Trial Online® by Replior

Trial Online ePRO

Product overview

August 2023

Elevate Patient Engagement with Trial Online ePRO

Empower patients with our all-in-one ePRO Software through gamification elements, voice recordings, reminders, and an extensive suite of 20+ features crafted to minimize dropouts and motivate users.

- √ Extensive toolbox to effectively AND efficiently create your trial
- √ User-friendly
- √ Cost efficient
- √ Integrated with EDC and eConsent
- √ Trial Online allows you to tailor and customise our software to suit your trial
- √ Option for additional custom-built functionality specific to your trial
- √ Extensive reminder settings to keep patients engaged
- √ Reward patients' progress with trophies to maximize compliance
- √ Customise reports or choose from the large selection of standard reports and exports
- √ A safe and compliant system: Trial Online is compliant with FDA 21 CFR part 11, and corresponds to GCP and FDA's Guidance of Computerized Systems Used in Clinical Trials. To ensure data security over the internet, Trial Online features 256-bit https data encryption.
- √ Available for Android and iOS devices
- √ Webbased, no special hardware or software is required to run the service, Trial Online runs in every browser.

Features: ePRO Web & App

Study Dashboard

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

Language support

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

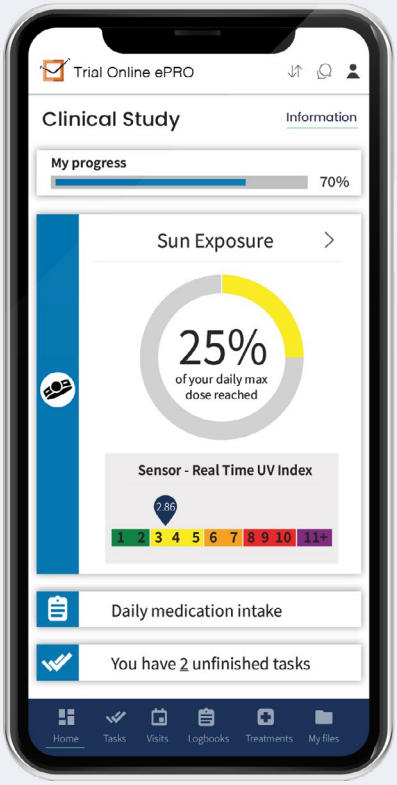
App homepage

The Trial Online ePRO app home page gives the patient an overview of current tasks, planned visits and quick access to the logbook and questionnaires.

The bottom navigation bar allows for easy navigation through the app.

Widgets allow you to customize and tailor the app to match your specific trial needs and implement a trial specific functionality.

**The widgets are developed by Replior on a per trial basis.*



Survey

Collect ad-hoc data from patients, such as medication intake and adverse events. Get reviews by the Investigator or CRA. Create user friendly Questionnaires and Logbooks, with multiple layout and structure options.

Questionnaires

Trial online ePRO lets you create custom questionnaires that covers all your needs, including multiple layout, structure and language options.

