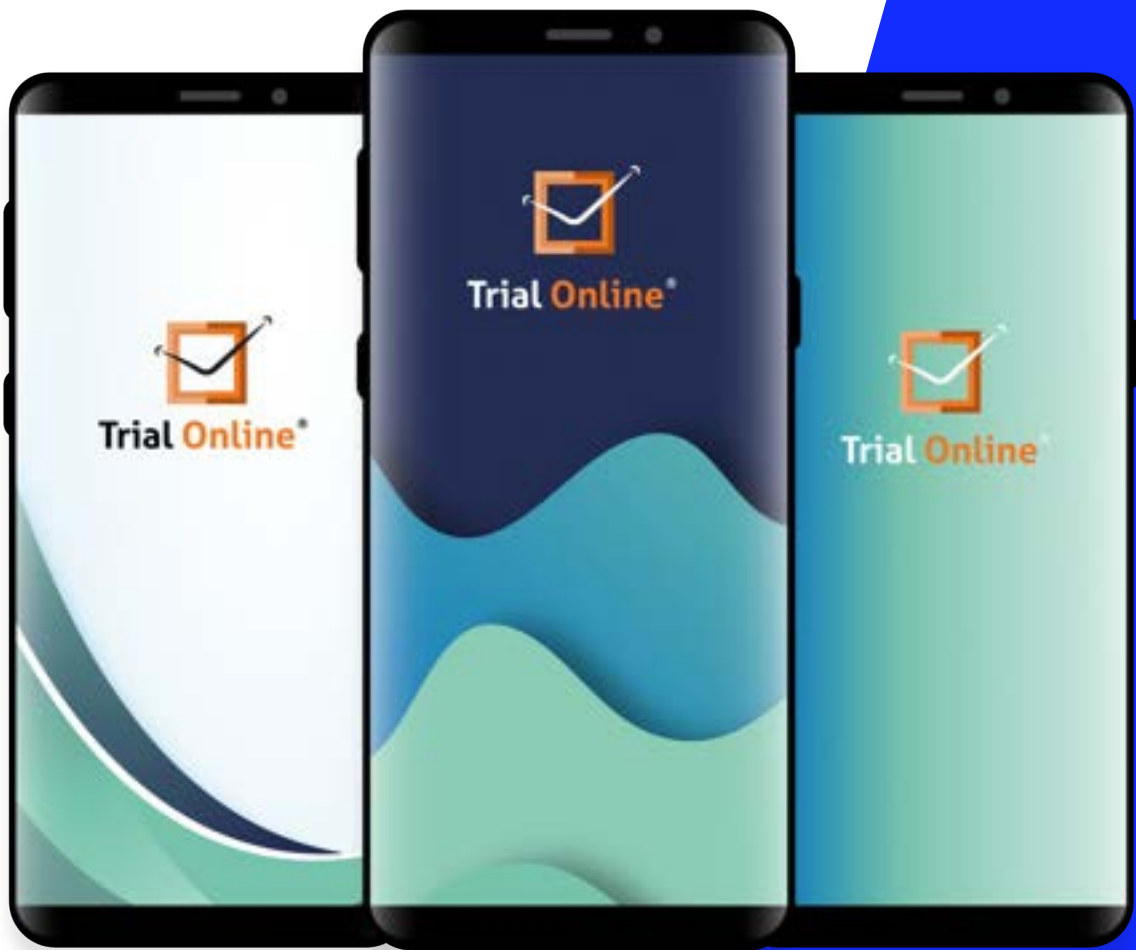




**Trial Online**<sup>®</sup>  
by **Replior**



# Device Supply Management:

Service overview & Screen Customisation

# 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

# Customization

The home and lock screens on the smartphones and tablets can be customized to fit your branding and colour scheme.

On the following pages are our layout selection. Each layout can be customized for your needs.



# Smartphones: Lock screens

SP\_Lock 1



SP\_Lock 1:

Example of colour customisation



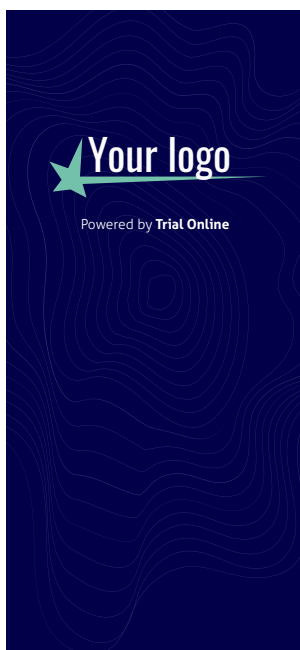
SP\_Lock 2



SP\_Lock 3



SP\_Lock 4



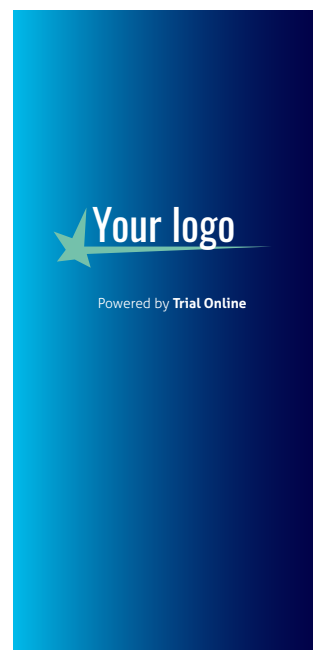
SP\_Lock 5



SP\_Lock 6



SP\_Lock 7



# Smartphones: Home screens

SP\_Home 1



SP\_Home 1:

