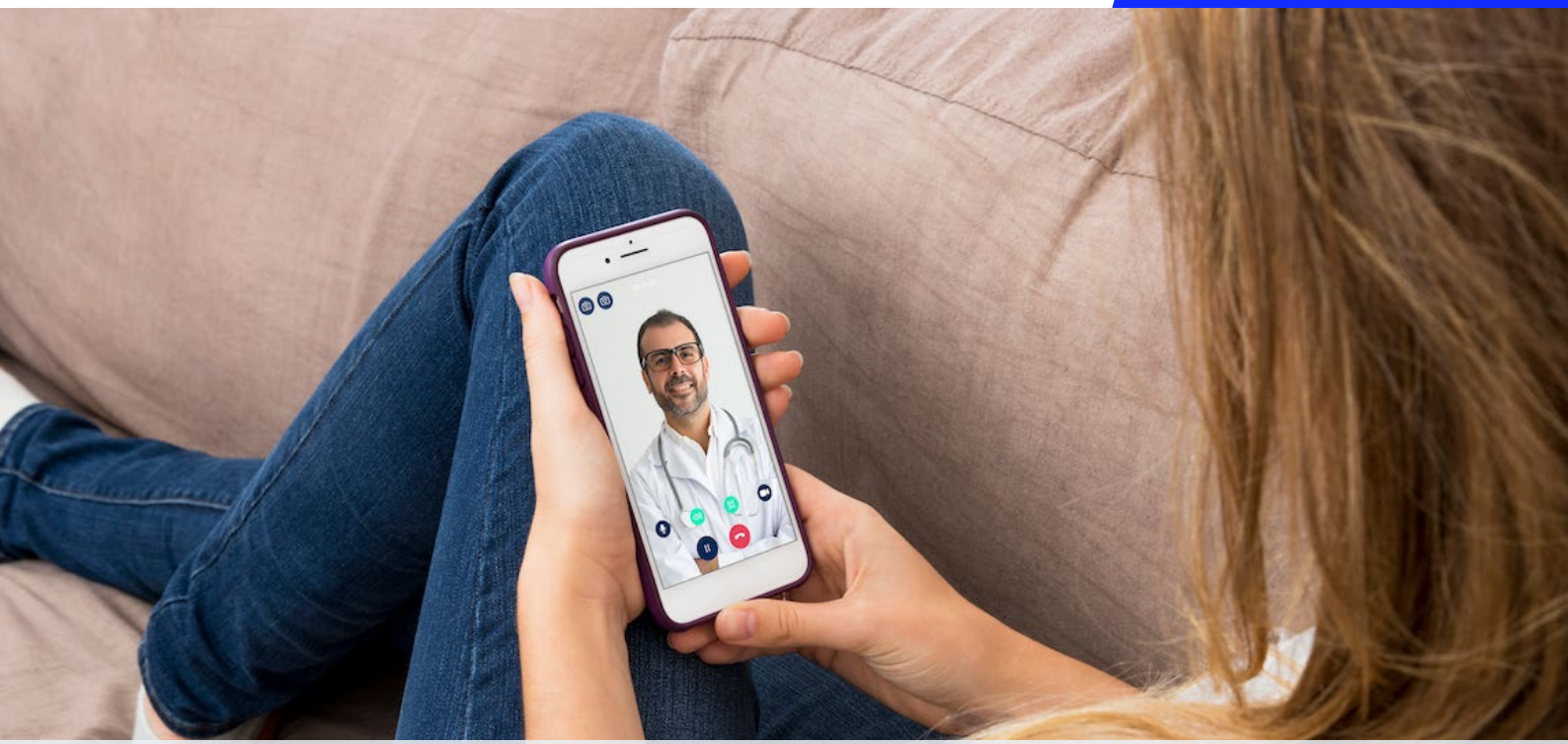
Trial Online® by Replior



Trial Online eVisits

Product overview

August 2023

Collect Data during site visits, between visits and in remote eVisits.

Using the Trial Online eVisit Telehealth solution gives patients the security and convenience of participating from their home, while the investigator safely monitors symptoms and tests upon collecting data.

