Trial Online® by Replior

Trial Online Product Suite

Product Overview

Trial Online Platform

An integrated EDC, eConsent, ePRO and Virtual Visit platform for the efficient conduct of clinical trials

Trial Online EDC

Trial Online EDC is a trusted and proven platform that streamlines clinical trial data collection. Designed with modern research in mind, it ensures flexibility while upholding rigorous regulatory standards.

Trial Online ePRO

Trial Online ePRO revolutionizes patient engagement in clinical trials by turning data collection into an engaging journey. With its unique gamification elements, patients can effortlessly track their progress, earn rewards, and stay connected every step of the way. It's not just a tool; it's a bridge between patients and groundbreaking medical research.

Trial Online Virtual Visits

Enable participant convenience of in-home virtual trial visits through video calls. Move visits from in-clinic to the home, conduct Virtual Visits to capture data, increase engagement and security.

Trial Online eConsent

Trial Online eConsent streamlines the patient consent process, making it digital, transparent, and user-friendly. Patients can receive and sign informed consents digitally, ensuring they're fully informed and confident in their decision to participate. It's modernizing consent, one click at a time.

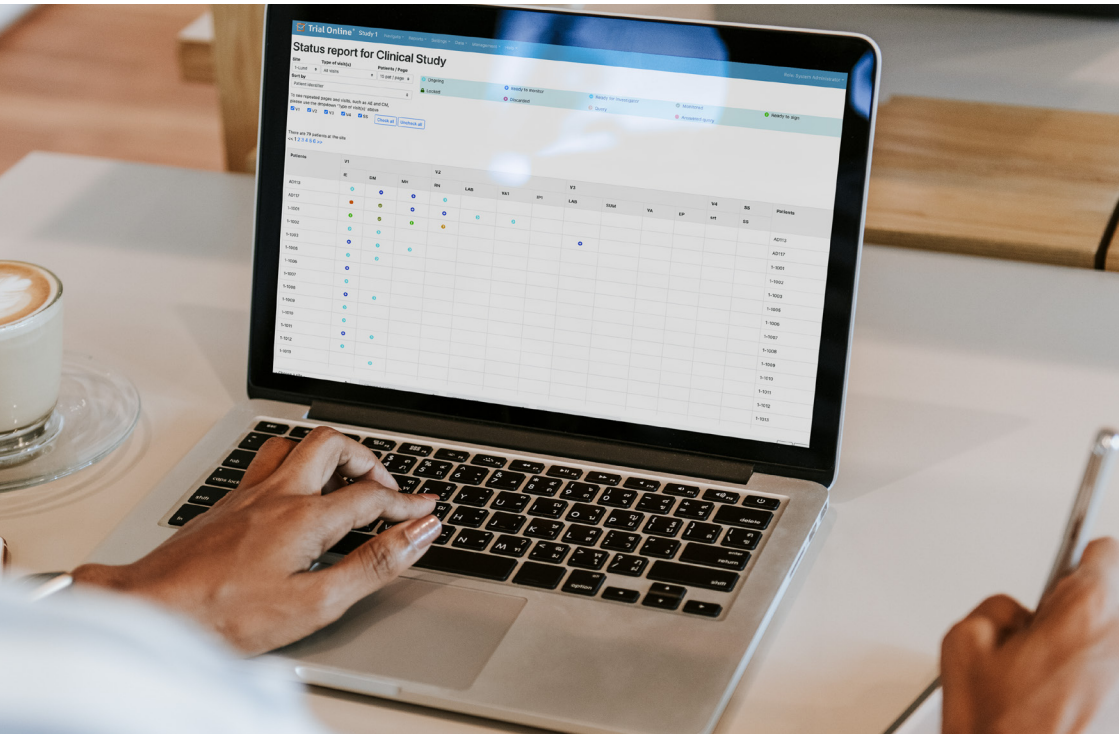
Integrations

Trial Online integrates with various partners based on the unique requirements of each clinical trial, facilitating comprehensive patient data collection. By linking your specific Electronic Data Capture (EDC), Randomization and Trial Supply Management (RTSM) system, wearable device, sensor, or medical device to Trial Online, you can streamline the flow of clinical trial data.

Trial Online EDC

In the clinical trials industry, the Electronic Data Capture (EDC) system plays a crucial role. Choosing the right EDC system is not just about improving operational efficiency—it's about streamlining the entire research process, from initial planning to execution and reporting. With the increasing demand for seamless EDC and electronic Patient-Reported Outcome (ePRO) integration, it's crucial to select systems with proven interoperability.

