Trial Online EDC

Product overview

About Trial Online

Trial Online has been in operation since the beginning of 2000, as a trusted eCRF provider for thousands of clinical studies made over the years, from small Phase I trials to global Phase III/IV trials.

In 2016 Trial Online ePro was launched to provide Patient Diary and Questionnaire service to clinical studies.

Trial Online is owned by Replior AB, a Swedish IT Operations provider focused on the Life Science sector.

Replior provide hosted software services for the Life Science industry.

Trial Online EDC has been in operation since 2000 and 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.

Operational services includes Managed Hosting, Backup Services, Security Services and Communication Services. Replior furthermore provide hosted software services for the Life Science industry.

Abiocess is a tailored Web-based service for collaboration and document management, constructed in accordance with the eCTD file structure.

All production equipment is hosted in a high security Data Center, providing extremely secure environment for IT-operations. This includes perimeter access, redundant electric power with n+1 diesel generators, redundant cooling, EMP/HPM protection and more.

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

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Trial Online EDC

There is a growing need for easy to use, cost effective and trustworthy Electronic Data Capture, EDC systems.

Trial Online is an EDC system that meets all three criteria.

All Trial Online activities are managed online and offer a modern and easily accessible platform for all involved in a study. 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.

Web based

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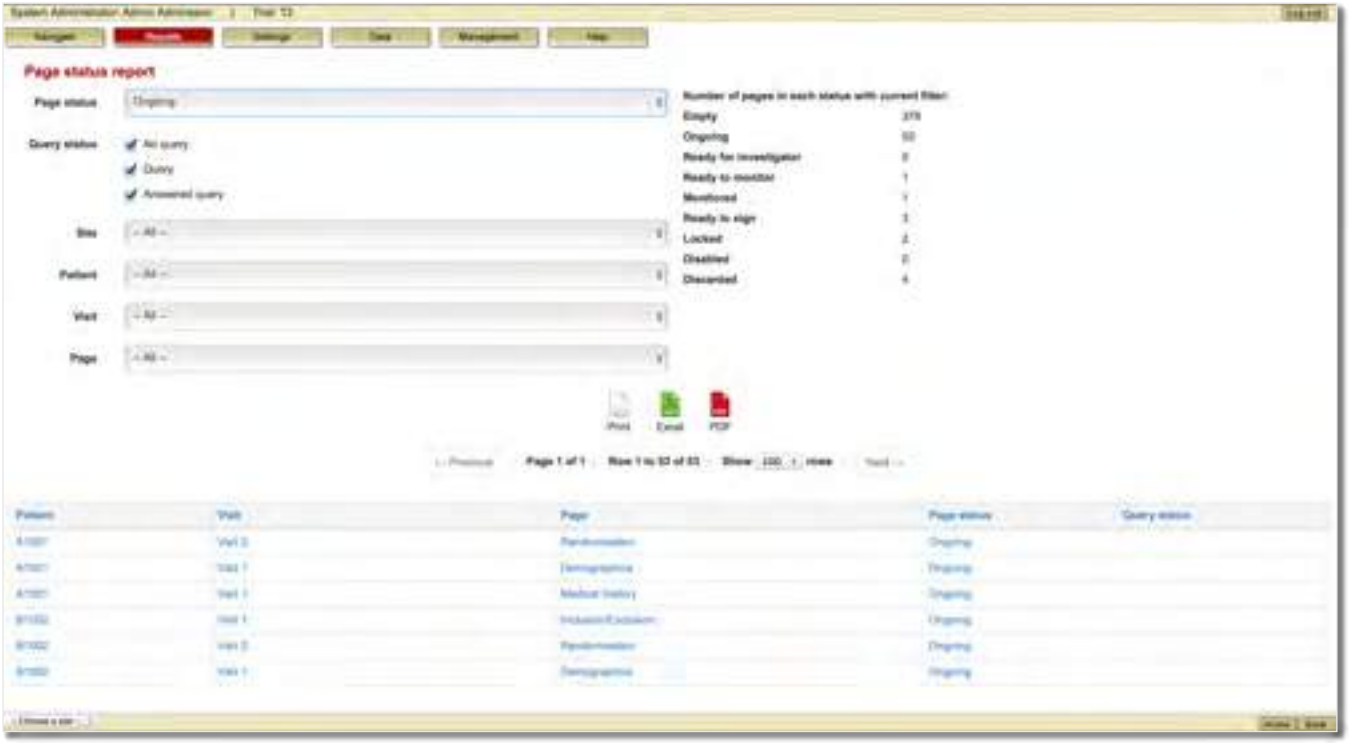
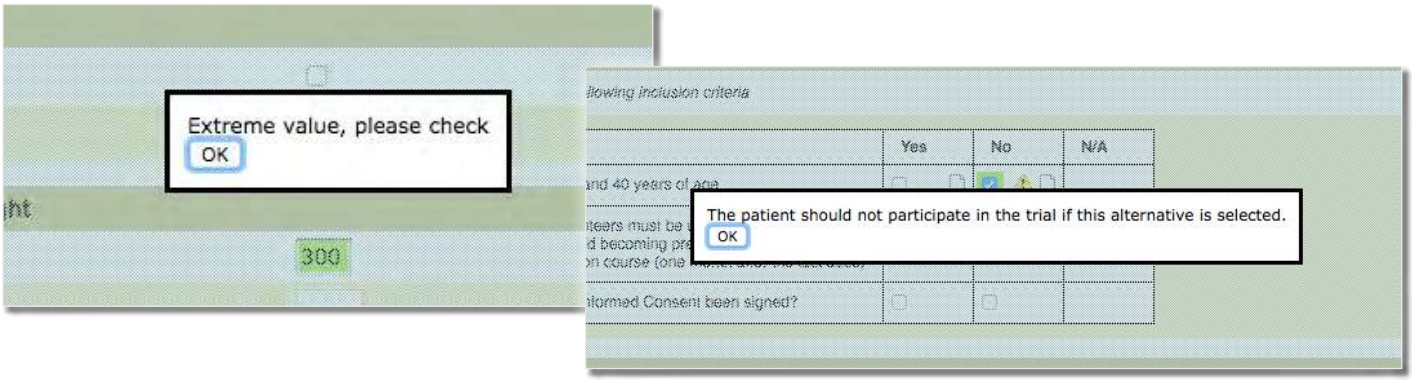