Virtual Visits allow the investigator to observe the participant, instruct them to complete assessments, and record their observations directly into the EDC system.

It is not uncommon that patients may have a fair distance of travel to attend each planned visit. Overcoming challenges like distance, while ensuring the health and safety of patients enrolling in your critical trial, can easily be tackled with our eVisits tool.

eVisits increase compliance as patients are more likely to attend a video call than having to travel far distances. This, in turn, reduces any reimbursement costs offered to enrolled patients as travel expenses don't have to be settled.

Virtual Visits is when a medical study visit takes place remotely with the investigator and patient in different geographical locations, connecting via the Trial Online system and ePRO app.

How eVisits works

Video and voice conversations are initiated by the Site staff at the time of the visit, the patient respond to the call in their mobile phone using the Trial Online app.

During the call its possible for both patient and investigator to switch on/off camera or sound or put the call on hold.

The patient can switch between front and back camera, take pictures or record a video to show details to the investigator. Photos and videos can be sent to the investigator using the messaging functionality of the system for safe transmission.

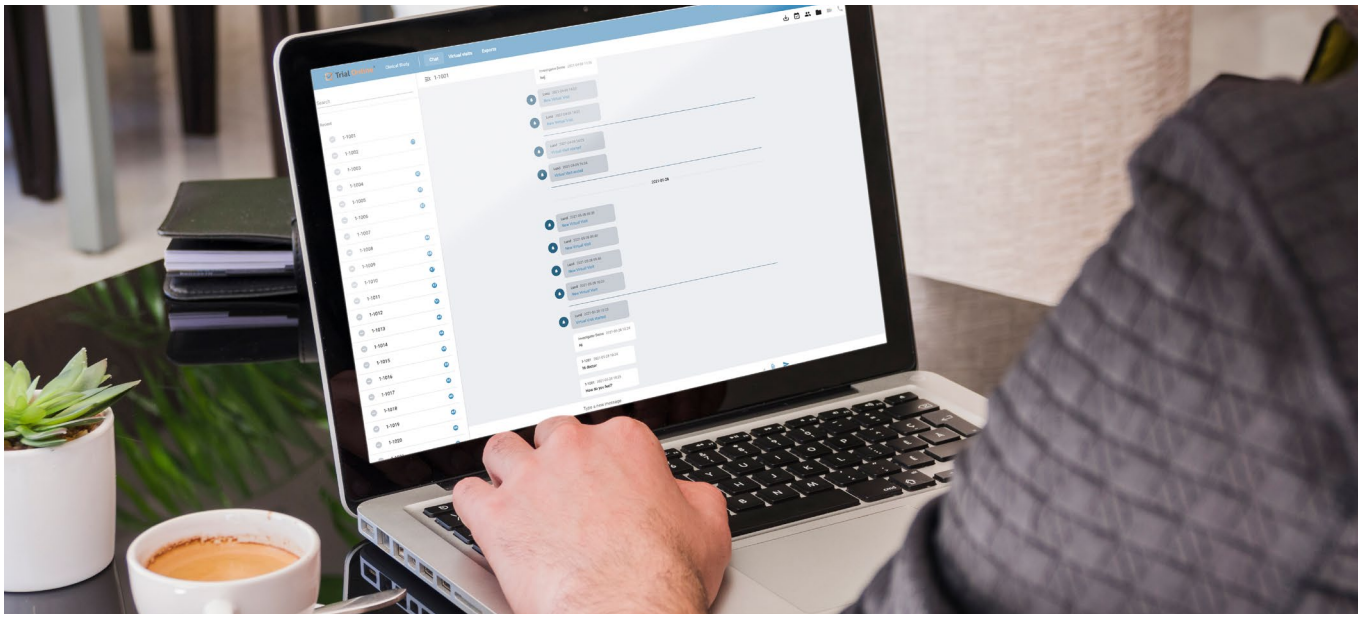
The investigator can if required transfer pictures/videos to storage or EDC.

Text messaging is available for the site staff at all times. It is possible to send messages to individual patients or a group of patients at the same time.