Logbooks

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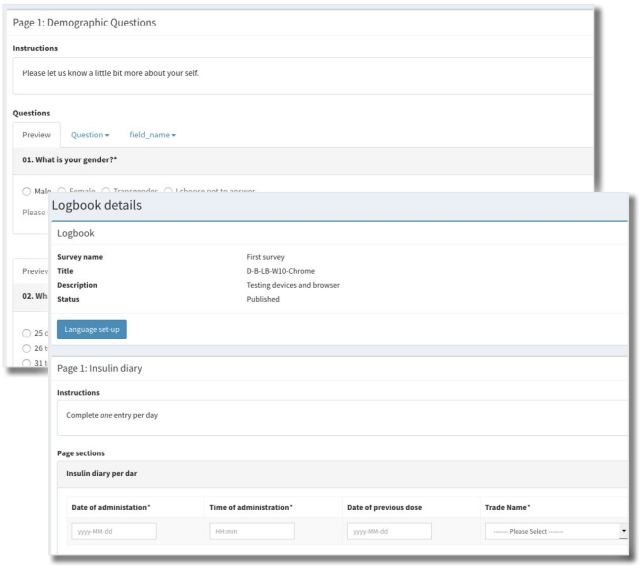
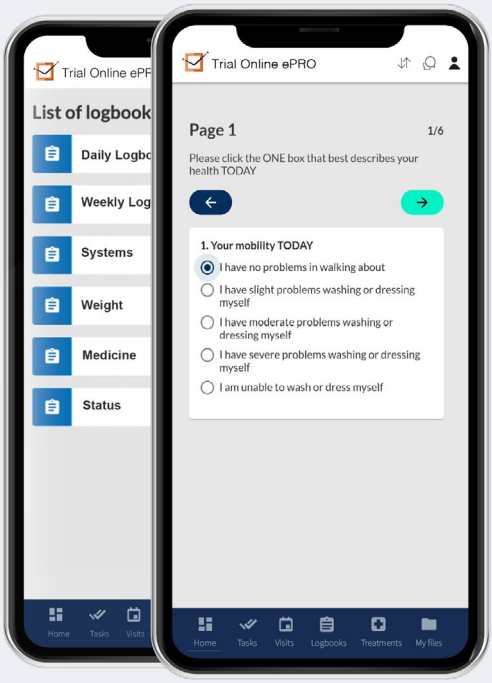




Questionnaires and Logbooks in App

Patients can complete, edit and submit questionnaires straight in the app.

Depending on the requirements of your clinical trial, logbooks can be configured to collect patient information periodically, upon downloading the app or ad hoc.

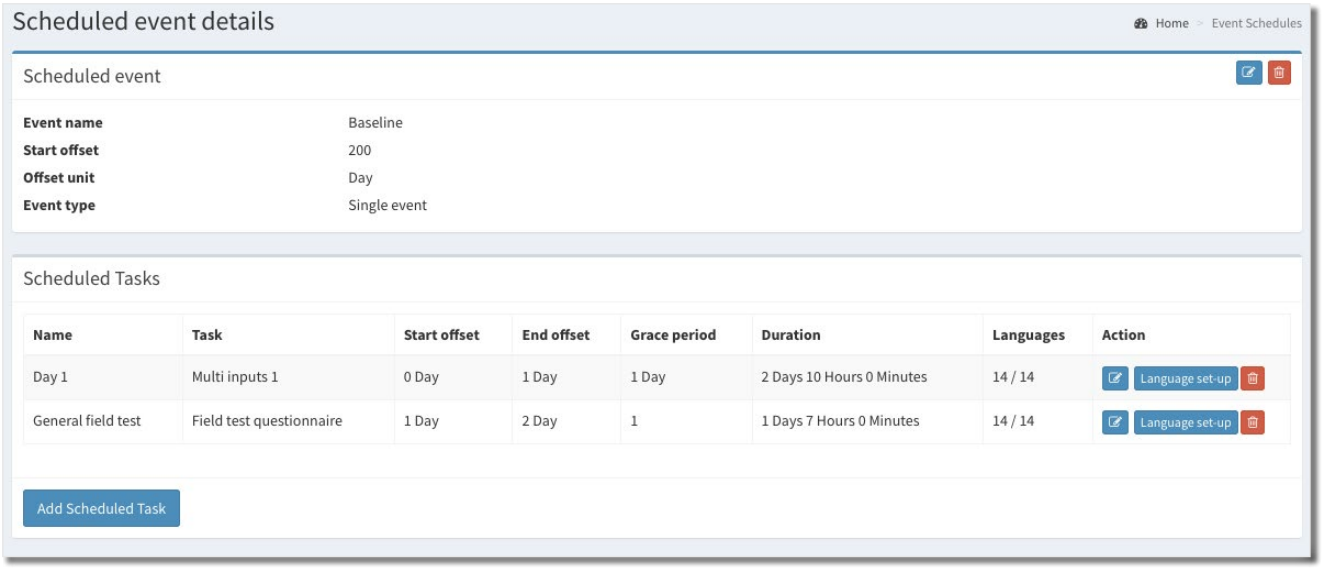
The logbooks can be used to collect data from patients about daily medication intake, blood pressure or any other information important to your trial.

