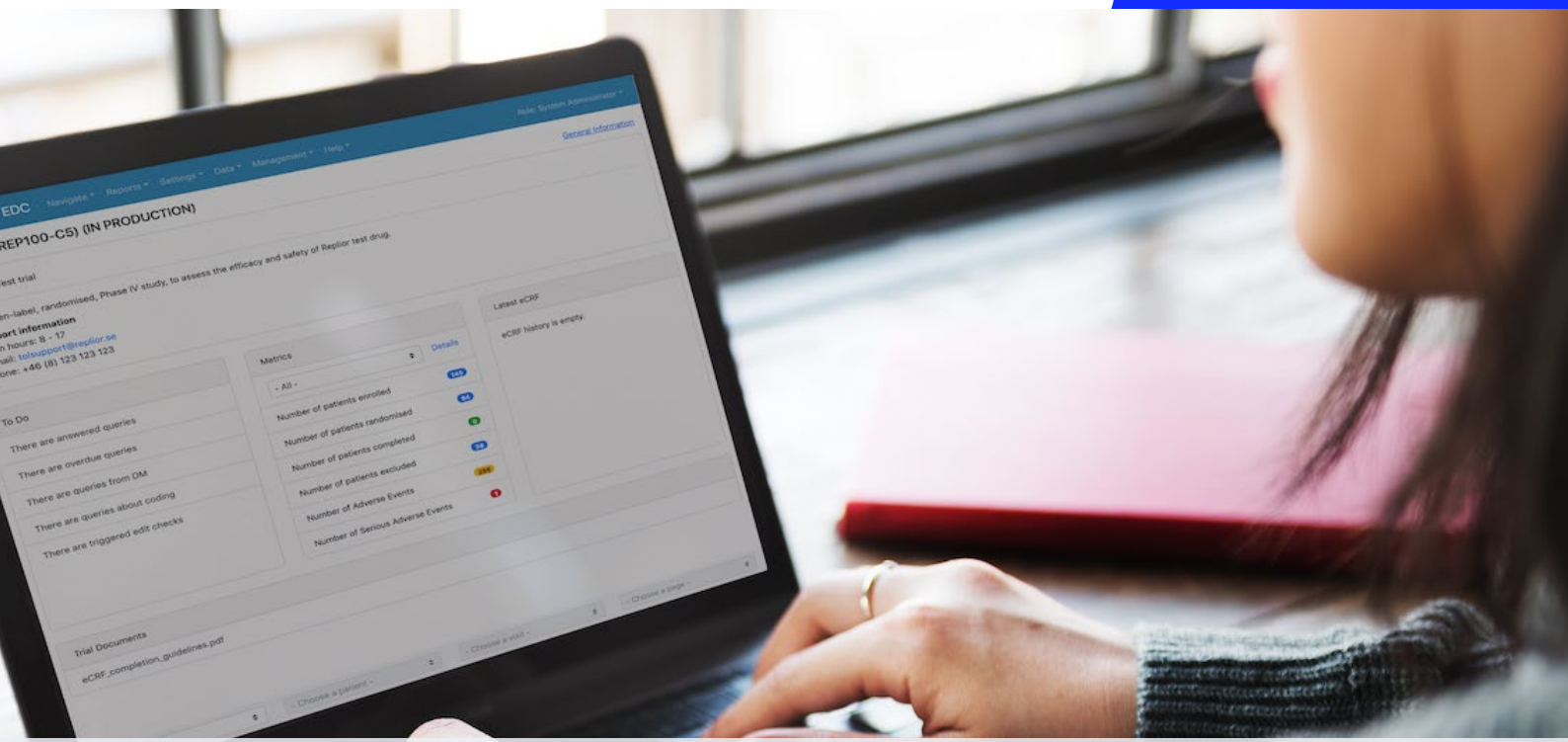
Trial Online®
by Replior



Trial Online EDC

Product overview

August 2023

Electronic Data Capture (EDC) Software

Trial Online's EDC is feature-rich, fulfilling the needs of even the most complex trials. Clinical sites appreciate the system's easy to use and intuitive approach. Quick study setup gives a short lead time for you to start collecting data.