Trial Online EDC empowers clinical study teams to effortlessly configure their trials from start to finish, all through an intuitive front-end trial builder .



Features

Platform Agnostic

Trial Online EDC has fully responsive design and works perfect on a desktop computer, laptop, tablet or on a smartphone.

Simple User Interface

Enable your site staff to enter data rapidly and accurately with logical user flow and form rules like edit checks. Calculated variables ensure that figures (BMI, imperial to metric, etc.) are always reliable.

User Roles

All roles have access to Trial Online with defined permissions and passwords. When logged on, the system provides a clear project overview, specific To Do list and email alerts.

Data is Saved Automatically

Store each value automatically once it is entered. No risk of losing data due to inactivity. Edit checks triggered directly for cleaner data. More effective monitoring and cleaning process.

Queries

CRAs, Data Managers and Medical Coders can create queries and forward them to the investigator/coordinator who will be alerted within the system or via a system-generated email.

File Import

Laboratory files can be imported into Trial Online. It is possible to upload images, videos and other binary files in Trial Online. Files may be assessed by an independent investigator in the system

Edit Checks

Trial Online ensures the validation of data entry through edit checks that can be set to trigger directly when an “incorrect” entry has been entered, or in batches at regular intervals. Edit checks are easily specified in the Construction Module. Trial Online offers a paperless query tool to generate, resolve and track queries online.

Reports

Trial Online includes several types of reports to simplify the overview, monitoring and security of the trial. In Trial Online the user can also create and customize additional reports. The Status Report Summary gives the user insight to work flow navigation and a visual overview of patient status. Excel, SAS, ASCII and PDF are standard export formats in Trial Online.

Audit Trail

A complete audit trail is maintained from data entry through all changes in the system. The Trial Online system includes many types of reports that simplify the overview, monitoring and security of the trial and additional, customized reports are readily available.

Trial Online ePRO

Trial Online electronic Patient-Reported Outcomes (ePRO) is specifically designed for a better patient experience throughout the study ensuring patients feel supported at every stage of the clinical trial, benefiting from visit and treatment reminders, informative guidance alerts, and progress tracking. Trial Online ePRO focuses on these three main aspects:

Improve Patient Experience

Trial Online ePRO is an easy to use app designed for a better patient experience throughout the study. Patients feel supported at every stage, benefiting from visit and treatment reminders, informative guidance alerts, and seamless progress tracking.

Boost Patient Retention & Compliance

Compliance and progress efforts are celebrated on Trial Online! Our ePRO embraces gamification elements to make the patient journey engaging and rewarding. As questionnaires are completed and milestones are achieved, we celebrate by awarding trophies and badges as tokens of the user's success.

Enhance Data Quality

Ensure high-quality exhaustive data collection and analysis at any point in the study with effortless questionnaires, event scheduling, compliance tracking, treatment management, wearable integrations, and real-time monitoring.

Powerful Features

Study Dashboard

Get a direct overview of study performance, progress, and compliance. Take actions based on real-time statistics.

BYOD but not only

Use the ePRO on your own device, web or provisioned device by Replior.

Reminders & Notifications

Schedule and send reminders
nd notifications for pending tasks
or upcoming visits

Gamification

Award patients with trophies and badges when they complete tasks and motivate them with progress and compliance status bars.

Calculations

Measure data and identify trends in patient or treatment development over time using advanced program calculations.

Treatments

Configure treatment schedules and provide how-to guiding information to patients.

Questionnaires & eDiaries

Collect ad-hoc data from patients, such as medication intake and adverse events. Get reviews by the Investigator or CRA.

Integrations

Connect the ePRO to Trial Online EDC, Virtual Visits or eConsent or to your study-specific vendor systems such as RTSM or wearable devices.

Language Support

Support for over 40 languages for patients, with additional languages added upon request.

Voice Recording

Allow patients to use voice recording as a memory note to remember how they felt at a point in the study.

