Trial Online®

ePRO Web & App
Product overview

Owned, Developed and Qualified by Replior

The complete package..

Move your trial surveys from paper-based to a secure and cost effective online ePRO platform.

Trial Online's ePRO was designed with functionality in mind and user-friendliness is at the core of our system.

The ePRO system is an extensive toolbox with app capability for both CROs and Pharmaceutical companies to create optimal clinical trial patient engagement.

An end-to-end solution, ePRO provides enhanced support for patients while optimizing the full benefits of electronic data capture.

- ✓ 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.

Trial Online ePRO Web & App

Web Dashboard

The Trial Online ePRO Dashboard gives you an overview how your Trial is progressing, featuring data from current and future events, participants compliance and task overview.

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

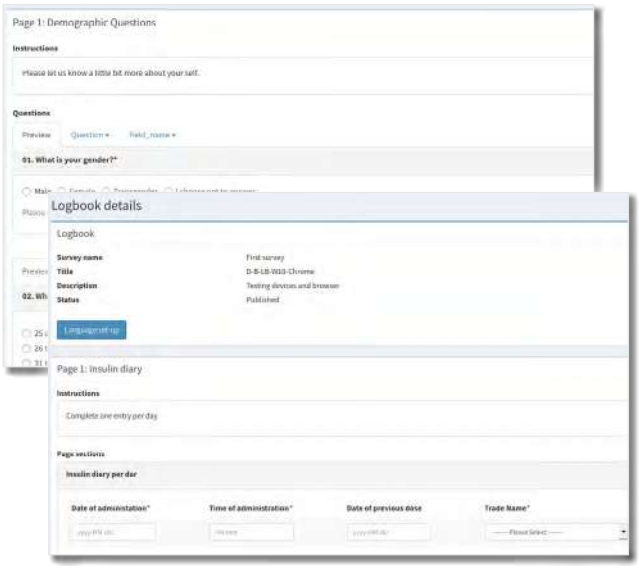
Create user friendly Questionnaires and Logbooks, with multiple layout and structure options. Customise survey descriptions and user messages, add usefull tips and design a questionnaire completely after your need.

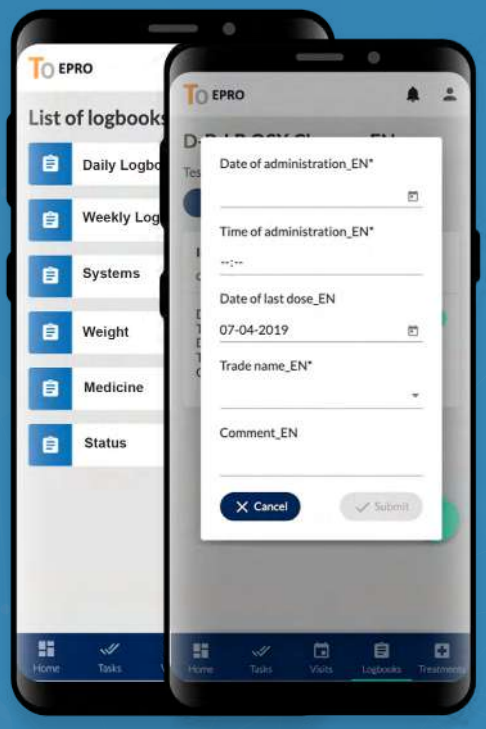
Questionnaires

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

Logbooks

As the questoinnaire the logbook let you make user friendly and customisablelogbook, with multiple layout, structure and language options.





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.