Clinical Trial EDC systems are an important part of every clinical trial. Selecting the right EDC helps address inefficiencies on the operational side of research, from clinical trial planning stages through preparation, performance, and reporting.

There is a growing need to address the complex process of electronic data capture implementation and select systems with proven interoperability as more and more pharma and biotech sponsors start to recognize the potential opportunities that exist with EDC-ePRO integration.

In response to this evolving landscape, our EDC platform has been developed to provide a high level of configurability to the customers.

Through our user-friendly study builder, customers have the ability to tailor their solutions entirely from the front end.

Furthermore, we are excited to introduce an enhanced design and layout for our EDC system. While retaining its easy-to-use and intuitive characteristics, the new EDC interface brings a fresh and modern look to the forefront, and is designed to be responsive across various devices and screen sizes. This means you will get the full experience no matter how you view Trial Online EDC.

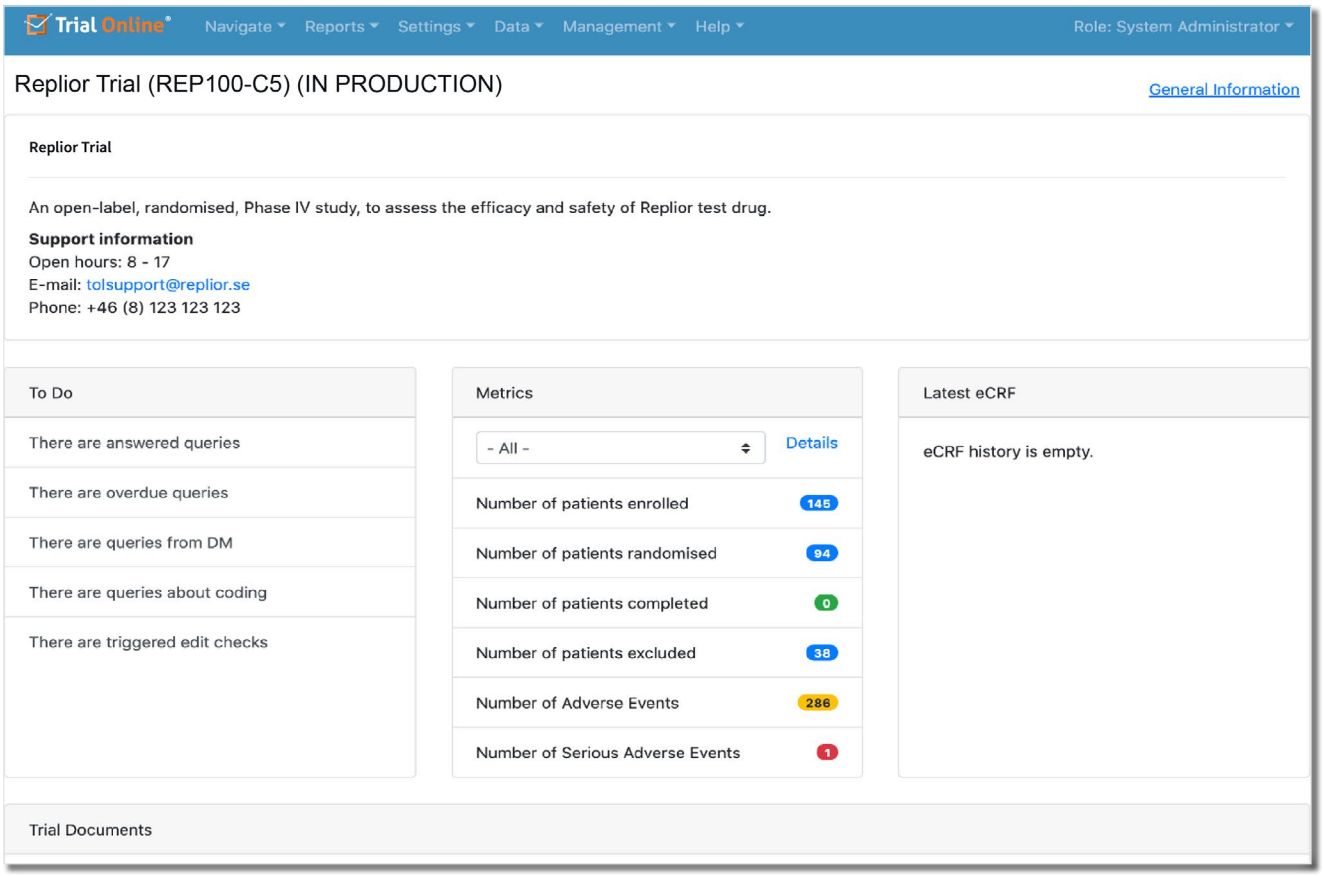
Configuration includes:

