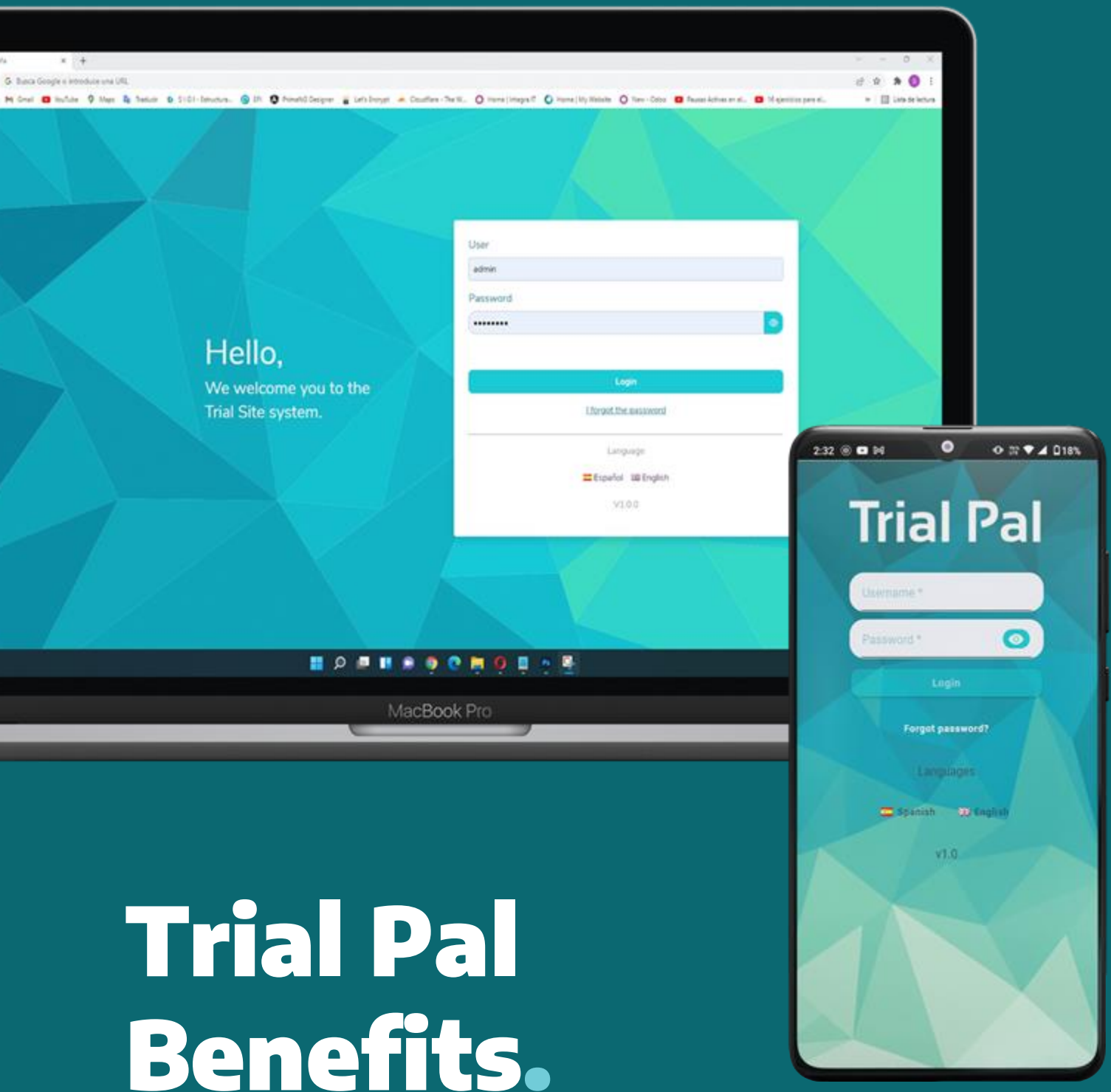
Integra's USSD



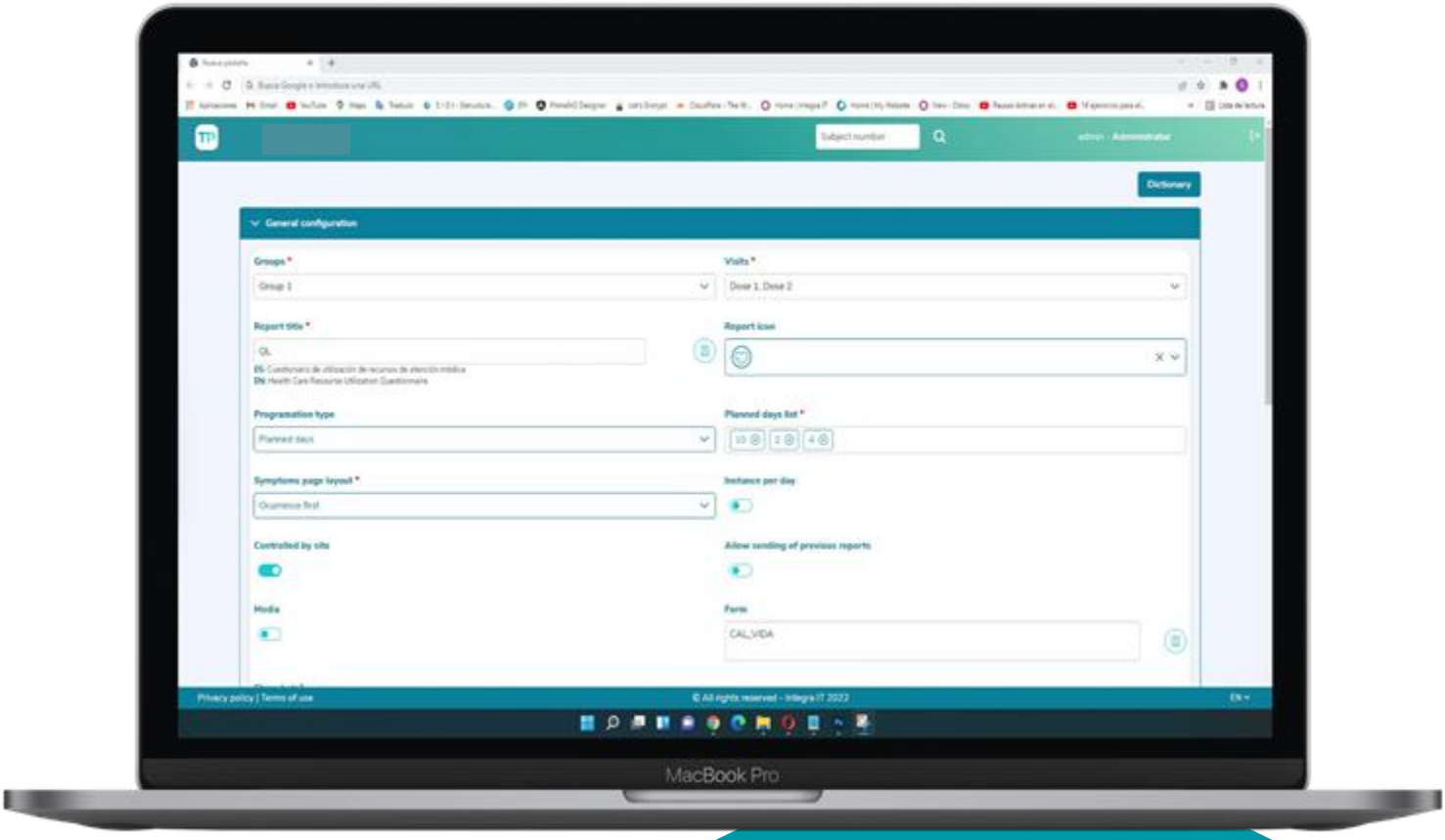
Integra IT has innovated to develop a new data collection channel option for the TrialPal (eCOA/ePRO) solution through a USSD dial pad flow.

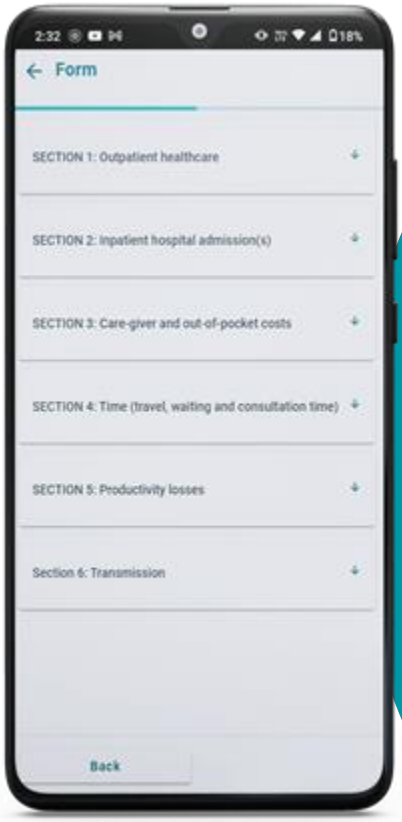
USSD (Unstructured Supplementary Service Data) is a mobile communication channel that doesn't require an internet connection, just a telecom network to capture data. This channel opens ePRO/eCOA possibilities in countries or regions lacking internet coverage. USSD allows reaching more participants, more diverse, through cell phones (no smartphones) by a BYOD or devise provision model; thus reducing operational costs and technology adoption barriers.

This channel has shown significant benefits in regions like Sub-Saharan Africa, where it is used for banking and other services, gaining trust and comfort among the population and bringing access to basic digital services.



Trial Pal Benefits.