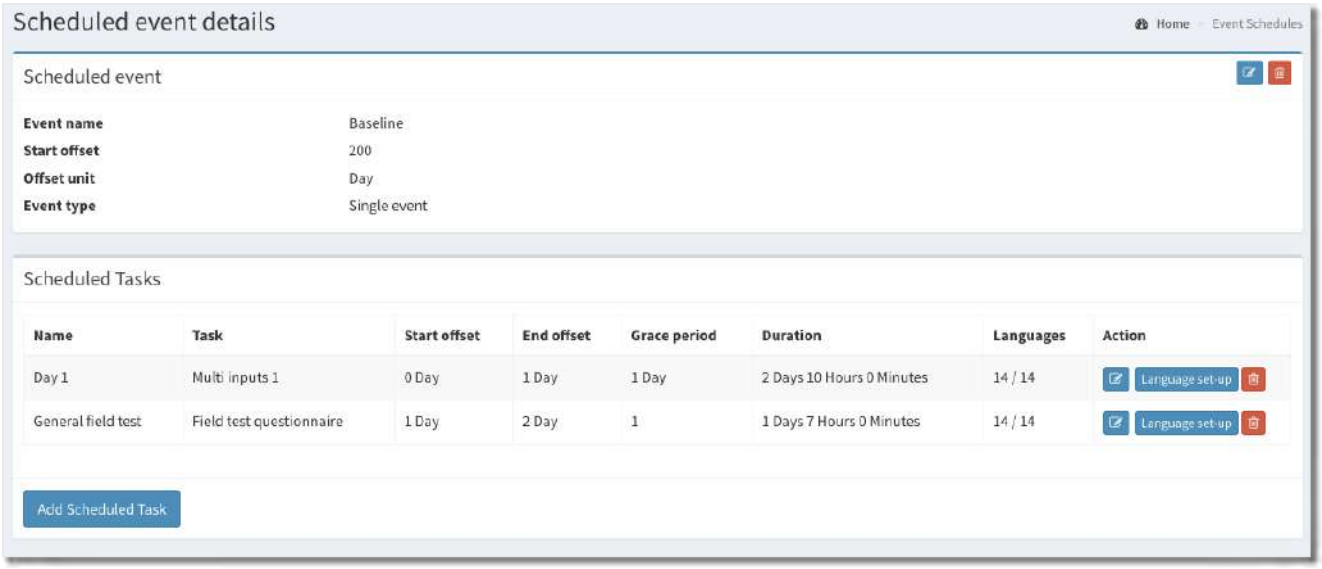
The logbooks can be used to collect data from patients about daily medication intake, blood pressure or any other information important to your trial.

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.

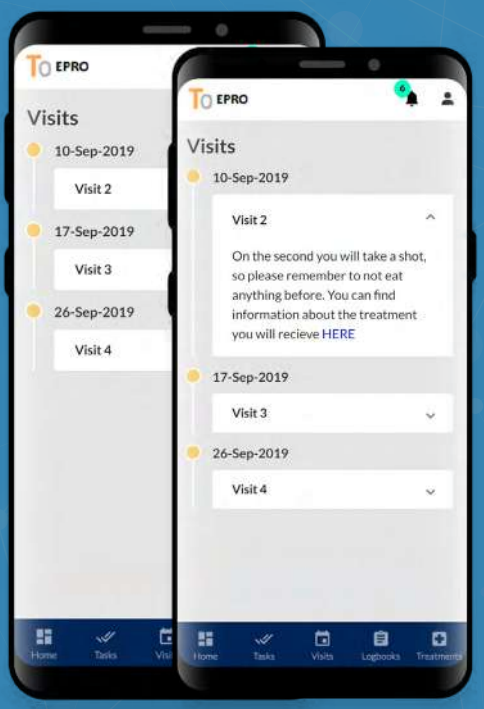
It is also possible to schedule physical events for paitents.



