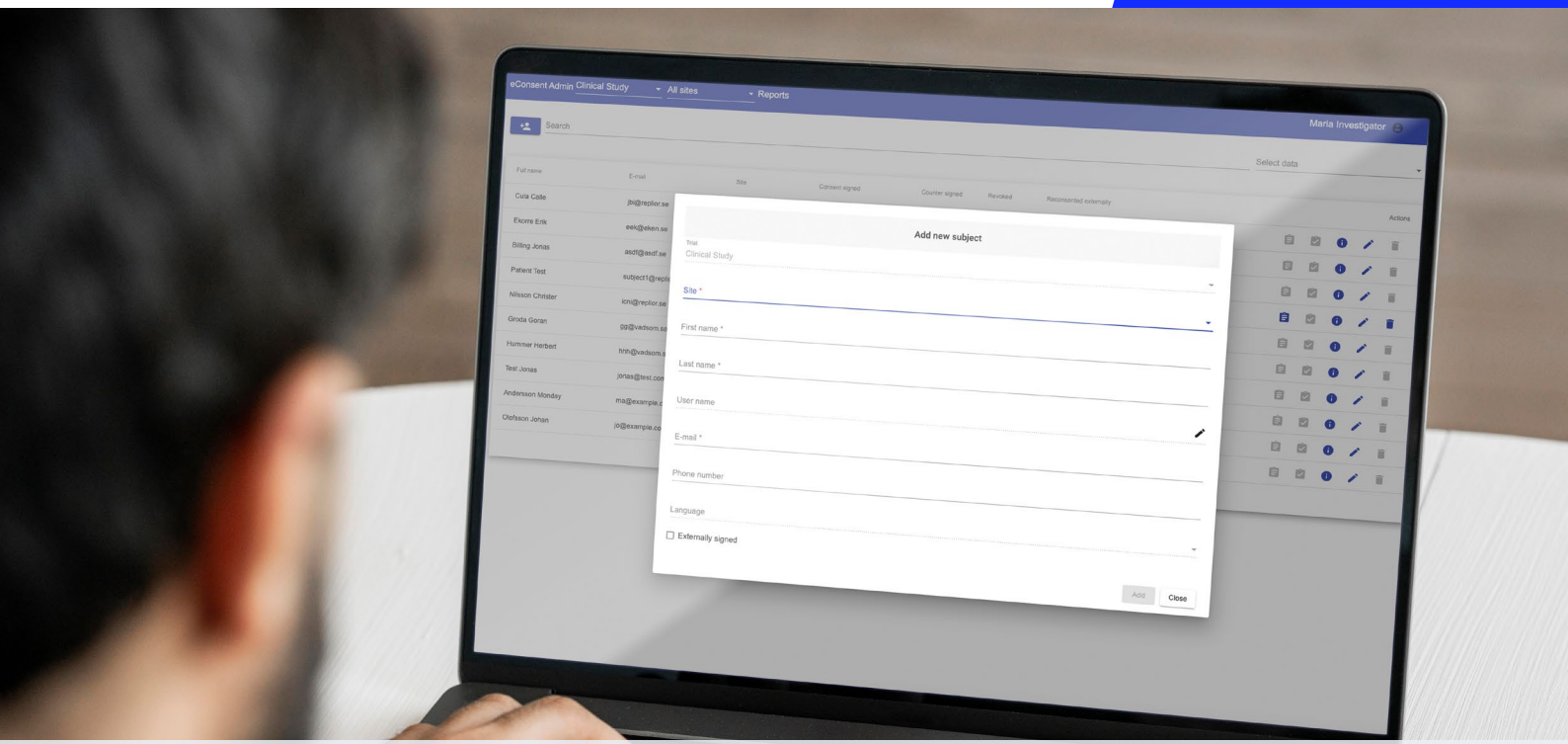
Trial Online® by Replior



Trial Online eConsent

Product overview

August 2023

Modernize your informed consent process with Trial Online's eConsent

Trial Online's eConsent allows you to make the shift from paper-based to an online solution.

Paper free informed consent will not only improve quality and compliance but retention for your clinical trial. eConsent provides patients with clear and understandable clinical trial information so you can make sure that they are fully informed when making a decision to participate in your trial. This saves not only time which is critical for optimal launch timeframes, but money for your budget.

Benefits

- √ Achieve higher quality and compliance
- √ Improve patient retention and satisfaction
- √ Informed consent forms are instantly available for review
- √ Easily upload and create consent forms across trials
- √ Enable process efficiencies and reduce corrective action
- √ Improve patient recruitment processes and reduce dropout rates

eConsent Overview

User Interface

The homepage gives users a quick overview of all trials they are currently participating in, allows users to easily change between the trials and view personal and specific trial information.

