



Product Overview

Owned, Developed and Qualified by **Replior**



A full suite of Clinical Research Products



ePRO

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



eConsent

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



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.



Virtual Visits

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



Logbooks & Surveys

Using the ePRO app for non-validated surveys, daily diaries and medication intake verification.



External data sources

Integration of external objective background data feeds like weather, pollen, UV radiation, air quality data.



Sensors

Integration of sensors, wearables, medical devices and health applications using the ePRO app as platform.



Engagement

Dashboard to track participant progress, provide ongoing training and give access to study specific information.



Trial Online EDC

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.

About EDC

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.

Our EDC allows the customer to configure their solution entirely through the front end with our easy to use study builder.

Trial Online ePRO

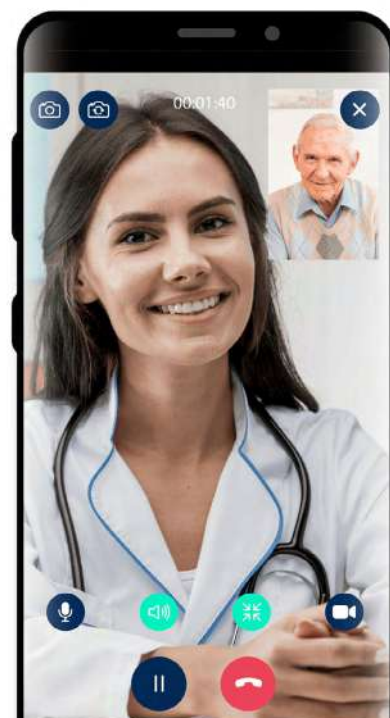
Move your trial surveys from paper-based to a secure and cost effective online ePRO platform.

About ePRO

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.



Native App

Trial Online ePRO is provided as a native app available for download in Apple's AppStore for iOS and Google Play for Android devices.

A native app enriches the patient experience by allowing more user-friendly solutions to be implemented such as push messaging.

Trial Online's ePRO is also available in any web browser from a desktop computer.

Trial Online Virtual Visits

Collect Data during site visits, between visits and through remote virtual visits.

Virtual Visits is a communication module to use for Site-to-Patient communication during clinical trials.

About Virtual Visits

Trial Online provides a complete suite of products to run clinical research projects with total flexibility.

Using the Trial Online Virtual Visit 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.

Trial Online eConsent

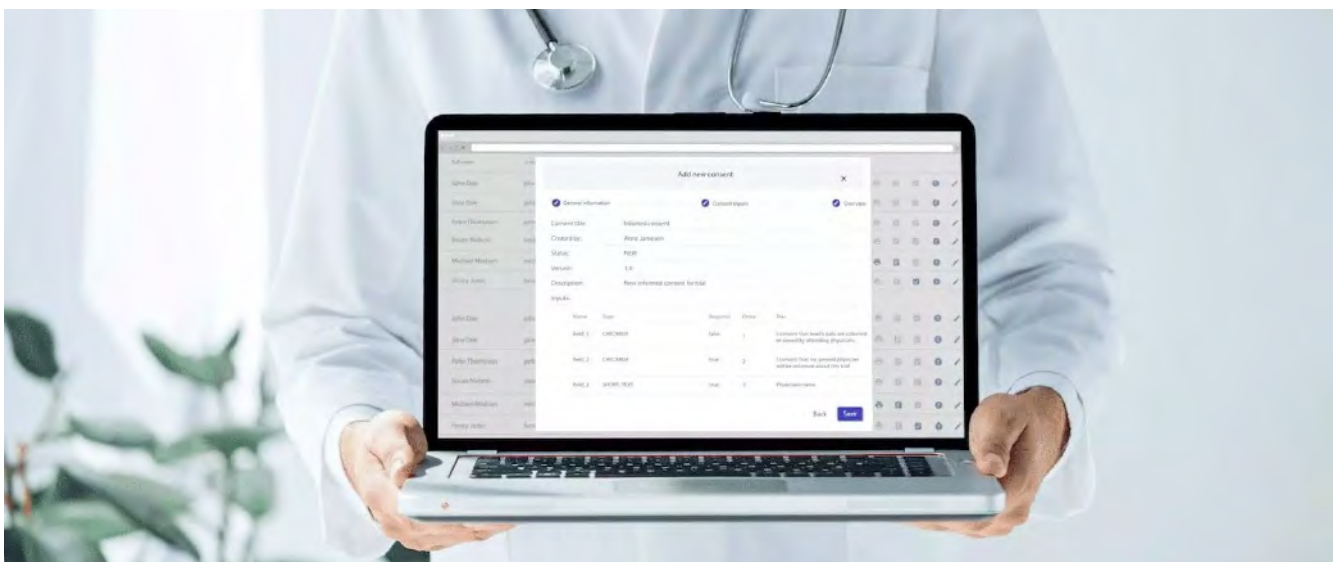
Modernize your informed consent process with Trial Online's eConsent.

Tools to easily keep track of consent versions and patient approval to remain compliant.

About eConsent

Patient safety starts with the patient's understanding of the trial and all of the inherent risks involved. This is where eConsent can offer more protection through a directed online experience.

The step-by-step process guides the patient to ensure understanding and presents a signature box only at the end of these exercises.



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

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Replior AB

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

We have offices in Stockholm-Sweden,
Lund-Sweden and Split-Croatia.

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