Trial Online eConsent

Product overview

Trial Online eConsent

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

Trial Online's eConsent allows you to make the shift from paper-based to an online solution.

Paper free informed consent will not only improve quality and compliance but retention for your clinical trial. eConsent provides patients with clear and understandable clinical trial information so you can make sure that they are fully informed when making a decision to participate in your trial. This saves not only time which is critical for optimal launch timeframes, but money for your budget.

Benefits:

- Achieve higher quality and compliance
- Improve patient retention and satisfaction
- Informed consent forms are instantly available for review
- Easily upload and create consent forms across trials
- Enable process efficiencies and reduce corrective action
- Improve patient recruitment processes and reduce dropout rates

User interface

The homepage gives users a quick overview of all trials they are currently participating in, allows users to easily change between the trials and view personal and specific trial information.

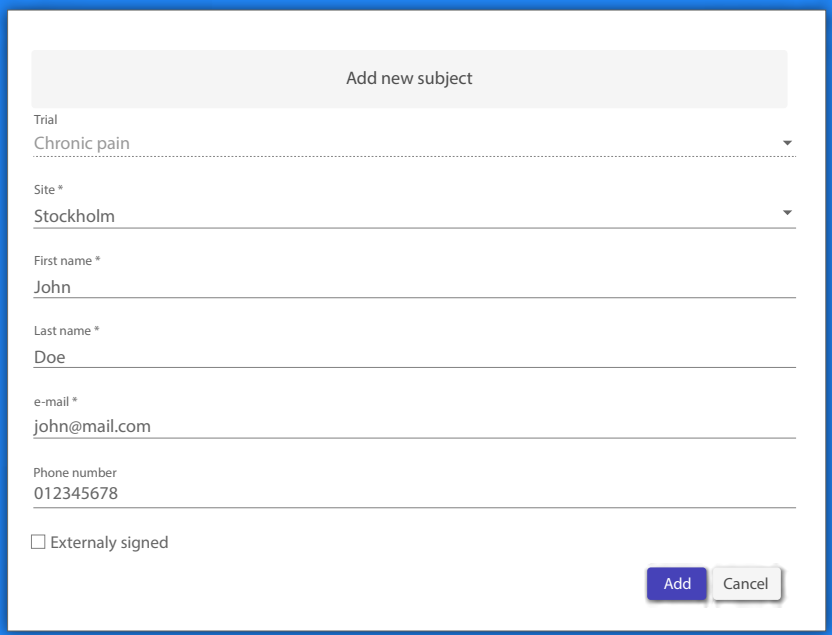
Patient overview

The patient overview table contains information about the patients participating in the clinical trial. Additionally the table is search enabled along with filters so specific information can be accessed quickly and easily.

Add new patients easily

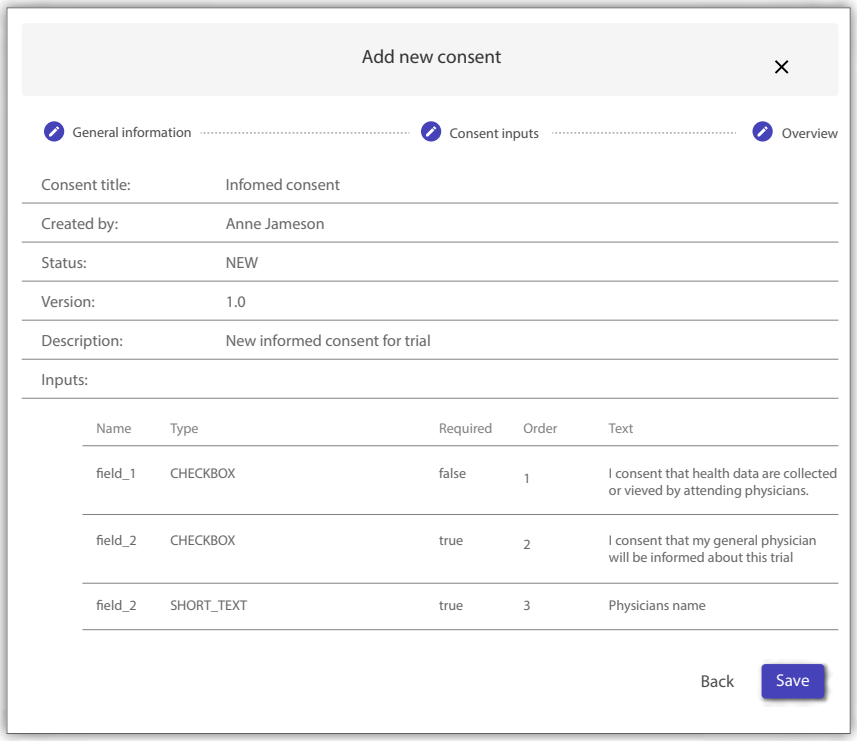
Adding new patients into the eConsent system is simple and quick.

If a patient has already signed a consent form externally they can still be added to the eConsent system. All that is required is checking a field upon the data input process.