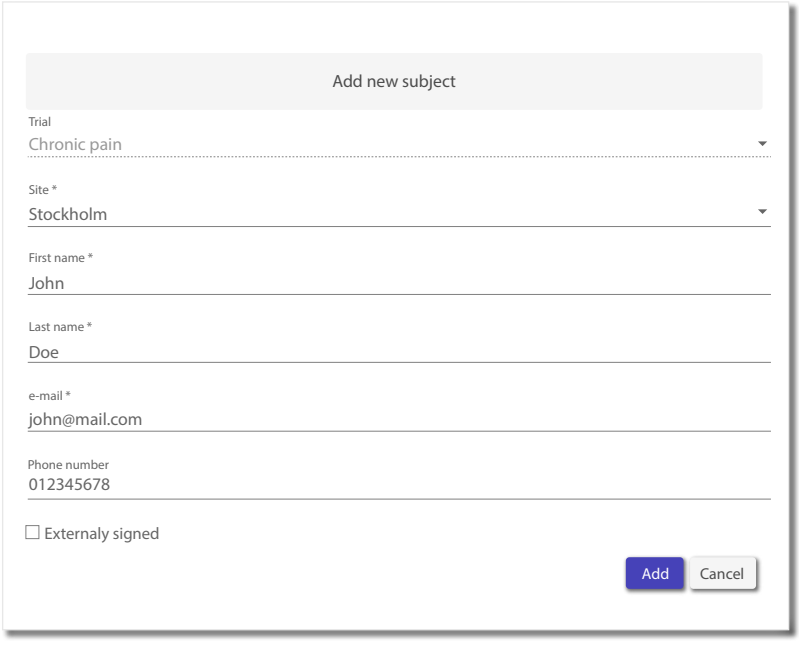
Patient overview

The patient overview table contains information about the patients participating in the clinical trial. Additionally the table is search enabled along with filters so specific information can be accessed quickly and easily.

Add new patients easily

Adding new patients into the eConsent system is simple and quick.

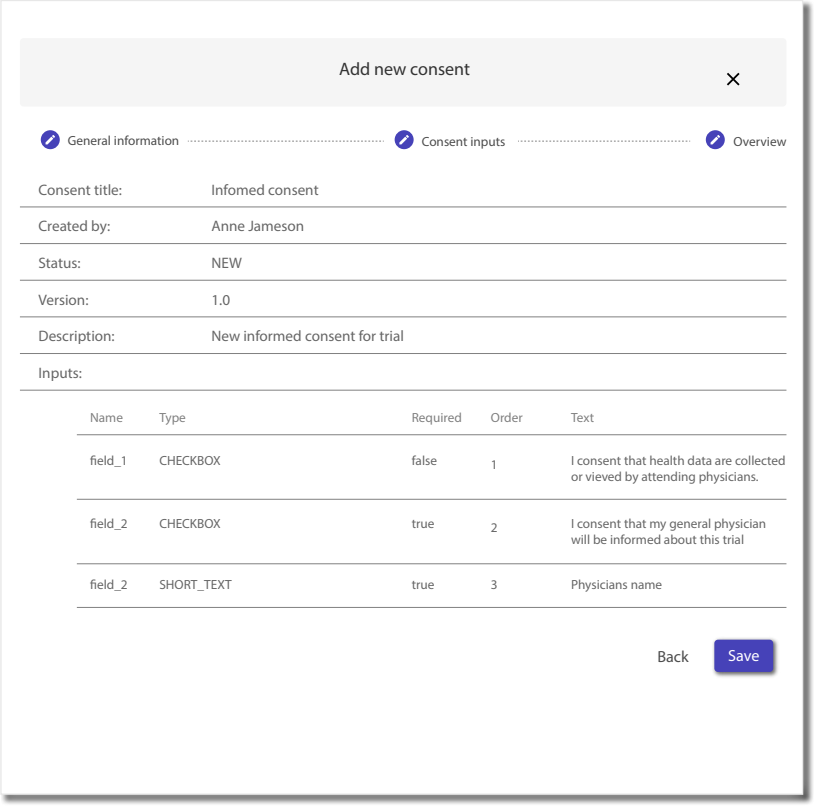
If a patient has already signed a consent form externally they can still be added to the eConsent system. All that is required is checking a field upon the data input process.



Add consent

Add new consent

The new consent form leads you through a simple 3 part form to add and define a new consent.



Consent sign

Clicking the sign consent button opens a dialog box which contains two parts: The consent content and the consent form. The patient must read and reach the end of the PDF file and fill in all required inputs before it is possible to submit the consent.