Example of colour customisation



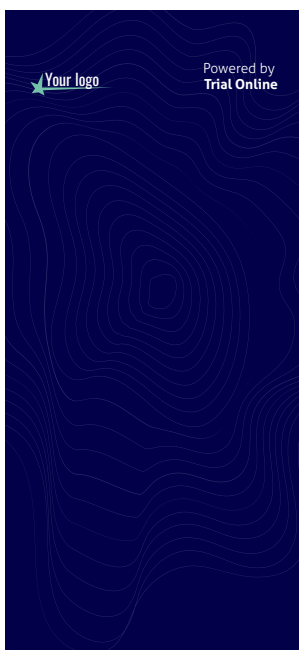
SP\_Home 2



SP\_Home 3



SP\_Home 4



SP\_Home 5



SP\_Home 6



SP\_Home 7

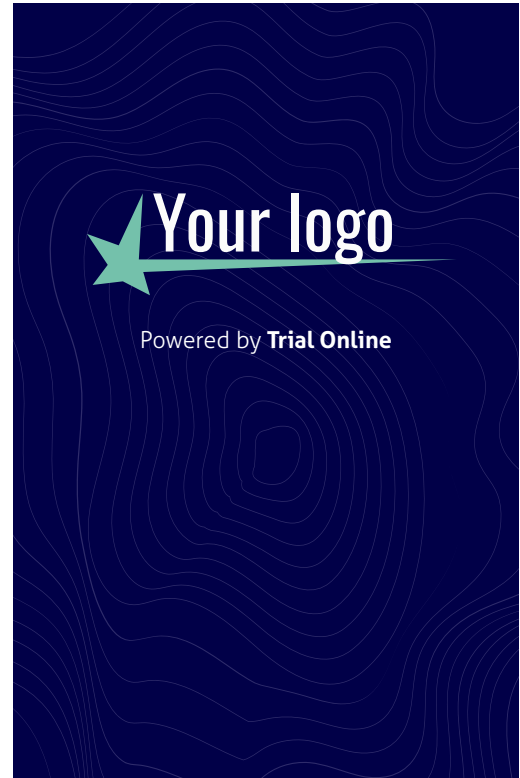


# Tablets: Lock screens

Tab\_Lock 1



Tab\_Lock 2



Tab\_Lock 3



Tab\_Lock 4

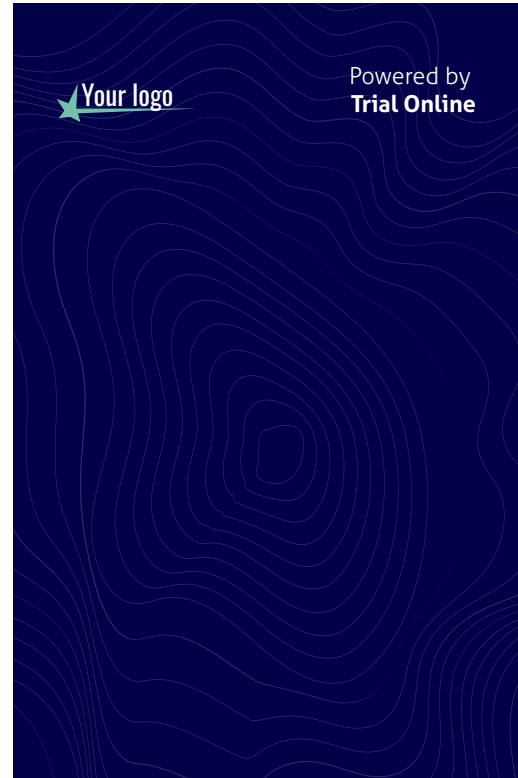


# Tablets: Home screens

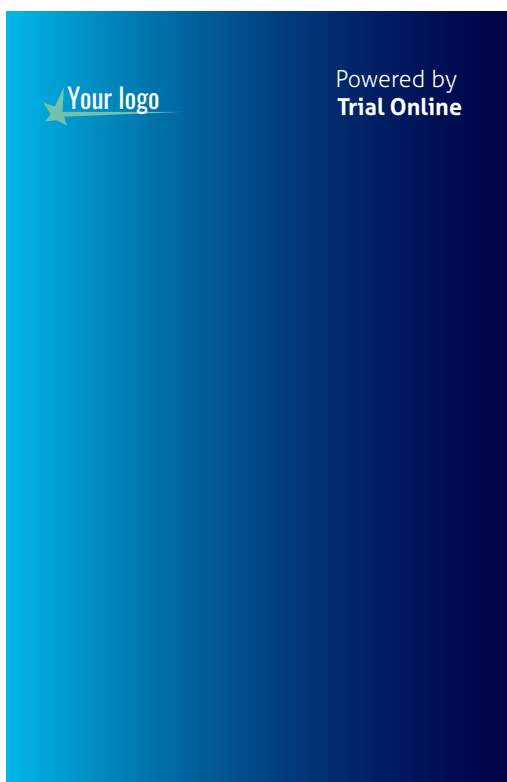
Tab\_Home 1



Tab\_Home 2



Tab\_Home 3



Tab\_Home 4



# 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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