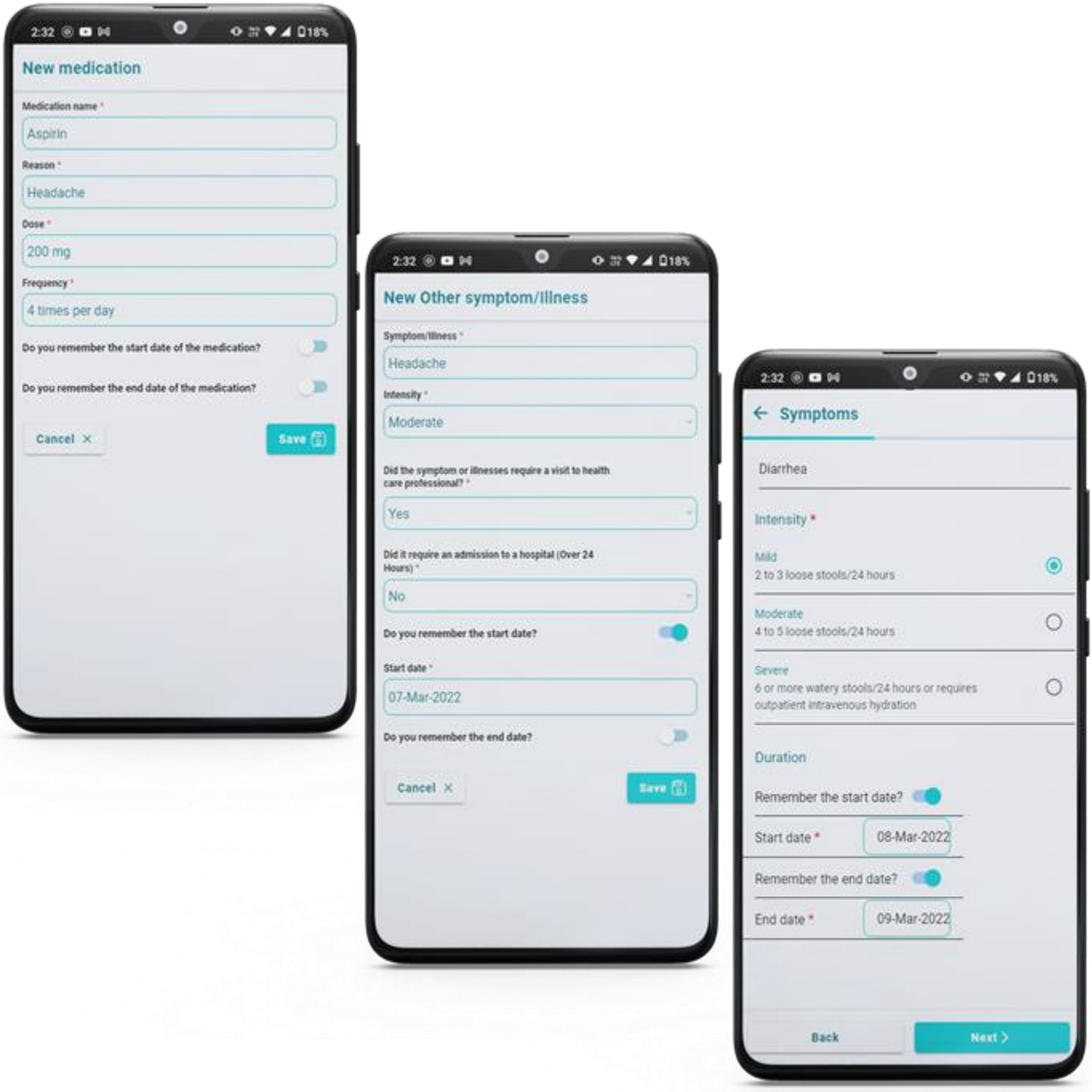


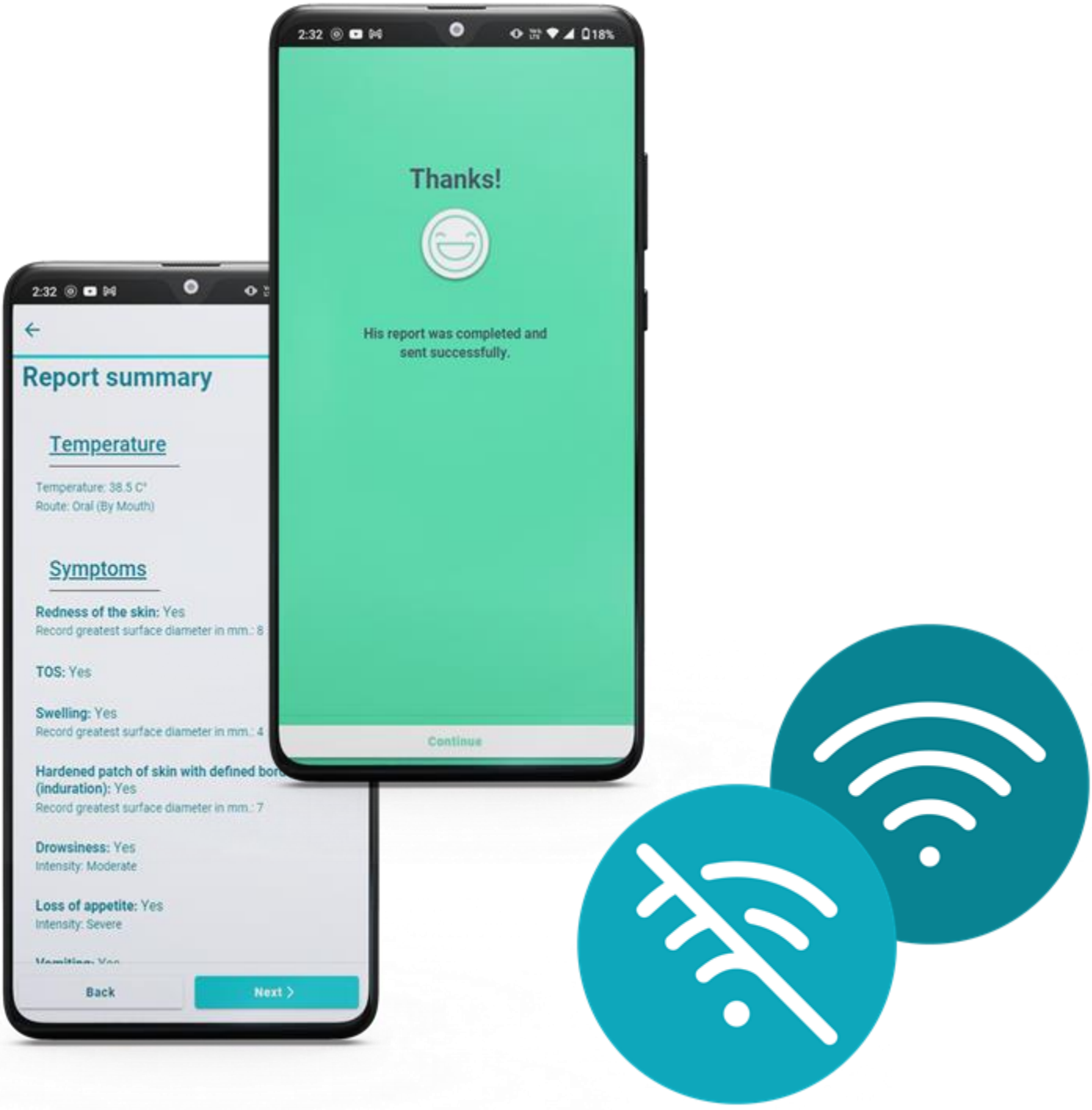
Self-Customizable

Your team can configure any form in order to be aligned with the protocol in just one hour.

User-friendly

It asks simple questions and sends the required information in less than a minute. Includes elderly population format.





No internet-No problem

The app saves the report on the device and once it is back online all the pending data will be sent automatically.