- ✓ Role-based access
- ✓ Edit check validators
- ✓ Skip/add logic
- ✓ Derived calculations
- ✓ and more

Interface

Simple User Interface

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



Web based

No special hardware or software is required to run the service, which utilizes standard internet browsers. Since the start-up time and creation of electronic Case Report Forms is very short, Trial Online can be used for all trials, regardless of size.

Function

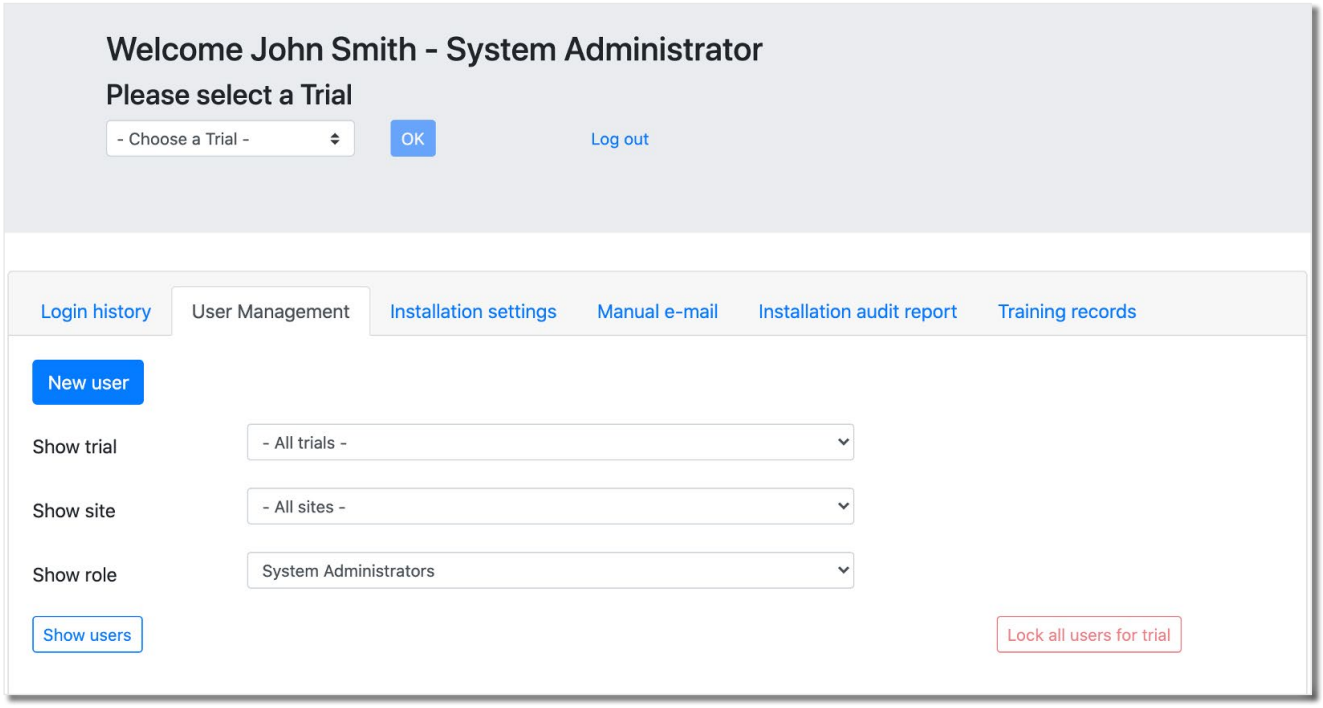
Trial Online EDC ensures the validation of data entry through edit checks that can be set to trigger directly when an “incorrect” entry has been entered, or in batches at regular intervals. Edit checks are easily specified in the Construction Module.