Add new consent

The new consent form leads you through a simple 3 part form to add and define a new consent.



Consent sign

Clicking the sign consent button opens a dialog box which contains two parts: the consent content and the consent form. The patient must read and reach the end of the PDF file and fill in all required inputs before it is possible to submit the consent.

After a patient successfully signs a consent, it is possible to countersign the consent.

Revoke consent

Clicking the revoke button opens a confirm dialog box where the patient's consent can be revoked.

Reports

eConsent includes several types of reports to easily gather the data you need for an overview. Reports show the first and last name and consent status for each patient participating in the clinical trial.

Notifications

It is possible to set up and define notifications, allowing for easier management of your trial.

All notifications in the system are sent using email as transport protocol.

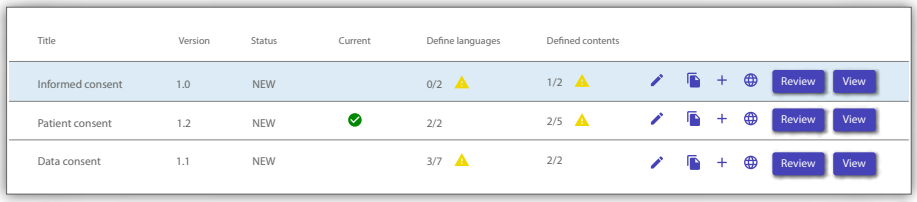
TrialOnline

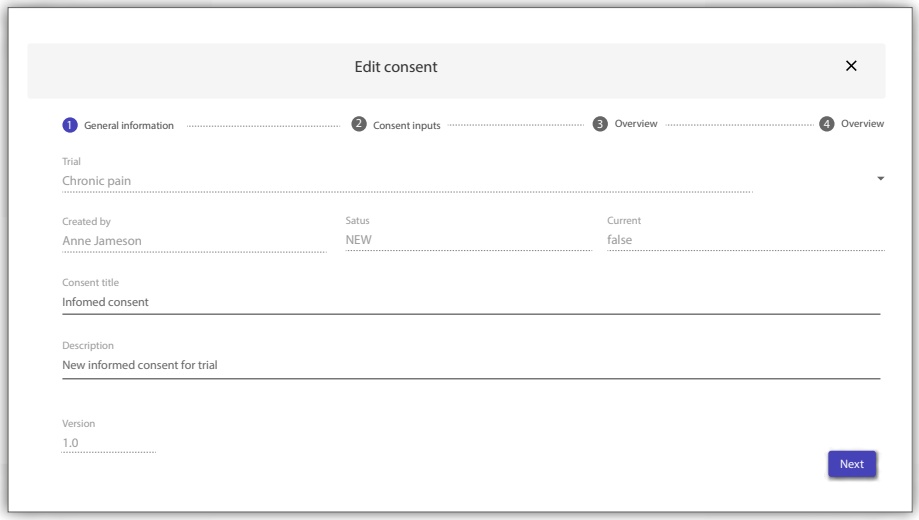
Full control over Trial Consents

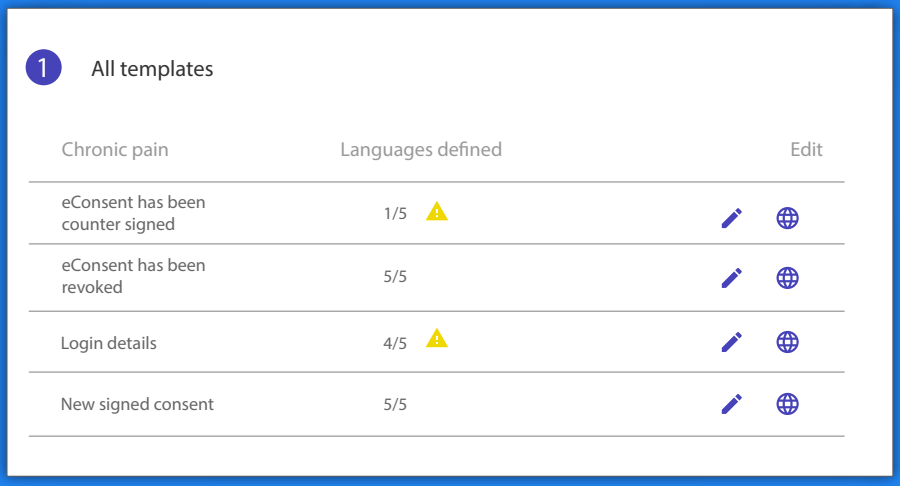
eConsent allows you to have full control over your trial consents just by clicking on ‘List of Consent’ for a selected trial.

You will be able to:

- Clone consent
- Add consent
- Edit languages
- Review consent
- View consent







Templates

Quickly view and edit your templates.

With one click you can manage, define and translate template languages.

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 technologicalsolutions 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 ClinicalInvestigations
- 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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Find out more:

Schedule a demo