Construction of eCRFs and edit checks

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.

Functions in Trial Online

Trial Online 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.

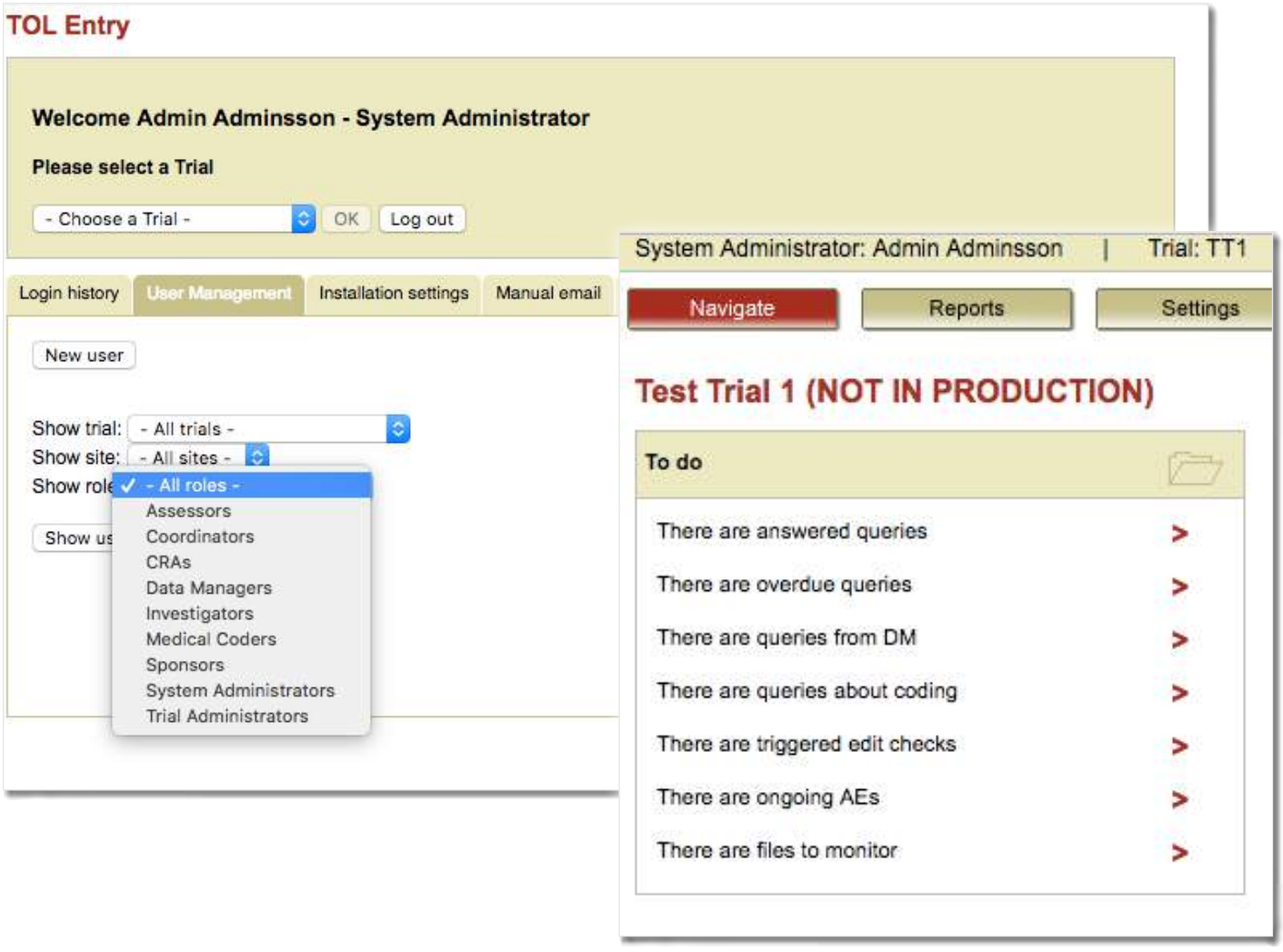
It is possible to upload images, videos and other binary files in Trial Online. Files may be assessed by an independent investigator in the system

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.

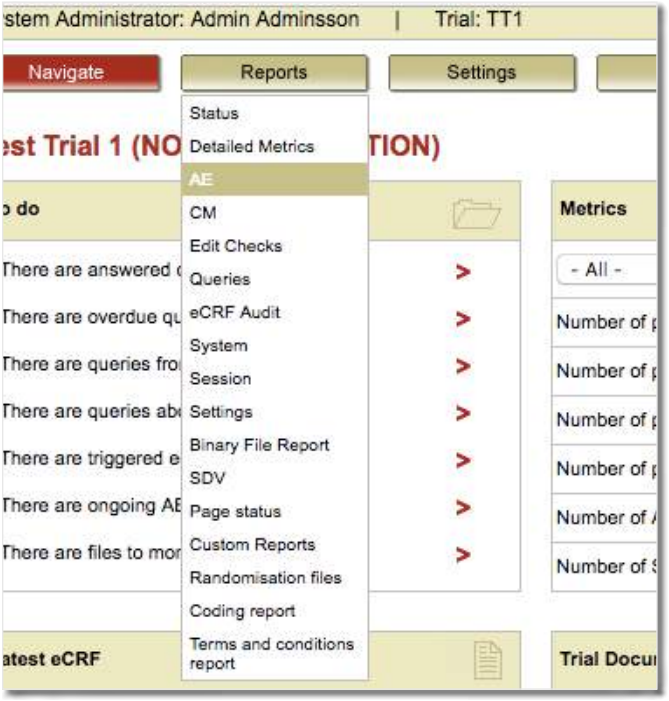
- Investigator
- CRA/Monitor
- Sponsor
- Trial/System Administrator
- Assessor
- Coordinator
- Data Manager
- Medical Coder (MedDRA and WHO-DDE coding)