Visits

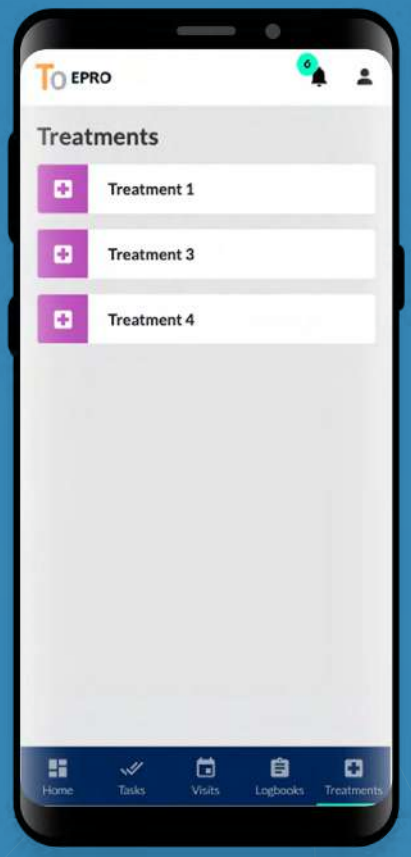
The visits tab appears as a timeline and gives the patient a full overview of all upcoming scheduled appointments.

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



Treatments

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

Survey & Event 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.

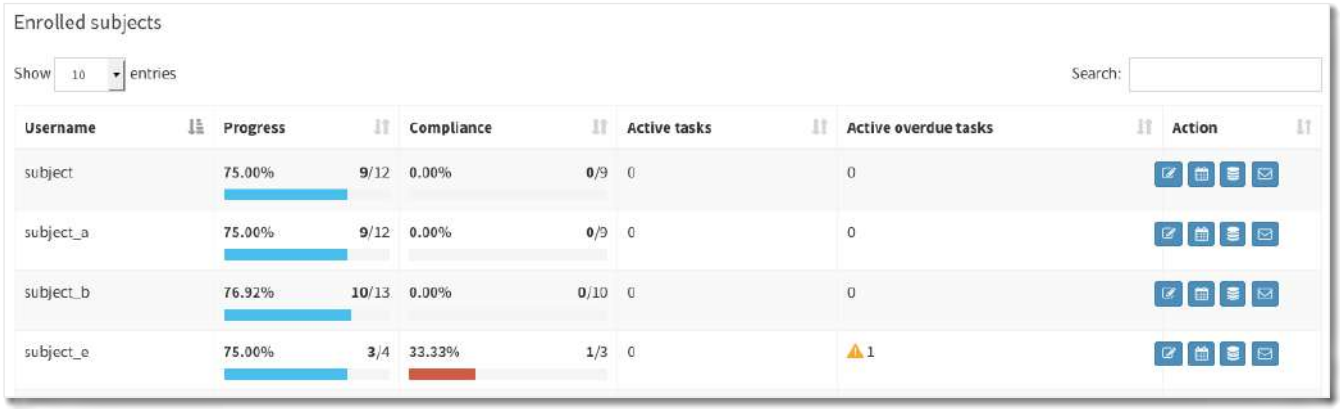
Reminders can be configured to be automatic or customized.

Trial Online
ePRO Web Features

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.



Reports & Exports

Trial Online ePRO includes several types of reports and exports to simplify the overview, monitoring and security of the trial.

Documents

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

Audit

A complete audit trail is maintained from initial data entry through all subsequent changes.

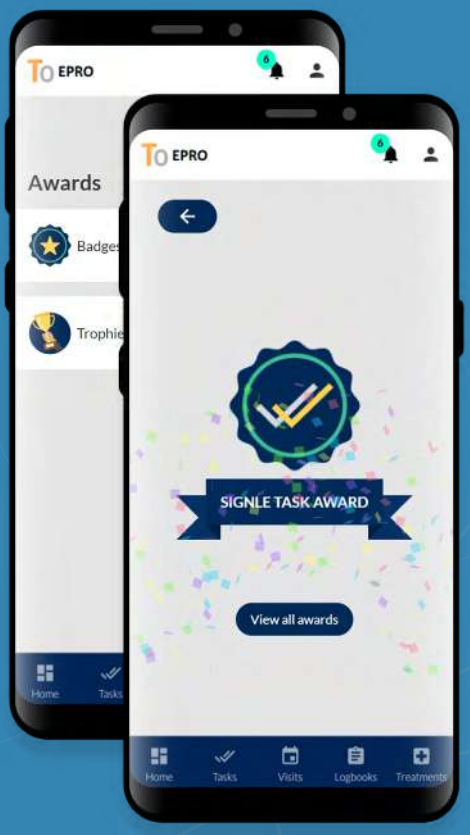
Trial Online ePRO App Features

Gamification

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.