Patient Groups

Enrol patients into different groups to enable group-specific tasks

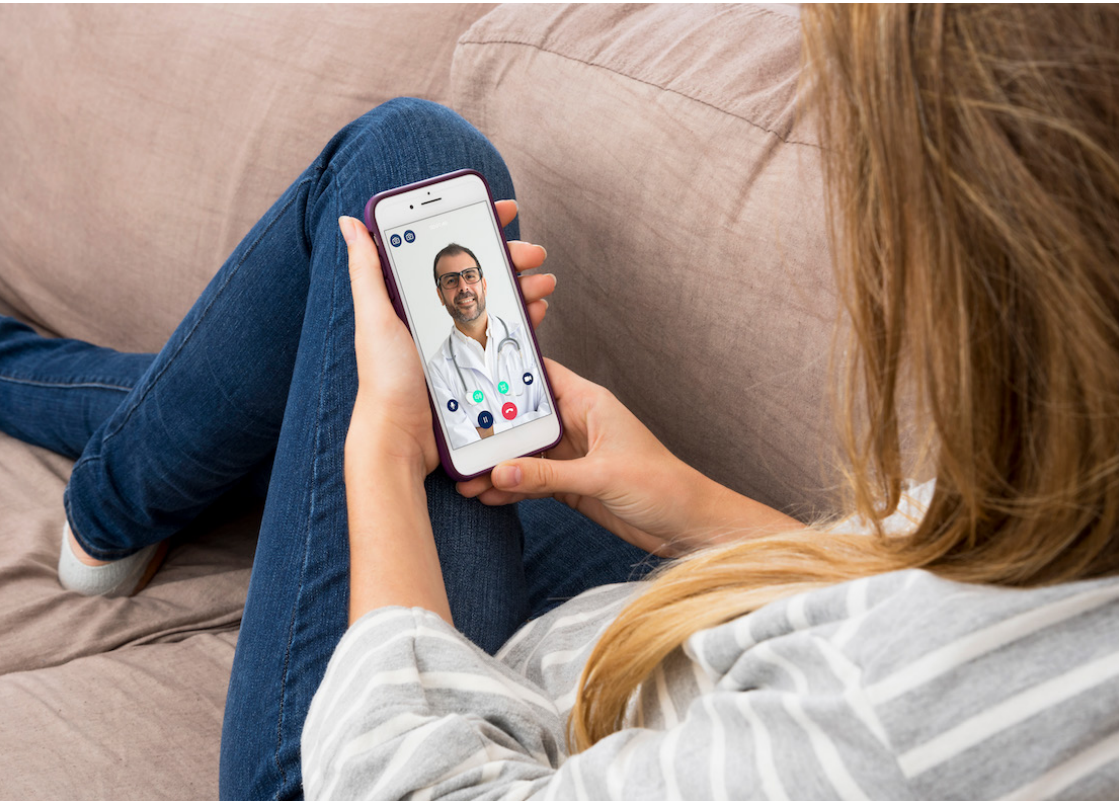
Exports

Multiple export options are available for data extraction, including audit logs, notifications, and questionnaire exports.

Trial Online Virtual Visits

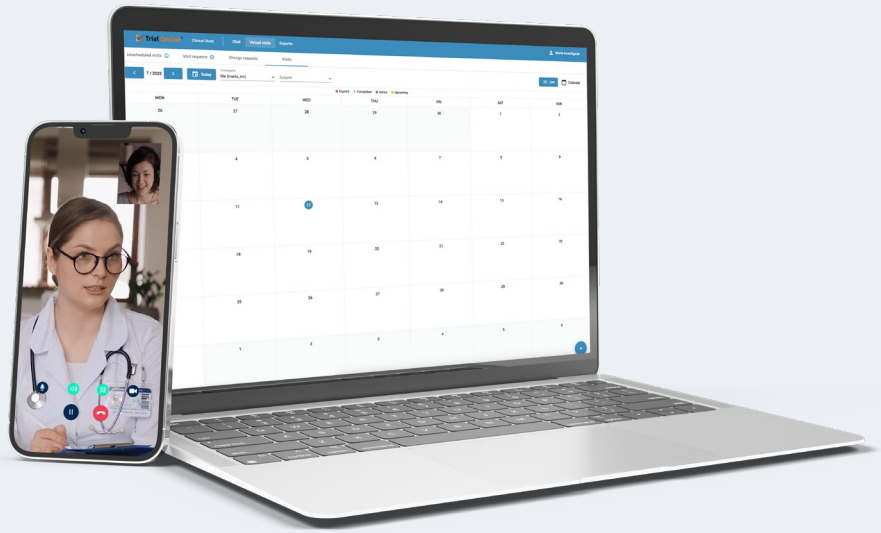
Virtual Visits is a communication module to use and collect data for Site-to-Participants communication during a clinical trial.