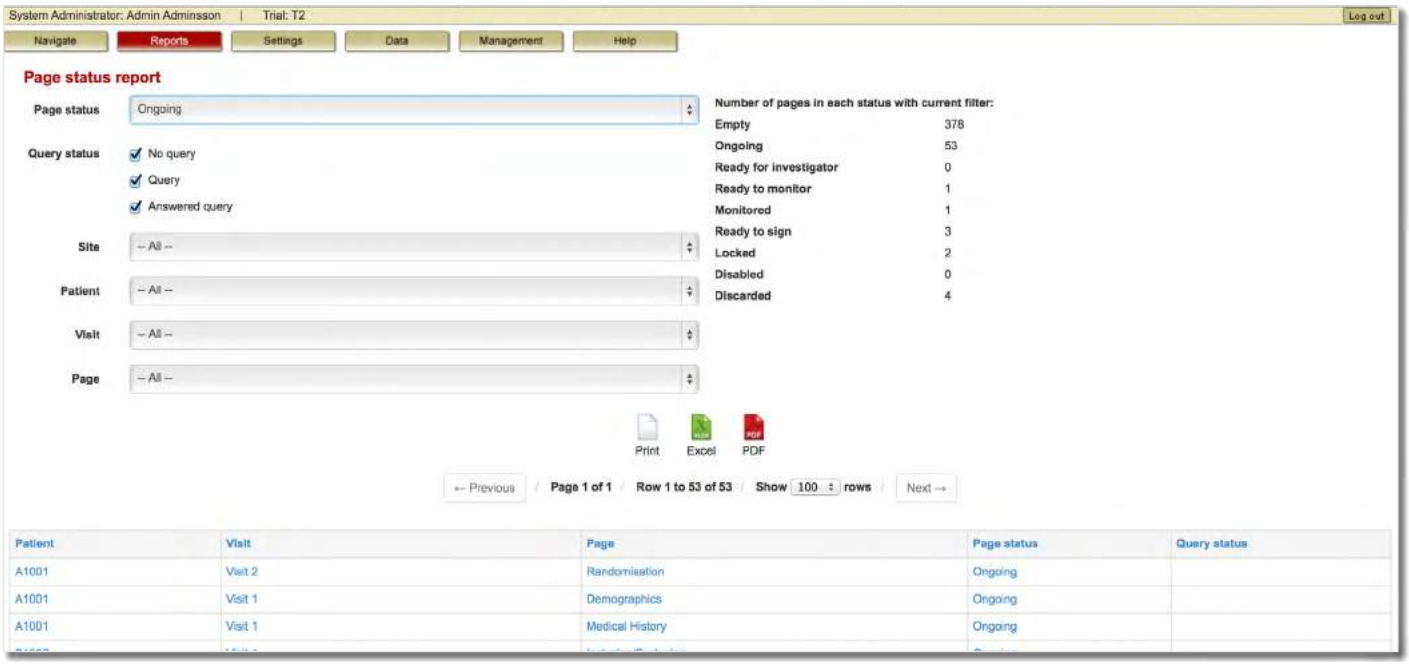
Reports

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

In Trial Online the user can also create and customize additional reports.