Event Schedules

Schedule when your questionnaires will be available for data entry.

Set start and end date for each questionnaire, group questionnaires together in events and add different languages.

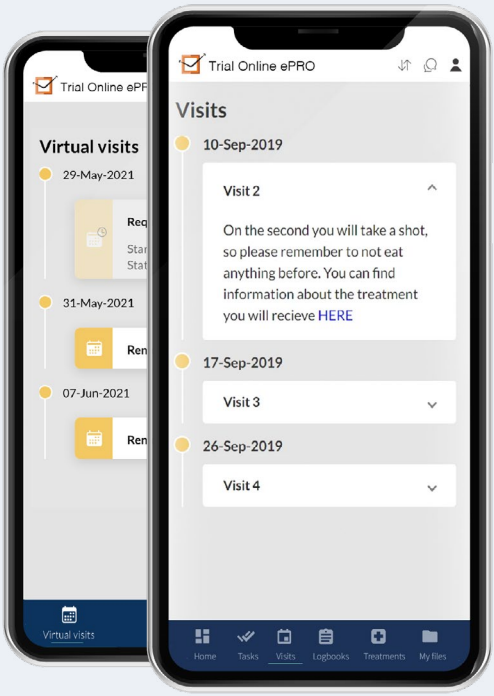
It is also possible to schedule physical events for paitents.



Visits

The visits tab appears as a timeline and gives the patient a full overview of all upcoming scheduled appointments.

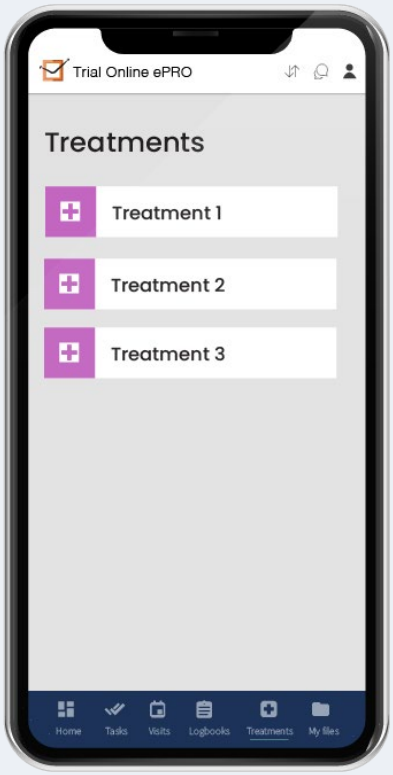
By clicking on a visit button, additional information can be displayed including specific preparation instructions or clinic direction.



Treatments

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

You can describe and configure the treatment scheme(s) giving patients as much information as required about each treatment and how to participate.



Treatments in App

Reminders and Notifications

Add notifications to Events and Surveys to be send to patient. Set start point, recurring interval and which media the notification will send through.

Using notifications can help ensure higher compliance for the clinical trial.

In App notifications

Notifications can pop up on the app itself or reminders can be sent directly to the patients through email and/or SMS.

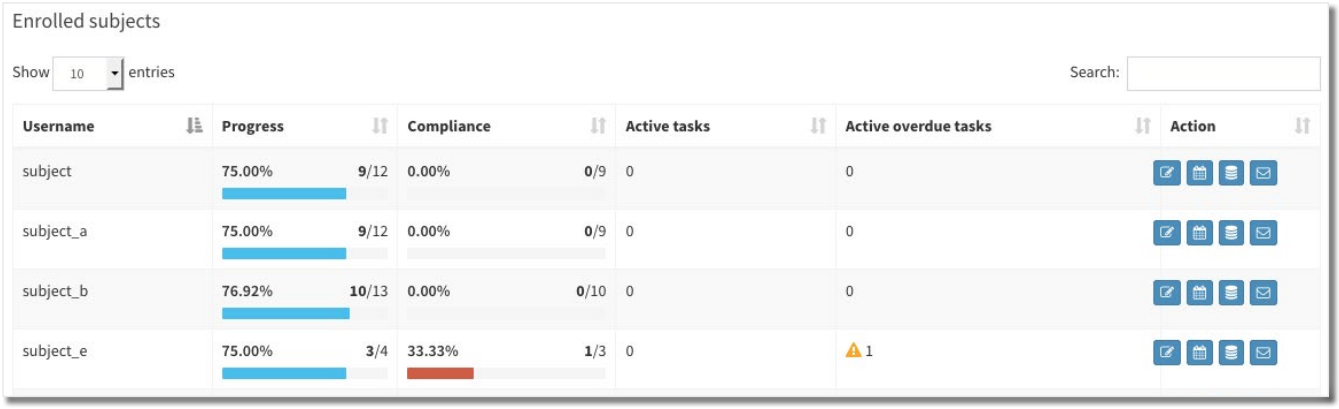
Reminders can be configured to be automatic or customized.