Through Trial Online Virtual Visits solution, participants can engage safely and conveniently from the comfort of their homes, while the investigator securely monitors symptoms and conducts assessments during the data collection process. Virtual Visits allow the investigator to observe the participant, instruct them on how to complete assessments and record their observations directly into the EDC system.



Trial Online Virtual Visits Benefits

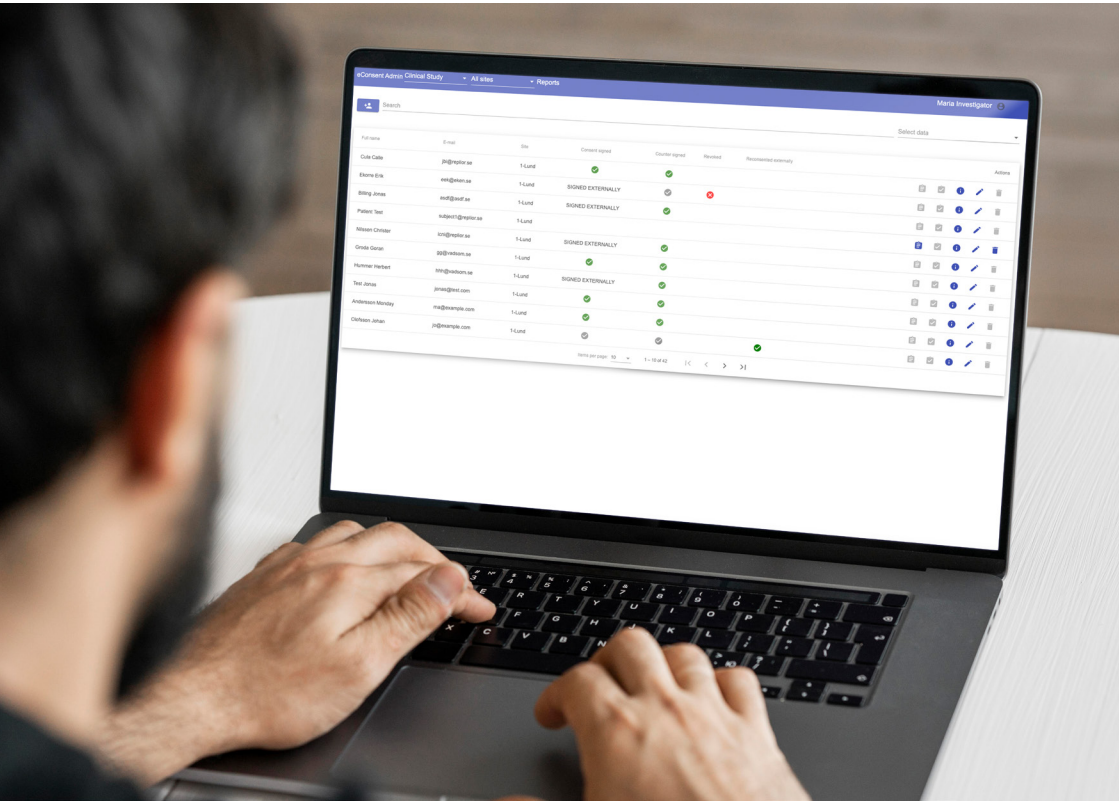
- √ All prior chat history with the participant is visible to the site staff before and during Virtual Visits for reference.
- √ Follow-up appointments can be scheduled, and participants receive notifications as well as reminders of the upcoming Virtual Visits in the ePRO app.
- √ To ensure no messages sent from participants to site staff are left unanswered, it is possible for sites to configure messages/information at site level for non-office hours, including automatic replies to participants about opening hours and re-directing participants to other contact paths for emergency situations.
- √ Virtual Visits work alongside electronic data collection as well as ePRO in any clinical trials or post-market studies.
- √ A full audit trail is available.



Trial Online eConsent

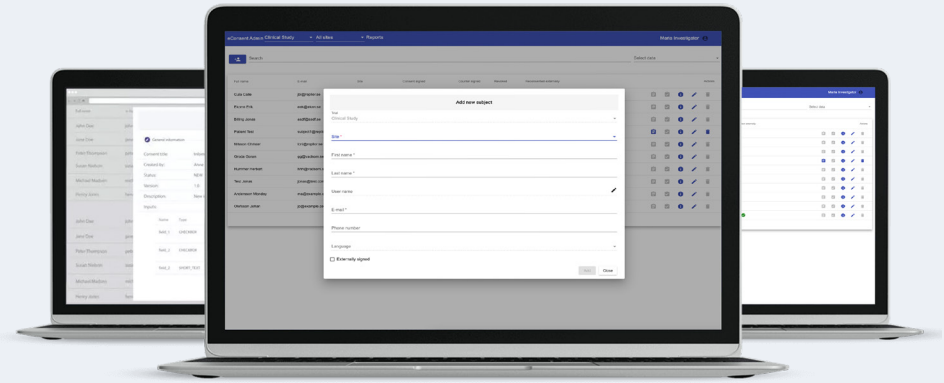
Participant safety and integrity start with the participant's complete understanding of the trial and all the inherent risks involved. This is where eConsent can offer more protection through a directed online experience.