Both patients and site staff can send messages to each other during the eVisits. This can be text messages, pictures or videos taken with the camera, pictures or files stored on computer or phone.

This is specifically useful if investigator need to send instructions to the patient, or the patient need to show something to the investigator.

This can be used to show medication instruction, proof of intake of medication, procedures to use/measure with medical devices or show visible changes to the patient. Investigators can store pictures or movies in other systems if required.



How to use eVisits

Site staff (Investigators, Study nurses and other Site users) can access the eVisit system from the Trial Online EDC or Trial Online ePRO system directly by selecting a patient from the ordinary lists and click the new Call Button. Alternatively if Trial Online eVisit is used as a stand-alone solution, the eVisit module can be opened and a patient to meet online be selected to initiate a call.

The patient will receive the call in the application installed on the mobile phone and use the phone as in a normal video or voice call. During the call intuitive icons for handling camera functions are accessible on screen, and if privacy require the call can be paused, muted or video switched off.

It is possible to configure messaging on a site level to allow patients to contact the site via text messages during office hours, defined by the site.
Since it is important for a patient to know how to contact the site, normal contact information can be provided if a patient try to send a text message via the app.

To ensure no messages sent from patient to site are left unanswered it is possible for sites to configure message/information on site level for non-office hours to about opening hours and direct patients to other contact paths, for instance in emergency situations.

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

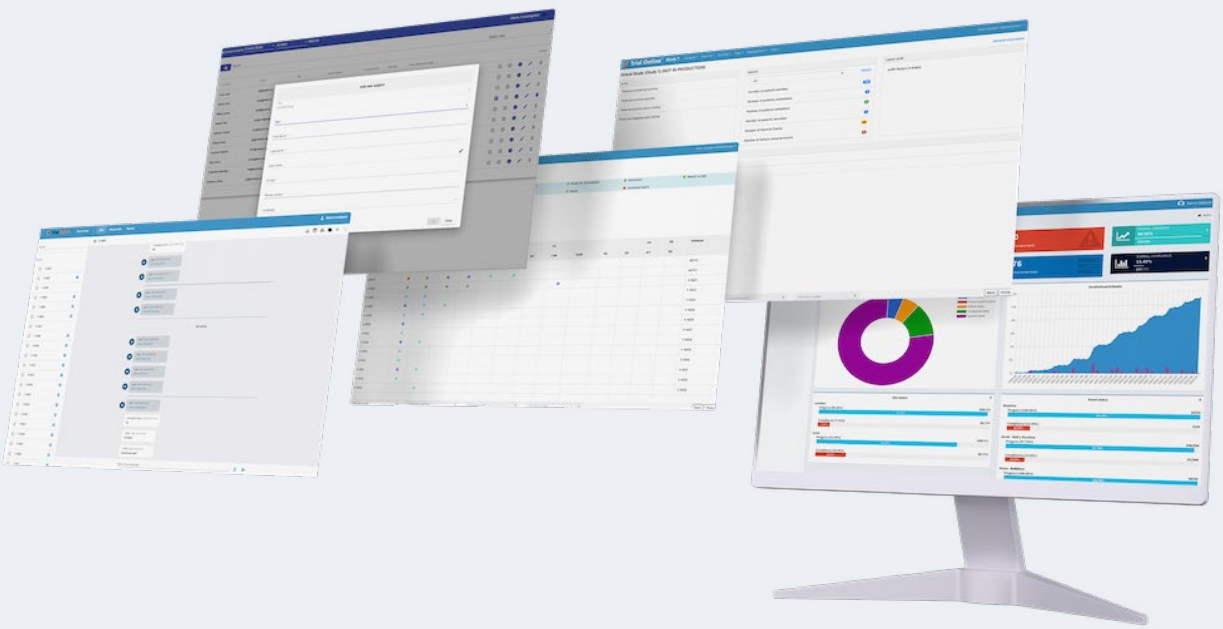
Proven EDC system based on 20 years and over 1000 trials track record. Fully role-based to enable review, query, verify, approve and sign-off on forms to produce quality data.