Features: ePRO Web

Participants

Enrolling the patient will enable the user account, generate a password as well as it let you assign settings as default language, timezone and contact details used by the system for notifications.

Get an easy overview of enrolled patients, with details of progress, compliance and tasks.
View questionnaire and logbooks entries, and see a list of notifications send to the patient either by mail or SMS.



Exports

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

Audit

A complete audit trail is maintained from data entry through all changes in thesystem.

Documents

Upload custom documents for users and subjects. Define viewing rights by role and languages.

Patient Groups

Enrol patients into different groups to enable group-specific tasks

Divide patients into groups that decides events and questionnaires the patients will get.

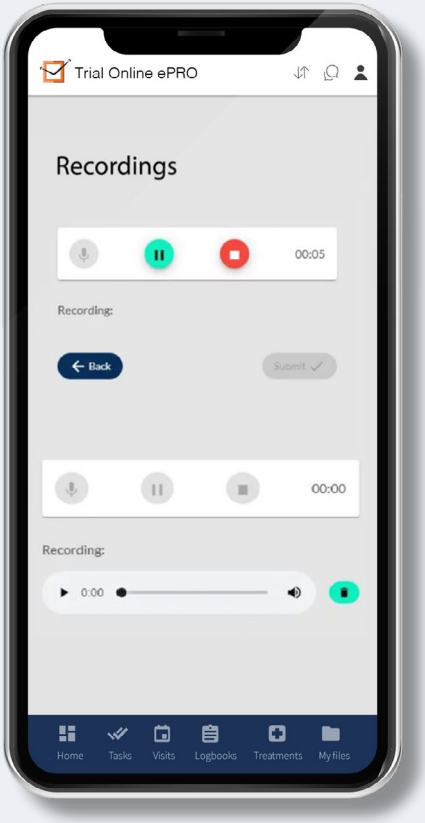
Features: ePRO App

Compliance & Progress bars

Keep the patient engaged and motivated with compliance and progress bars.
The overview bar track the patients personal progress throughout the trial.

Calculations

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



Voice Recording

Asking a patient to recall a symptom, or how they felt 8 weeks ago, is something only few patients can do. But with the new Recording functionality in Trial Online ePRO app this has just become easier.

The recording functionality allows you to schedule when a patient should submit a recording and when the patient should listen to a recording.

Using a recording over a written memo requires less effort for the patient and hearing a previous recorded memo in his or her own voice, will make it easier for the patient to recall certain moments, symptoms or feelings.