The step-by-step eConsent process guides the participant to ensure understanding and presents a signature box at the end of these steps.



Trial Online eConsent Benefits

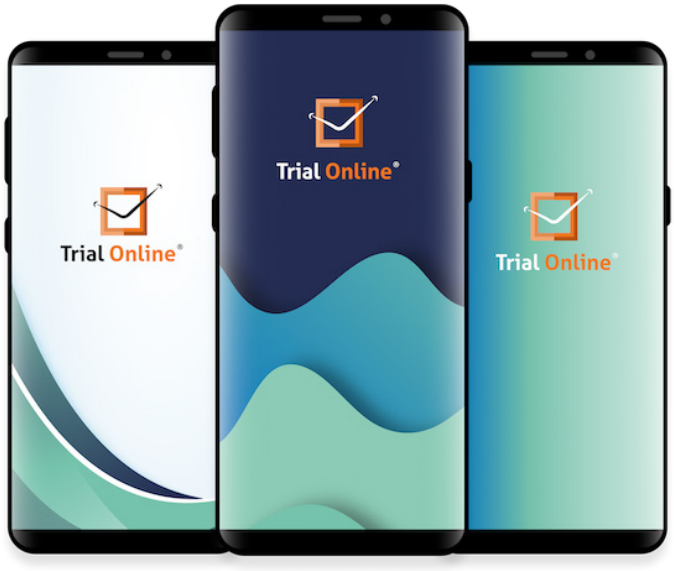
- √ Paper-free, fully electronic participant informed consent forms
- √ Easy tracking of consent versions and which consent has been signed by what participant
- √ Sign, countersign, and revoke consent capability
- √ Multi-language support
- √ Automatic creation of participants in EDC and/or ePRO after signature of eConsent
- √ Multiple reports and exports are available



Device Supply Management Service

For clinical trials that needs patient diary entries or questionnaire responses, BYOD (Bring Your Own Device) is a commonly employed method. However, it may not be the optimal solution for all patients or trials. In response, we've developed a comprehensive service that provides the required devices and everything essential for seamless data entry, all at a fixed price.

Whether it's a BYOD trial with patients lacking suitable smartphones, participants hesitant to use the app on their personal phones, opting to answer questionnaires on-site using tablets, or trials where smartphones are provided to all patients, our adaptable setup caters to any trial requirements.



Device Provisioning Service includes:

- √ Rental of smartphone or tablet device
- √ Global cellular network coverage
- √ SIM with dataplan
- √ Global express shipping
- √ Full insurance and replacement service
- √ Installation of apps and configuration
- √ Lock-down (kiosk mode) to only allow communication with trial services
- √ Return shipping after trial

About Replior

Founded at the turn of the millennium, Replior began as provider of IT operation services for the Life Science industry.

Over the years, we've evolved, acquiring the Trial Online EDC software system in 2010 and setting out on a mission to become a trusted partner for data collection in clinical trials.

Our journey has been marked by collaboration, innovation, and a commitment to advancing patient care and research.

Our Approach

We believe in the power of technology to transform clinical trials. But more than that, we believe in putting patients at the heart of everything we do. From introducing gamification elements to enhance patient engagement to developing the ePRO platform for streamlined and standardized data collection, we're always looking for ways to make the clinical trial experience better for everyone involved.

Our Products

Our flagship offering, Trial Online, is a suite of systems designed to make data collection in clinical trials as seamless and efficient as possible. Whether it's EDC, ePRO, eConsent, or Virtual Visits, we've got you covered. And with our capabilities to integrate with wearable sensors, we can provide robust measurements to provide evidence of your product's efficacy.

Our Commitment

Honesty. Transparency. Integrity. These aren't just words to us; they're the principles that guide everything we do. We're fully auditable, compliant with all relevant regulations, and dedicated to providing services that meet the highest standards of quality. Our IT operations boast certifications like ISO 27001, ISO 9001, ISO 14001, and PCI DSS, and our infrastructure is fully redundant, operating from geographically separated data centers.