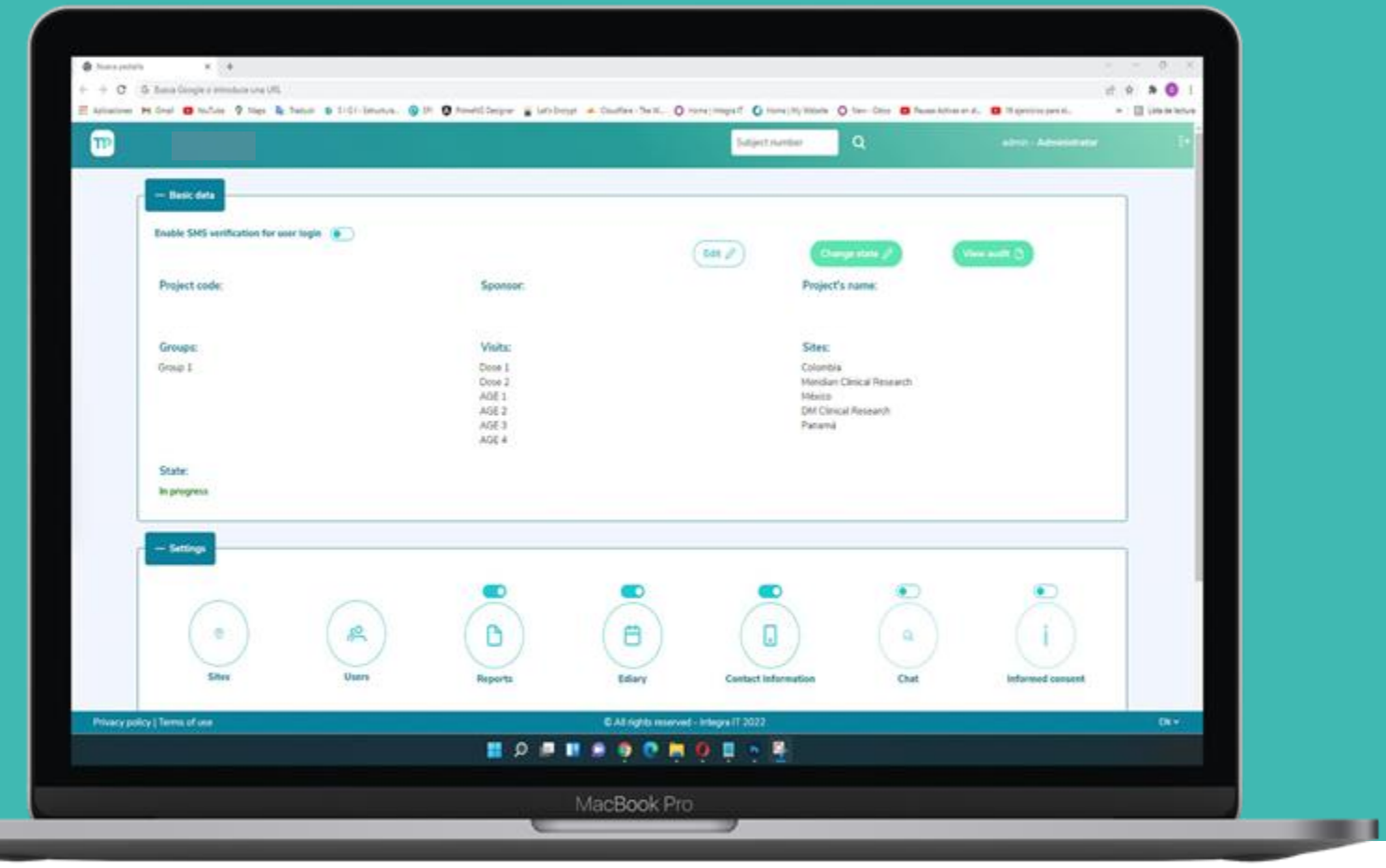
HIPAA COMPLIANCE

GDPR

GCP COMPLIANT

21 CFR PART 11 FDA COMPLIANCE

EU ANNEX 11



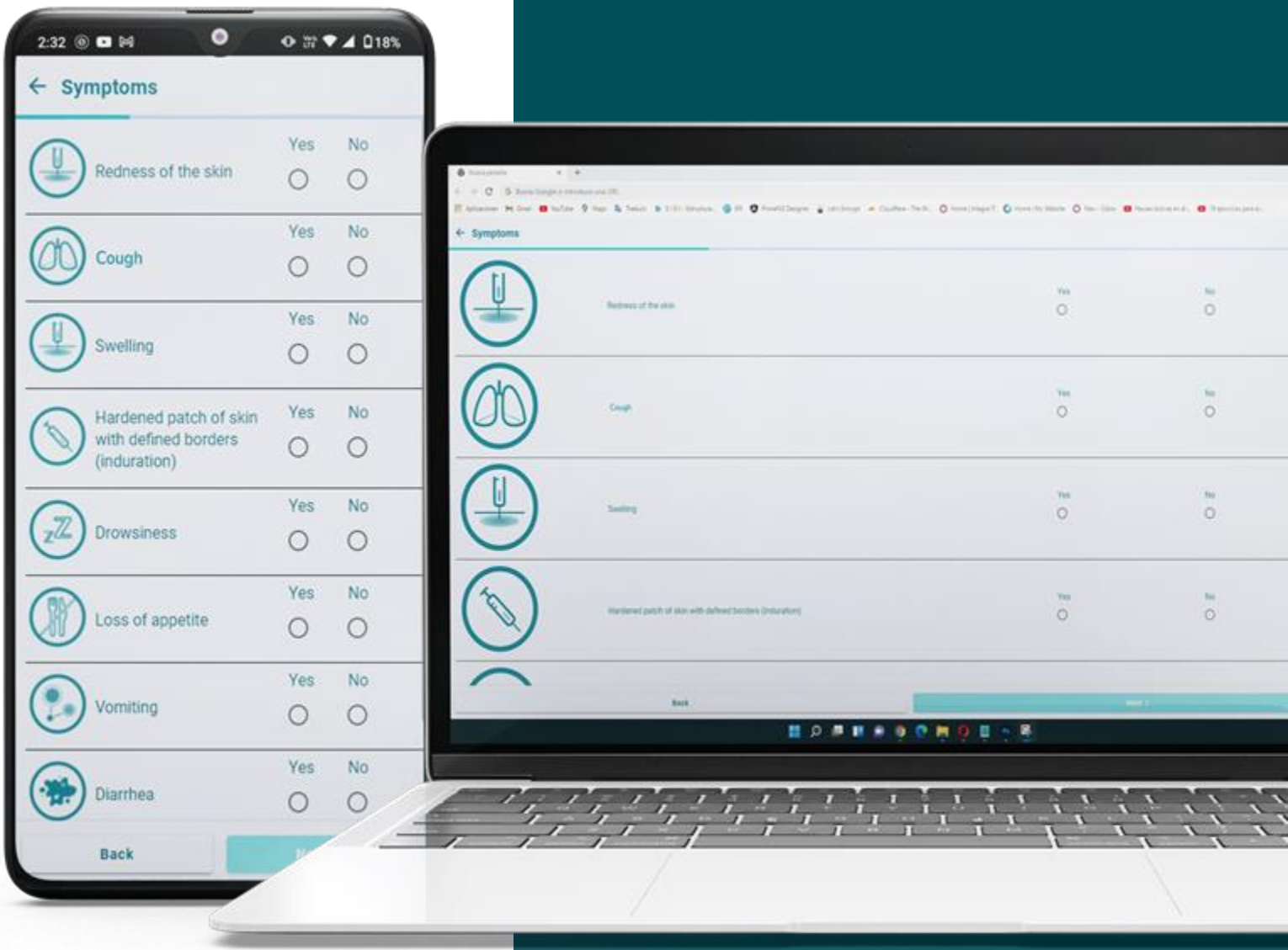
Traceability

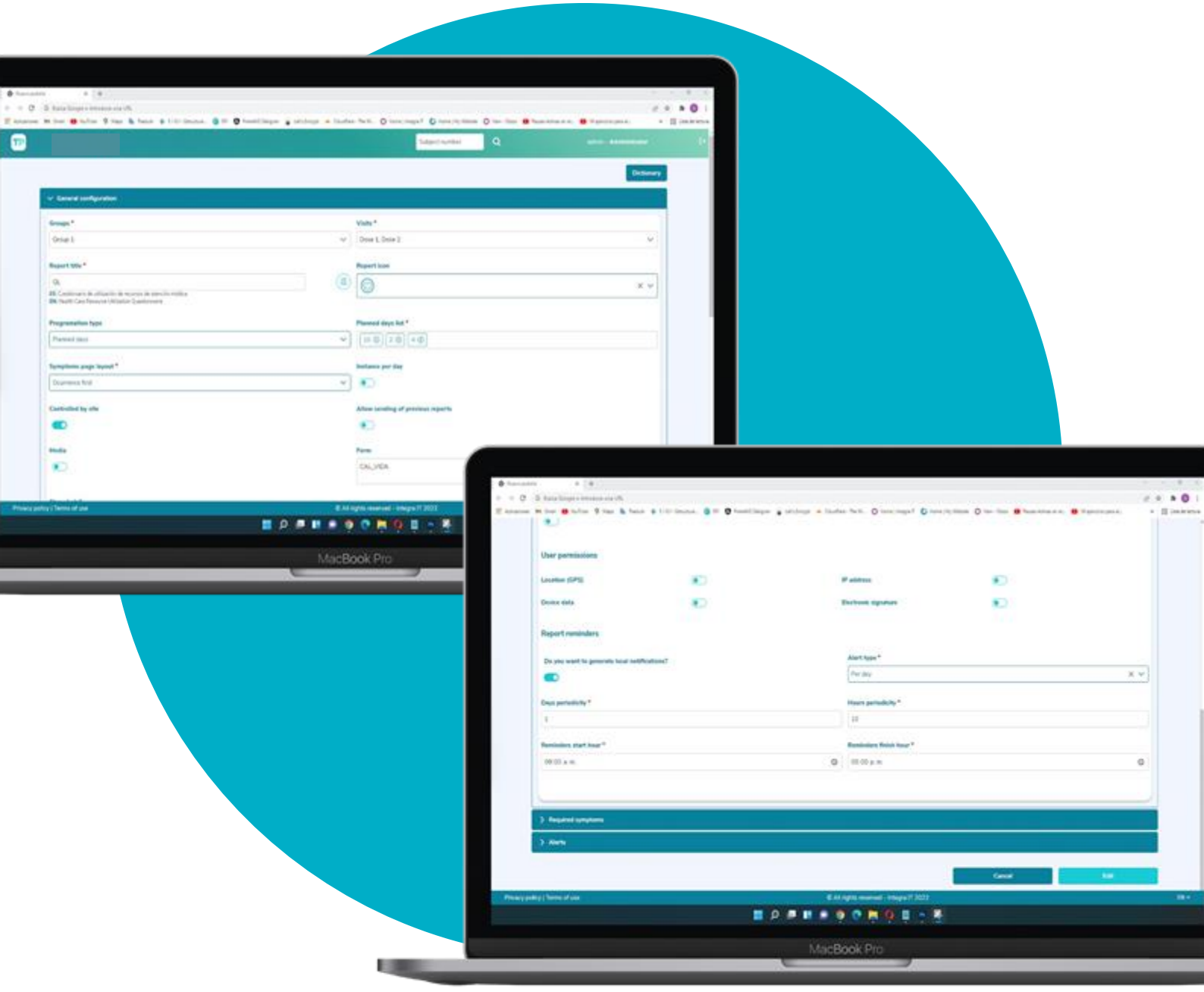
All the information from subjects is stored, encrypted and compliant with all industry's guidelines providing audit trial with who, when and what was changed.

Any device

Both web and mobile application options available so patients can always send reports.

Mobile application is suggested for Latin America, considering the ability to report even without internet connection.