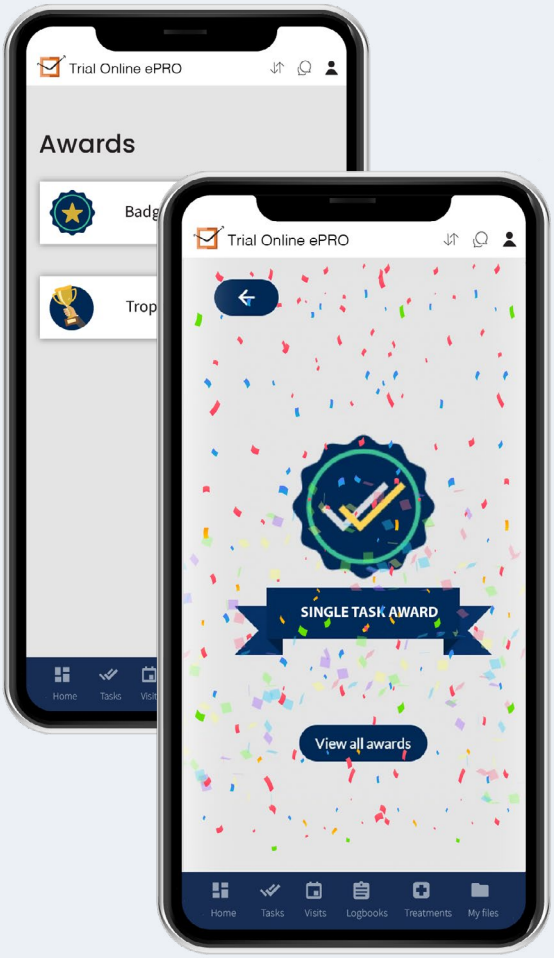
Gamification

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

A key feature in our ePRO app is the ability to keep patients engaged and the retention rate high with gamification.

Easily customizable to fit your trial, adding gamification by awarding trophies and badges for completion and progress.

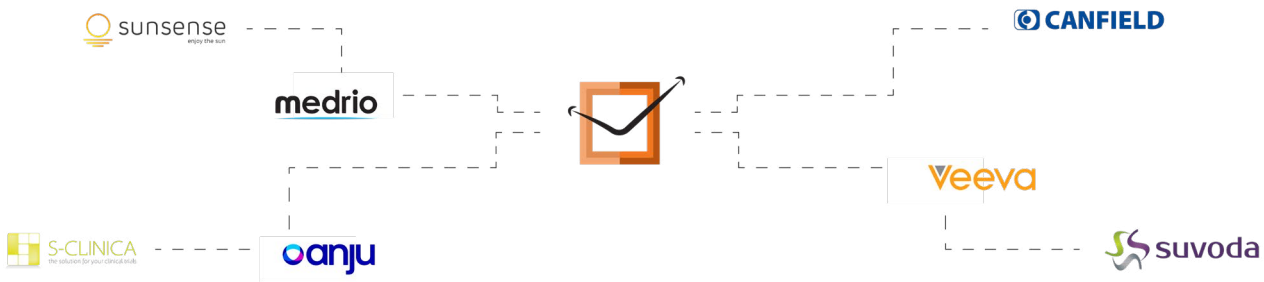
By using gamification you can keep the patients inspired, and help reassure that the patient will stay engaged in the trial.



Integrations

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

Trial Online ePRO 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) or Randomization and Trial Supply Management (RTSM) system to Trial Online, you can streamline the flow of clinical trial data.

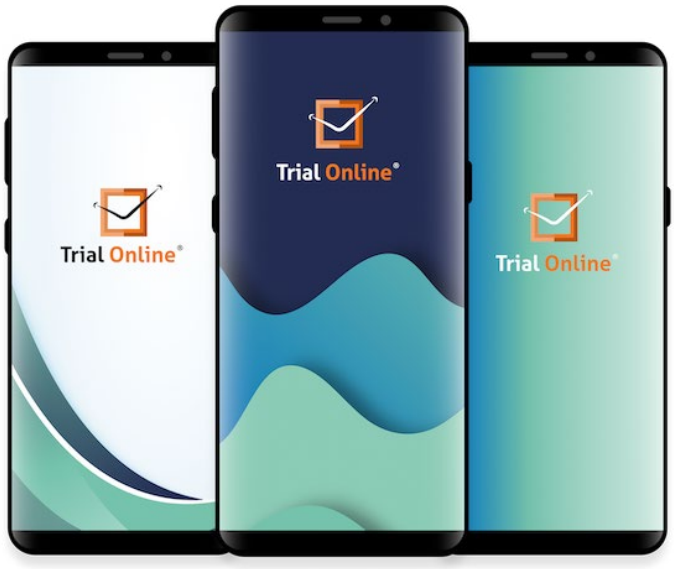


Device Supply Management Service

For clinical trials that require patients to enter diary data or answer questionnaires a popular way is to use BYOD (Bring Your Own Device). For all patients and for all trials this is not the best solution.