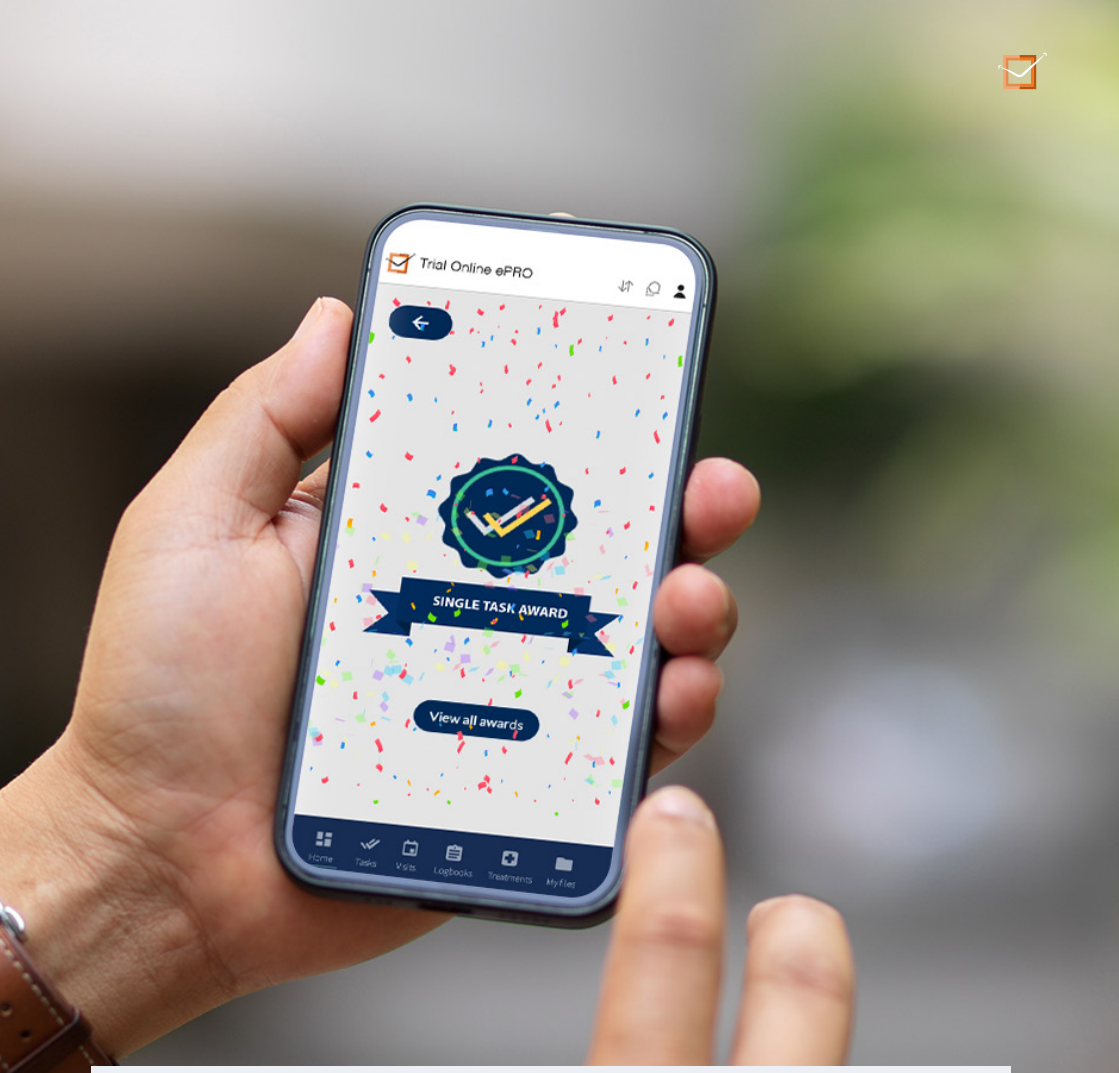
ISO 9001 ISO 27001 ICH GCP compliant GAMP

FDA 21 CFR PART11 EMA EudraLex Volume 4 Annex 11 GDPR Compliant

Join Us on Our Journey

If you're looking for a partner who values innovation, integrity, and the patient experience, you've come to the right place. Let's transform the world of clinical trials together.

Thank you for considering Replior. We're here to make a difference, and we're glad you're with us.



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