Trial Online offers a paperless query tool to generate, resolve and track queries online.

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.

Laboratory files can be imported into Trial Online. Excel, SAS, ASCII and PDF are standard export formats in 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.



Construction of eCRFs and edit checks

The eCRFs are created in a construction module that is a stand-alone software.

This module offers a fast and easy way to build eCRFs and edit checks, with flexibility in design and format. The module includes a library function where you can store and reuse standard forms. The eCRFs are easy uploaded in the Trial Online interface. Changes in the eCRFs during an ongoing trial is also possible and easy to handle.

System

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.

- Investigator
- CRA/Monitor
- Sponsor
- Trial/System Administrator
- Assessor
- Coordinator
- Data Manager
- Medical Coder (MedDRA and WHO-DDE coding)

Reports

Trial Online includes several types of reports, which simplify the overview, monitoring and sxecurity 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.

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.

Regulatory submissions

From ICH/GCP and 21 CFR Part 11 to GDPR and HIPAA, we provide you with complete confidence that your data is compliant with our tools, so you can focus on the trial. To ensure data security over the internet, Trial Online features 256-bit HTTPS data encryption.

Trial Online® by Replior

A full suite of Clinical Research Products

Trial Online ePRO

Next-generation patient data collection for validated questionaries on patients own phone (BYOD), or on Replior provided pre-installed phones.

Trial Online EDC

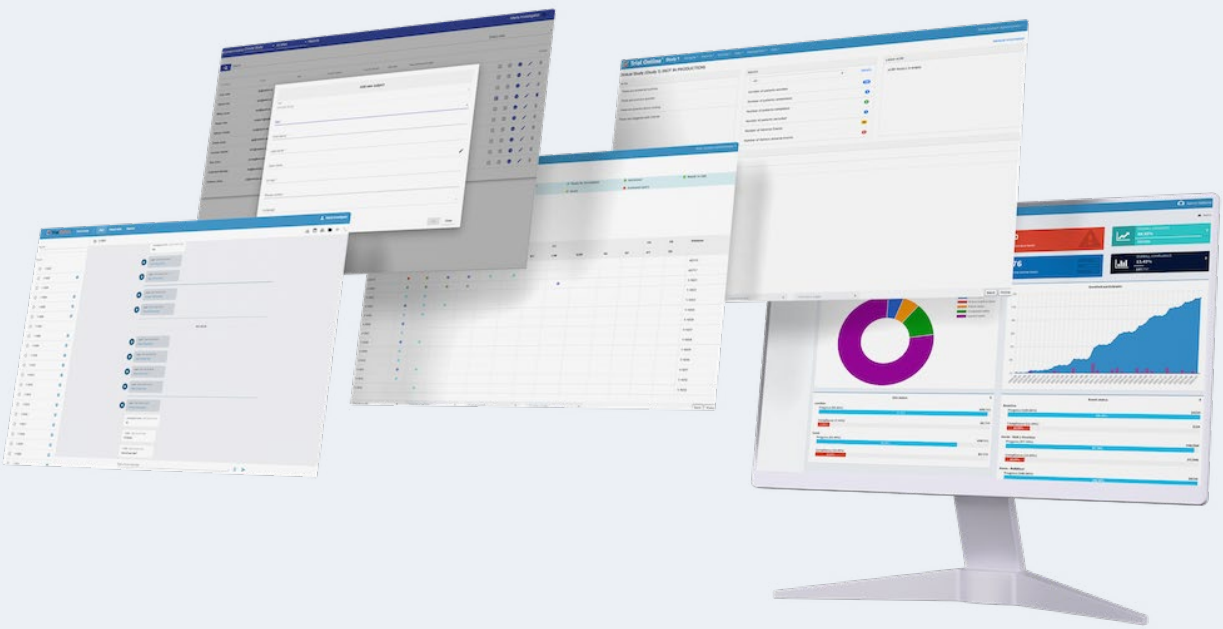
Proven EDC system based on 20 years and over 1000 trials track record. Fully role-based to enable review, query, verify, approve and sign-off on forms to produce quality data.