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.

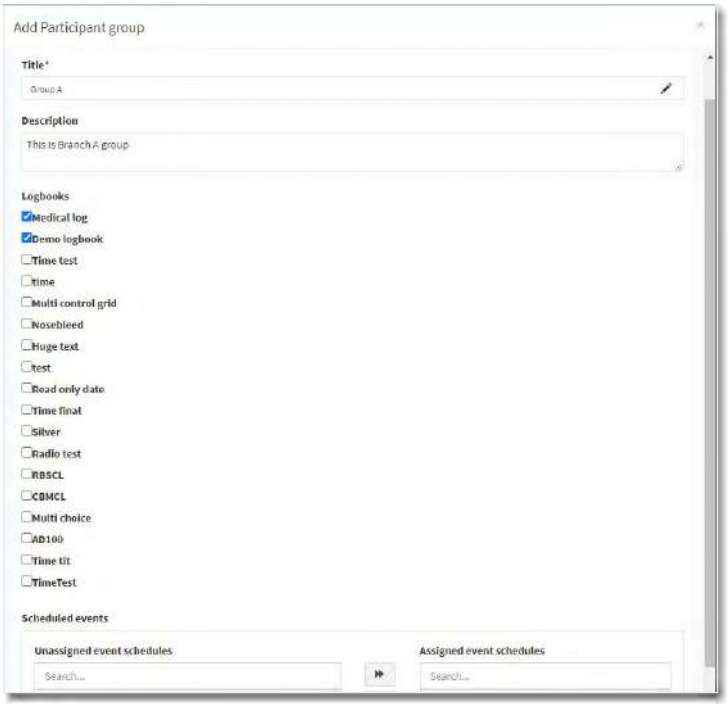
Scoring

Automatic scoring gives an overview of the results of a questionnaire. Scoring can be programmed for any questionnaire and all calculation scenarios can be implemented.

New ePRO features

Patient Groups

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



Recordings

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.

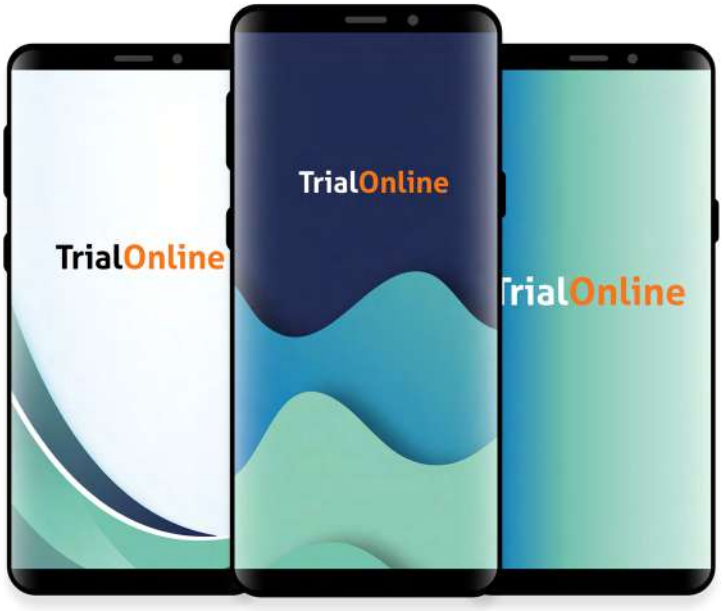
Using a recording over a written memo requires less effort for the patient and hearing a previous recorded memo in his or her own voice, will make it easier for the patient to recall certain moments, symptoms or feelings.

Trial Online®

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 Trial Online

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 Areas

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.

All Trial Online's products follow these guidelines as well as industry standards to ensure product quality. This includes Software Development Life Cycle, System Qualification, and Quality Assurance Testing.

Replior AB

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

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Lund-Sweden and Split-Croatia.

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Schedule a demo