After a patient successfully signs a consent, it is possible to countersign the consent.

Revoke consent

Clicking the revoke button opens a confirm dialog box where the patient's consent can be revoked.

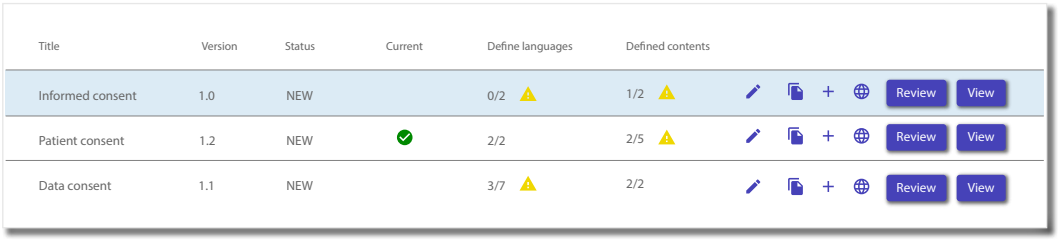
Add consent, cont.

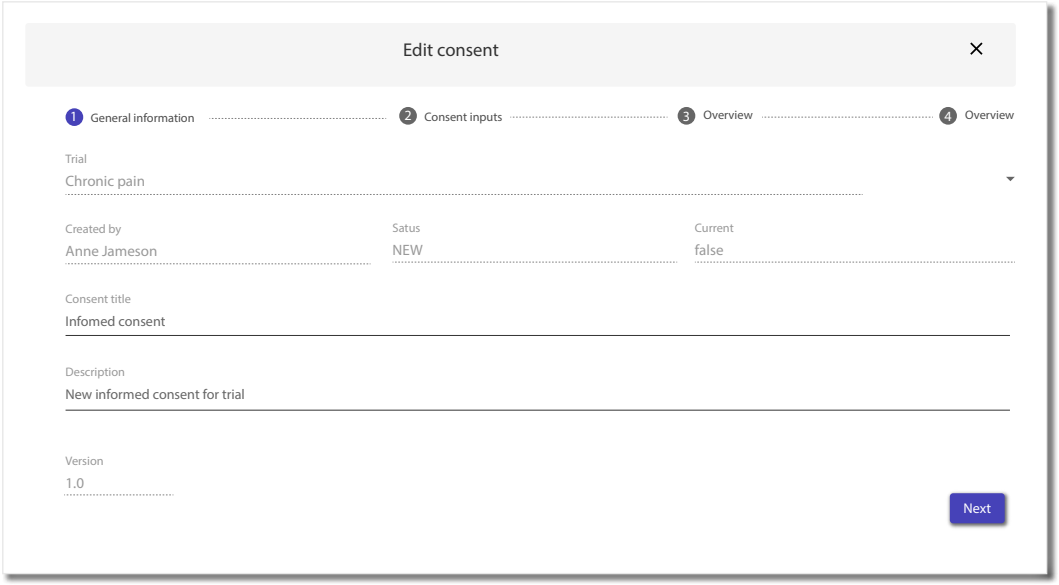
Full control over Trial Consents

eConsent allows you to have full control over your trial consents just by clicking on ‘List of Consent’ for a selected trial.

You will be able to:

- Clone consent
- Add consent
- Edit languages
- Review consent
- View consent





General features

Reports

eConsent includes several types of reports to easily gather the data you need for an overview. Reports show the first and last name and consent status for each patient participating in the clinical trial.

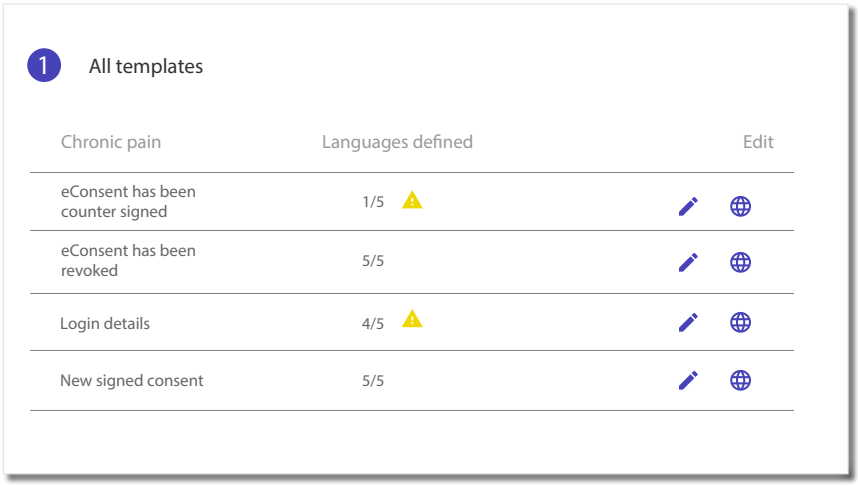
Notifications

It is possible to set up and define notifications, allowing for easier management of your trial. All notifications in the system are sent using email as transport protocol.