Trial Online eConsent

Enables patients and researchers to take the first critical contact remotely in a safe and secure way

Trial Online eVisits

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



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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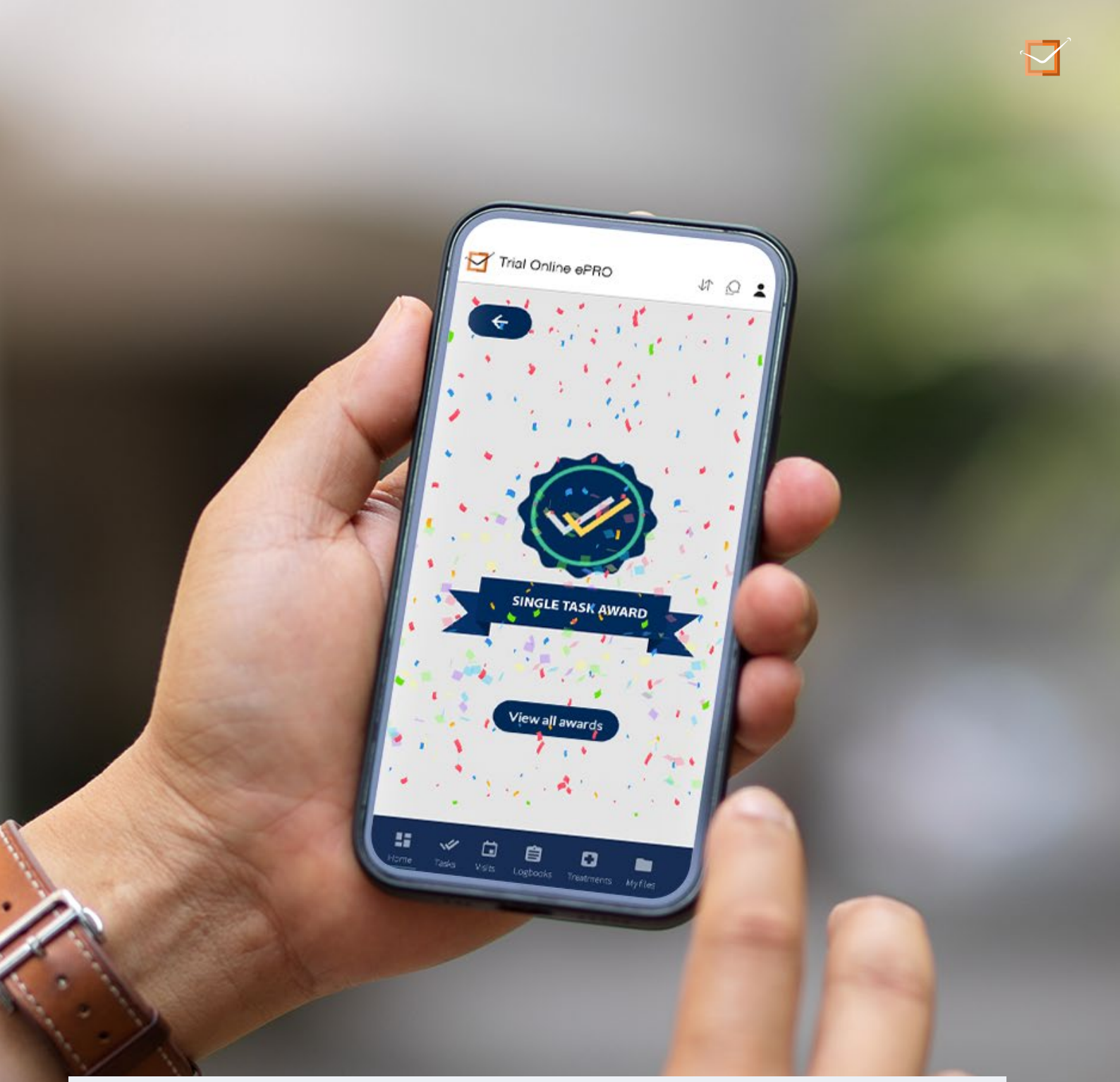

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