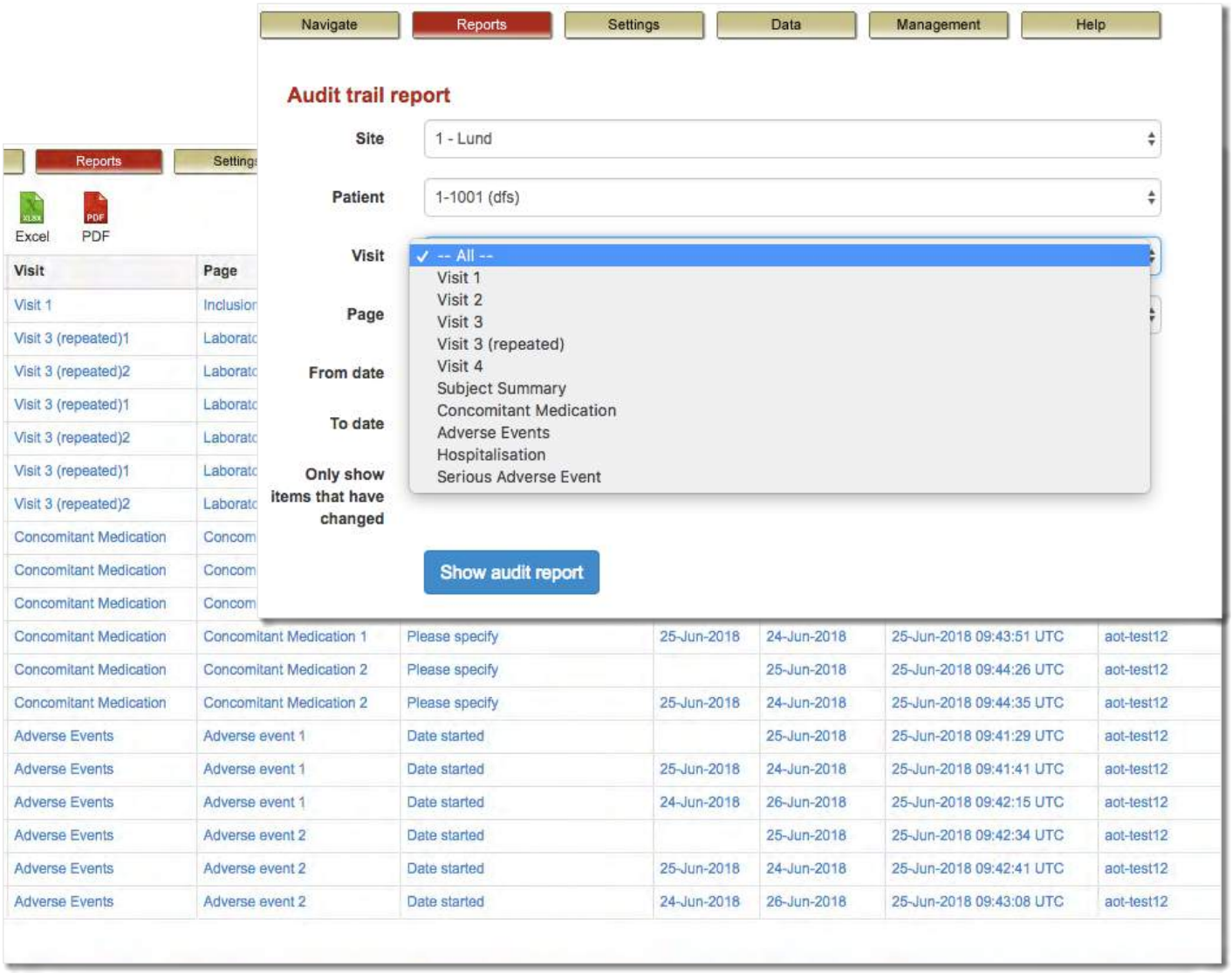
The Status Report Summary gives the user insight to work flow navigation and a visual overview of patient status.



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.



Data is saved automatically

- Store each value automatically once it is entered
- No risk of losing data due to inactivity
- Edit checks triggered directly for cleaner data
- More effective monitoring and cleaning process

Security / Regulatory

Trial Online is compliant with FDA 21 CFR part 11. Trial-on-Line also 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. The user is automatically logged out if no activity has been noticed during a predefined time.

Quality and Compliance

Trial Online is a designed, developed, and tested computer system as defined in PIC/S 'Good Practices for Computerised Systems In Regulated "GxP" Environments'. And Trial online is of course compliant with FDA 21 CFR Part 11.

Our Quality Management System is built on quality standards in the industry, e.g. guidelines and directives provided by ISPE, FDA and EMA.

Replior and Trial Online are audited regularly by its clients (regulated companies).

Trial Online is dedicated to deliver 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 regulatory standards such as:

- US FDA: Title 21 CFR Part 11, Electronic Records and Electronic Signature
- US FDA: Guidance for Industry for Computerised Systems Used in Clinical Investigations
- US FDA: Title 21 CFR Good Clinical Practices
- International Conference on Harmonization(ICH), E6 Guideline for Good Clinical Practice

Product Quality

All systems and processes used to manage a clinical trial are a part of a regulated process that must be validated and needs to meet both FDA regulations and ICH guidelines.

All Trial Online's products follows 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.

Replior is a privately held company with an annual revenue of close to 10 million SEK.

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

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Schedule a demo