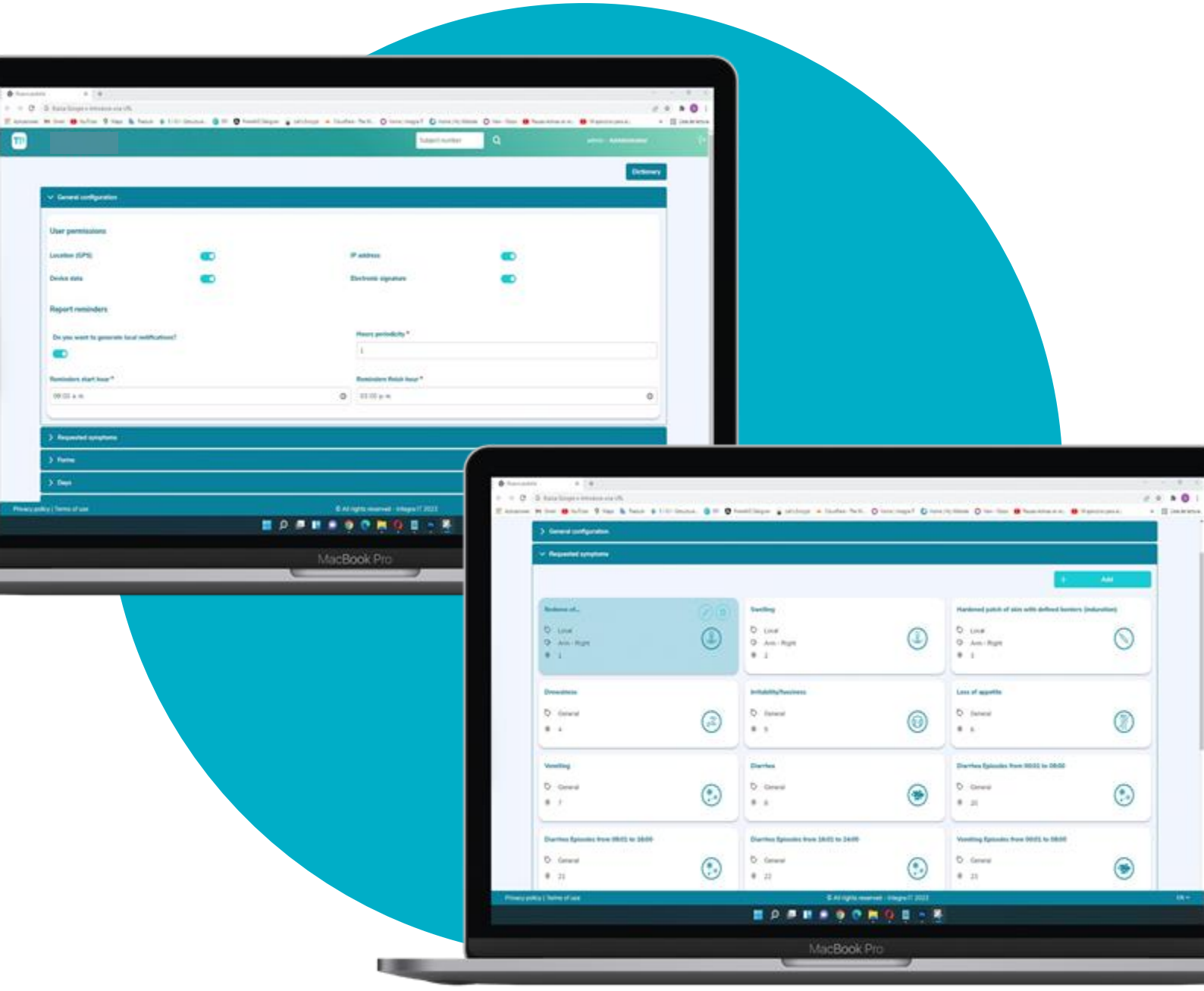


eDiary Screenshots

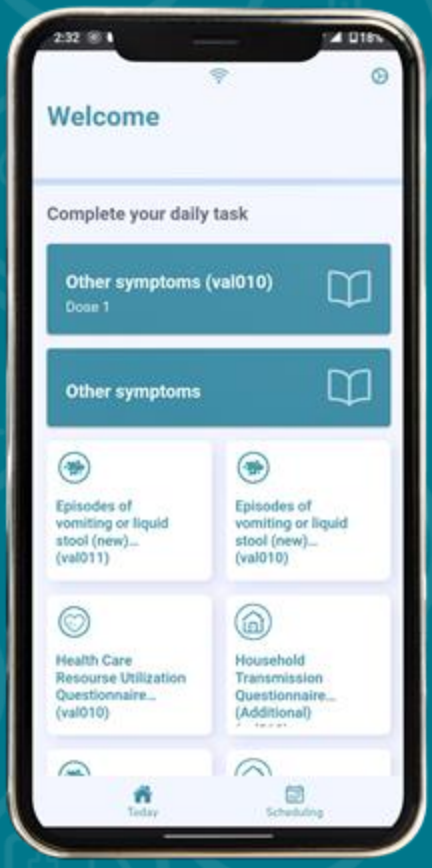
eDiary Screenshots submission in 2 to 3 days.

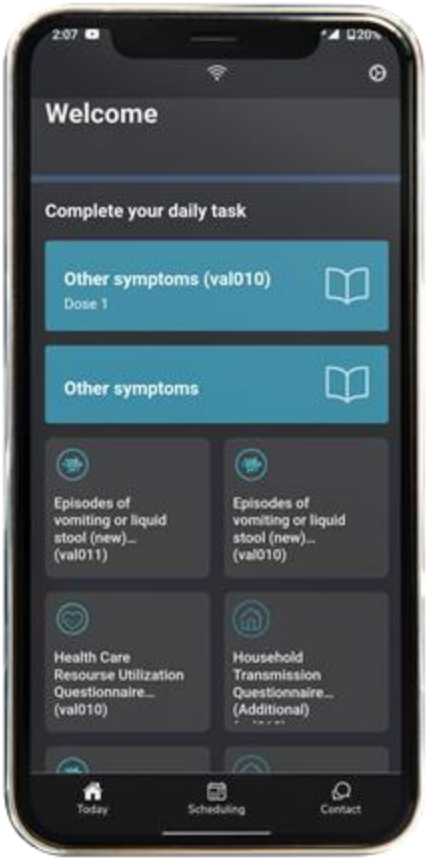
eDiary Setup

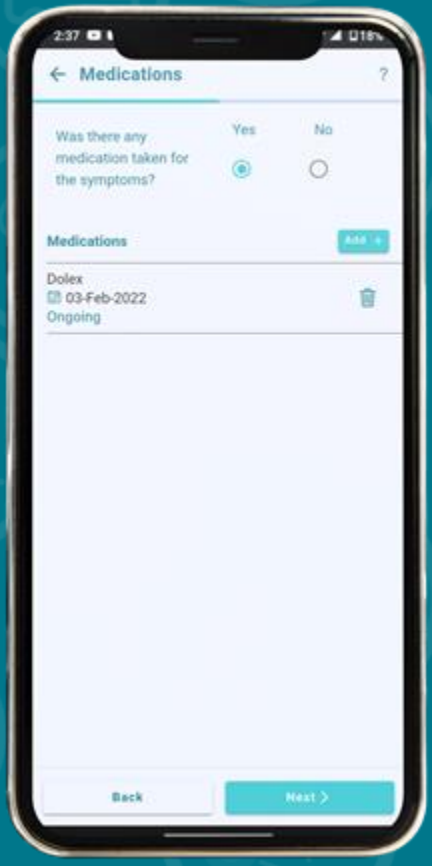
eDiary setup services for UAT in 5 days after receiving study protocol.



Light and Dark mode







Customer Success Story.