Templates

Quickly view and edit your templates.

With one click you can manage, define and translate template languages.



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

All systems and processes used to manage a clinical trial are part of a regulated process that must be validated and needs to meet both FDA regulations and ICH guidelines.

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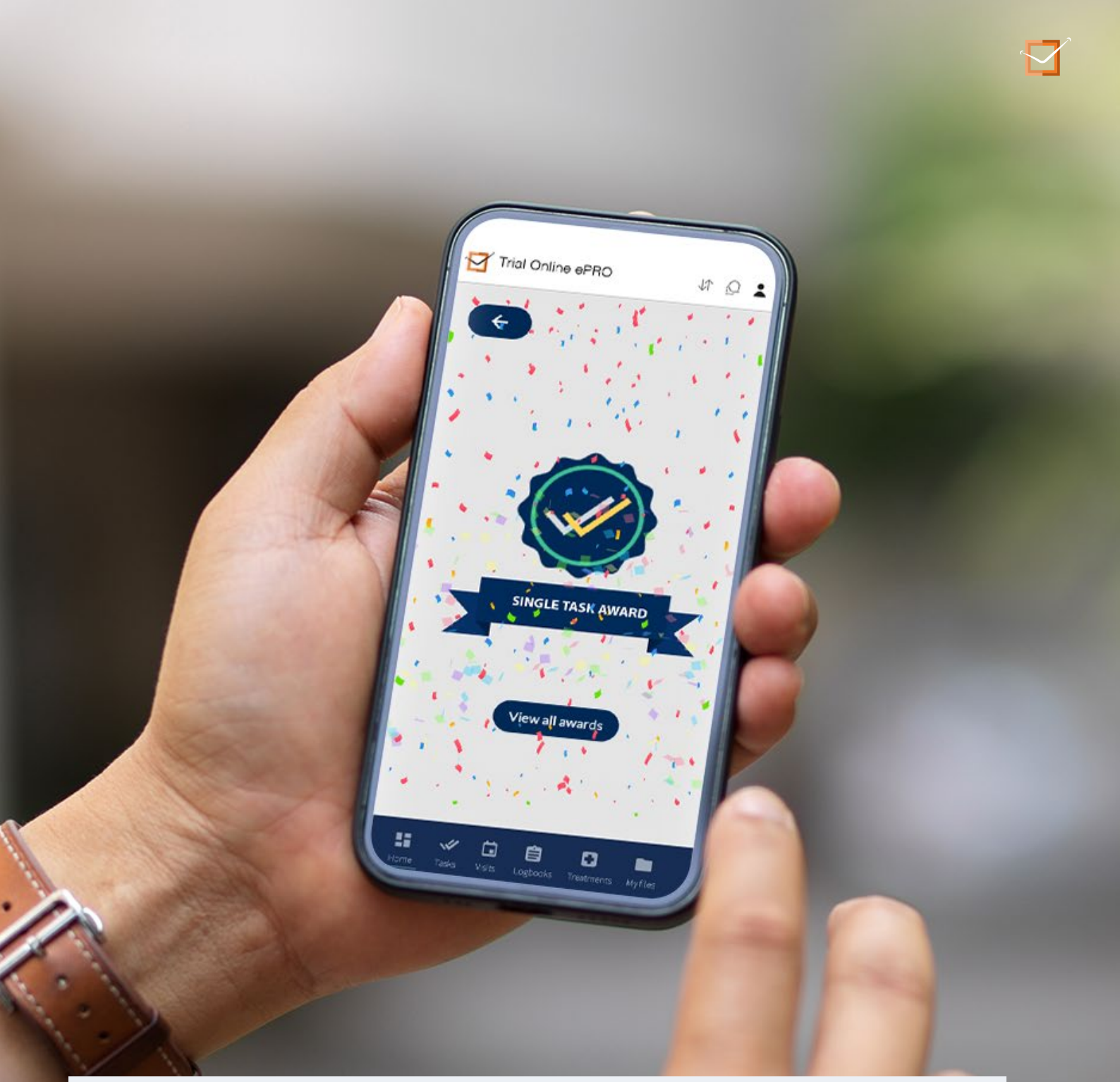

Trial Online® by Replior

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Book demo

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