So we created a service to include the device and everything needed to start entering data, at a fixed price.

Whether it is for a BYOD-trial but where some patients don't have the correct smartphone to suit the solution, patients who don't want to run the App on their own phone, patients answering questionnaires at site on a tablet or a trial where the smartphones are included for all patients, we have the setup for it.



The Device Management Service includes everything

- √ Rental of smartphone device
- √ SIM with 500MB dataplan
- √ Unpacking
- √ Initial charge
- √ 1st time phone setup
- √ App installation
- √ Lock-down (kiosk mode) to only allow communication with trial services
- √ Packaging with instruction documentation
- √ Shipping to site/CRA with over-night freight
- √ Return and replacement service
- √ Normal delivery within 6-8 days from order

About Replior

Trial Online EDC and Trial Online ePRO is owned, developed and qualified by Replior AB.

Replior is a privately held Swedish software solutions company focused on clinical trial support systems and offering a full suite of data collection products.
Replior develops in-house software and delivers Software as a Service, SaaS, solutions to Pharma companies and CROs.

The company is headquartered in Stockholm and has offices in Lund, Sweden, and Split, Croatia.

The EDC product Trial Online has been in operation since the year 2000, collecting data in over 1000 trials. Trial Online is a trusted eCRF provider for thousands of clinical studies made over the years, from small Phase I trials to global Phase III/IV trials. Trial Online ePRO provides Patient diary and questionnaire service to clinical studies.

About Trial Online EDC and ePRO

In early 2016, Trial Online ePRO was launched. Trial Online ePRO can be used as an integrated service with Trial Online EDC or as a stand-alone service.

In 2019, the Trial Online ePRO app and eConsent tool was launched.

Trial Online is owned by Replior AB as a part of the Hiberion Group.

Therapeutic Experience

Trial Online has conducted over five hundred studies in a wide range of therapeutic areas.

Our software can accommodate the most complex of clinical trial designs, with an easy and time-saving set-up. Conducting a study has never been easier.

- √ 100% Web-based EDC and ePRO
- √ Clients are able to perform all activities themselves
- √ Easy and fast set up of the complete system
- √ Fully compliant with 21 CFR part 11 and GCP
- √ Hosted on a secure dedicated server
- √ User-friendly
- √ Medical coding: MedDRA and WHO-DD
- √ Flexible and fast eCRF design
- √ Facilitates networking with specialists and partners
- √ Cost-effective even for small MedTech and BioTech studies
- √ Easy construction of Data Sets – adaptable data export
- √ E-training

Quality and Compliance

Our services and products shall always meet our customers' and users' expectations and requirements. By understanding our customers' needs today and, in the future, we deliver competitive services and products with the right quality, on time and according to agreed terms.
A cornerstone for our quality work is an engaged and aware staff and the company's collective knowledge and rules.

All systems and processes used to manage a clinical trial are part of a regulated process that must be validated and needs to meet FDA regulations, EMA regulations and ICH guidelines.
All Trial Online's products follows these regulations and guidelines as well as industry standards to ensure product quality. This includes Software Development Life Cycle and System Qualification.

Trial Online is a designed, developed, and tested computer system as defined in PIC/S 'Good Practices for Computerised Systems in Regulated "GxP" Environments'.
Trial online is compliant with FDA 21 CFR Part 11, GDPR and HIPAA. Our Quality Management System is built on quality standards in the industry, e.g. guidelines and directives provided by ISPE, FDA, EMA and ICH.

Our independent Group Compliance Officer performs regular internal audits on Replior and Complior. Clients (CROs and Sponsors) regularly perform audits of Replior and Trial Online.

We are dedicated to delivering a service of the highest quality in all aspects of our operation. Furthermore, we continually try to meet, or exceed, all expectations of our customers.