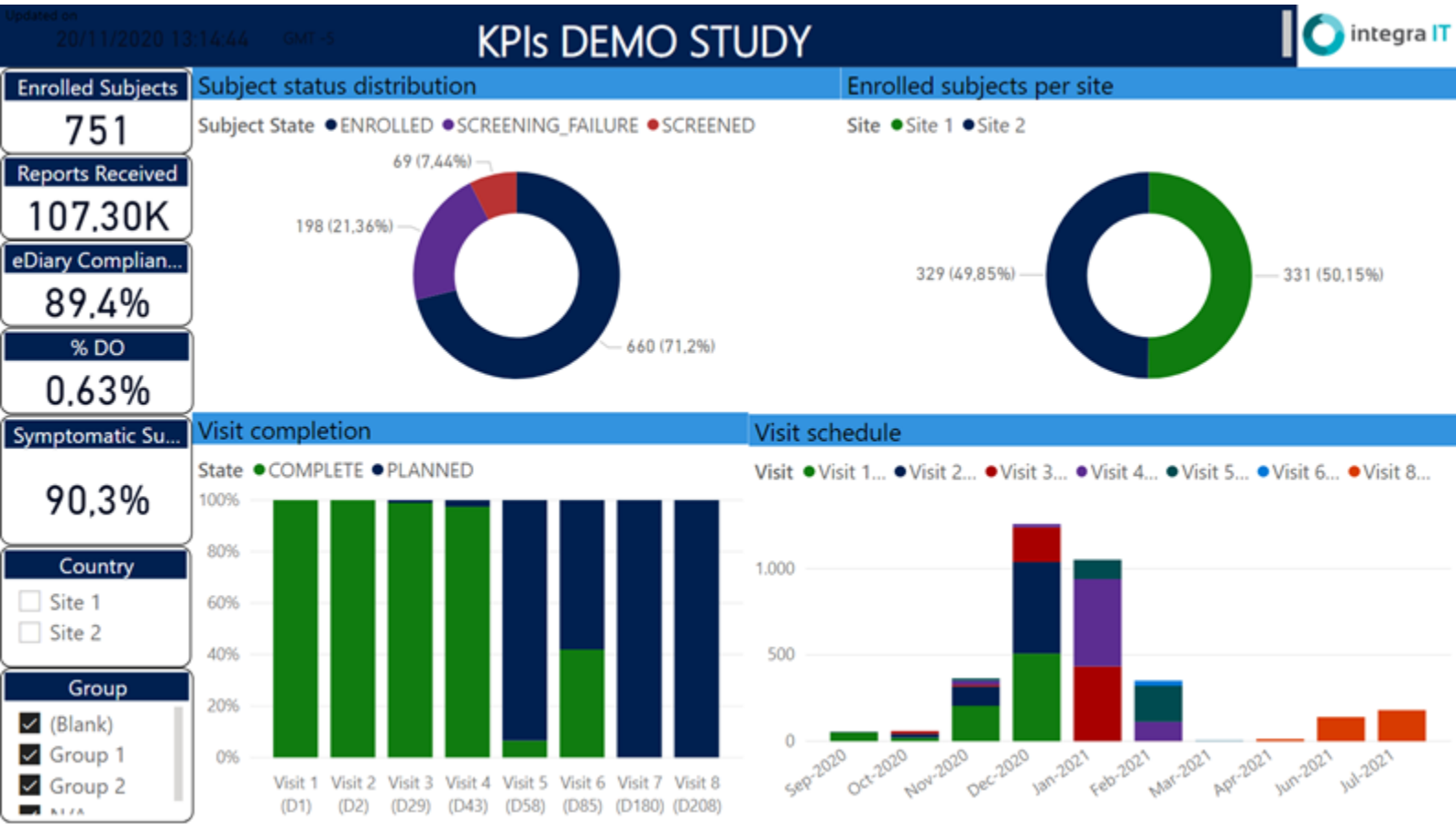
A German sponsor for a Phase II Covid-19 study with a Global CRO, conducted a Phase 2 dose confirmation clinical trial to evaluate the safety, reactogenicity and immunogenicity of the COVID-19 vaccine. Peru enrolled 335 participants over a 3-month period.

The information gathered from this group of volunteers was collected using TrialPal developed by Integra IT.

Lessons Learned

- Thanks to the experience with our application in this Covid-19 study, the site was better prepared for the Phase III study which included thousands of subjects, as well as the management of applications.
- As reported by the site, the Integra applications used for the study were very easy to use and had much more information accessible to investigators and participants, allowing timely decision-making.
- Integra IT support directly on site during the enrollment process facilitated patient engagement, training and cell phone provision when BYOD was not an option. This worked even at the beginning of the study when the health context of the pandemic made it complicated.

Real time reports similar to this one as part of the DSMB, helped evaluate safety findings in a Polio Study, in order to approve within one day the continuity of the study.



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, ITIL, ICH and ISO 27001.

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.

+58.000 participants

Diseases

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

Some of our Clients

- AstraZeneca
- Oxford University
- OPS
- Takeda
- Bill & Melinda Gates Foundation
- MINSA Panama
- FIDEC
- GSK
- JSS Research
- PPD
- University of Colorado
- Asesorías Médicas Integral a los Niños
- ASSIGN
- AJ Vaccines
- Shire
- Vax Trials
- Cevaxin
- Mainz University
- p95
- Afidro
- PAI in Panamá
- Valneva
- Clover
- Medigen
- HilleVax
- CureVac
- Botucatu City in Brazil
- Brazil Site Network
- Policlinico Social del Norte
- 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

Clinical Trial Stats

1.405.855
Activities Managed

148.972
Visits Managed

524.093
Subject Follow-ups

11.498.107
RECEIVED REPORTS.

Tested with millions of records in a multicountry, multisite and multilingual configuration.

16.269
Lab samples managed

846.193
Forms.

423.848
MOBILE APP RECORDS

Over time we have improved patient experience including elderly population with eDiary adherence over 95%.

Our clients speak for us

integra IT

We'd like to hear from you and your challenges. Click here to schedule a Demo with our product representative:

Schedule a Demo

For more information visit:

www.integrait.co/solutions/trialpal-epro-ecoa/

Or write to:

contact@integrait.co