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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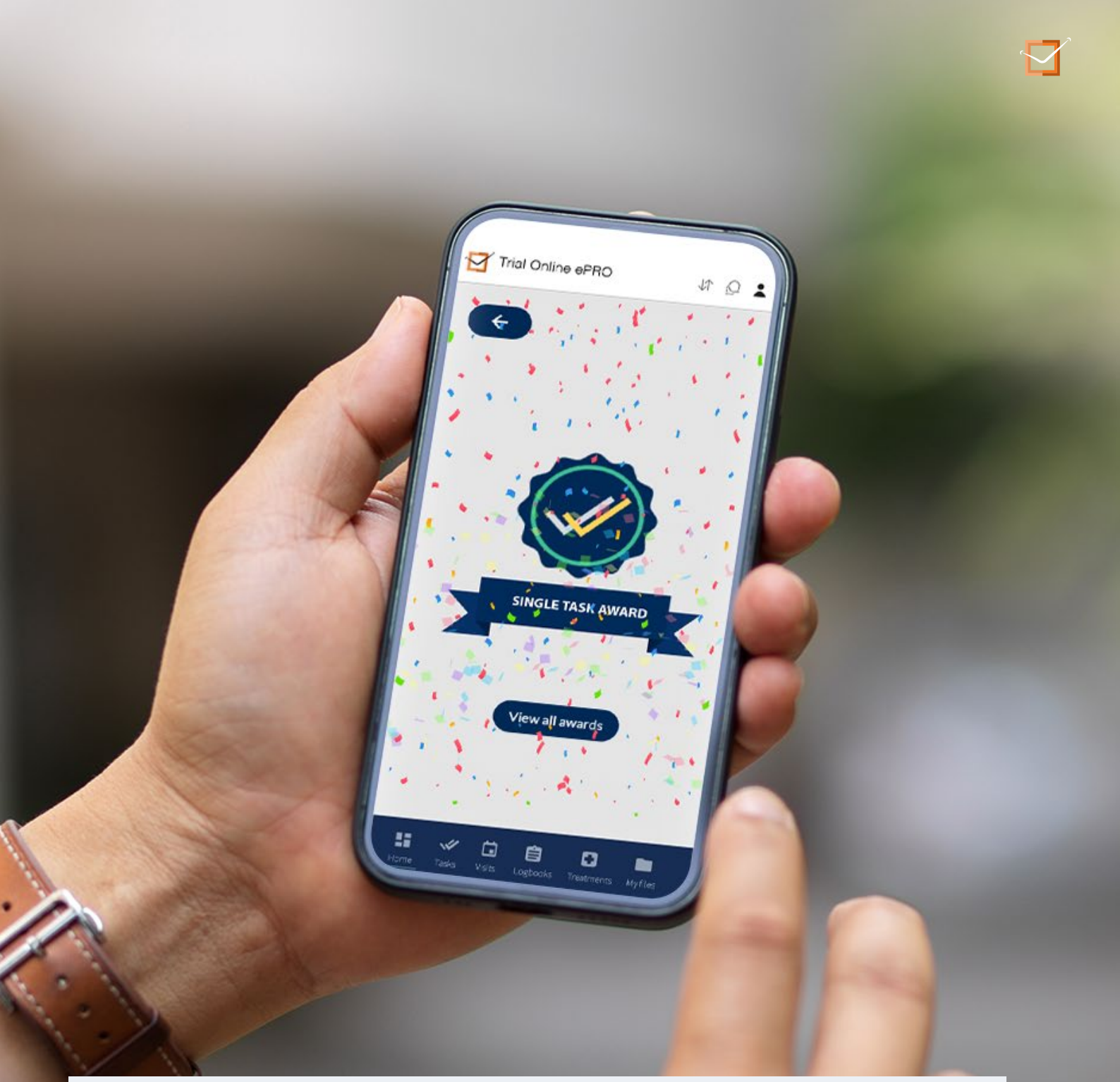

Trial Online® by Replior

www.replior.com

Book demo

info@replior.com

+46 8 601 13 30

Replior AB,
Hammarby Kaj 18,
SE-120 30 Stockholm,
Sweden