From development, through general product release, we have a high focus on quality and compliance. We have accomplished this by leveraging the latest technological solutions and according to regulatory standards and guidance.

Product Quality

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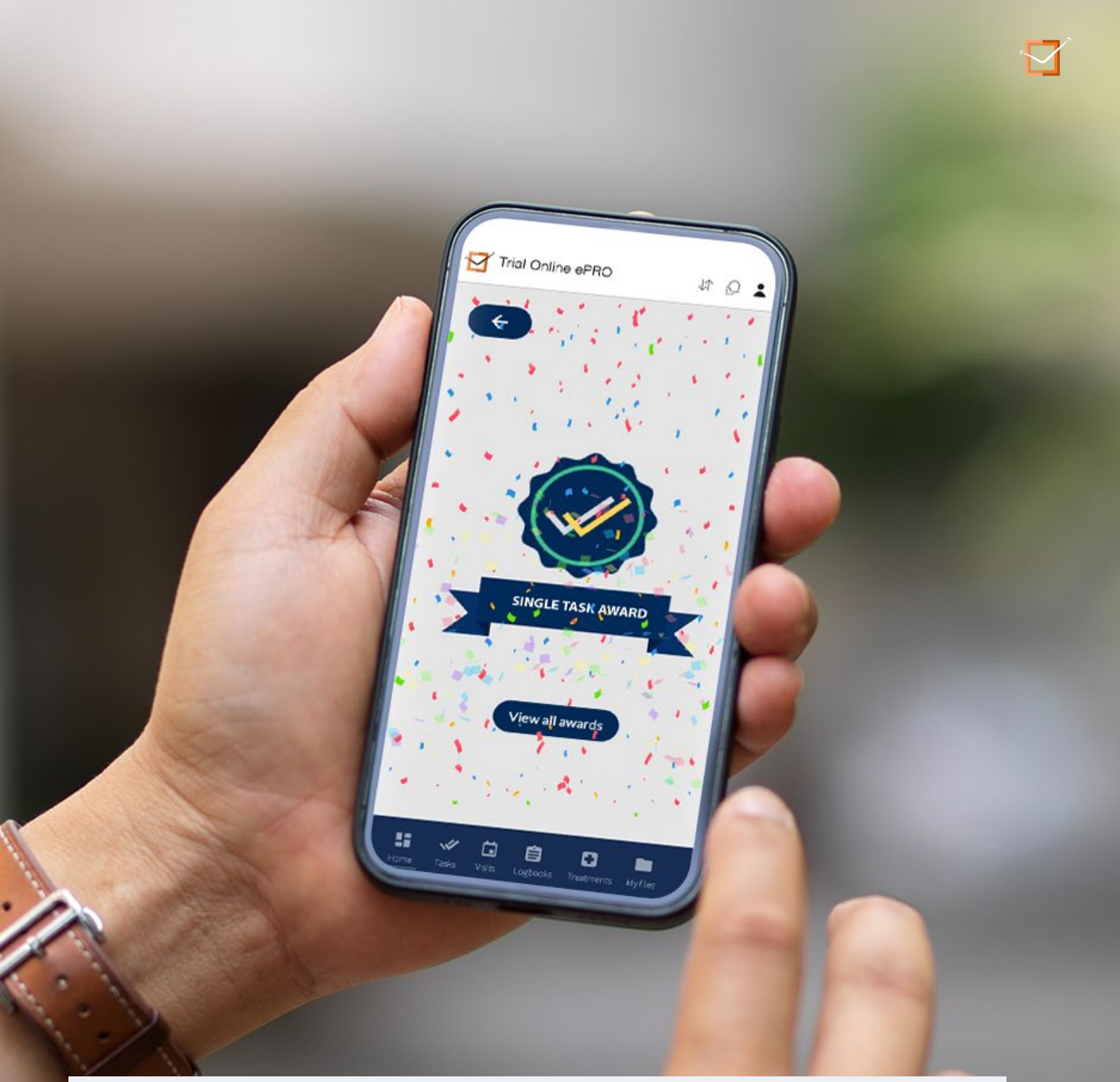

Trial Online® by Replior

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Book demo

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