Trial Online® by Replior

Frequently Asked Questions

Trial Online EDC

What are the core functionalities of Trial Online EDC?

Trial Online EDC is designed specifically for the needs of extensive clinical trials. It is a robust and secure while still intuitive system that accelerates clinical study setup and data collection. It allows clinical study teams to configure trials effortlessly through an intuitive front-end trial builder, including role-based access, edit check validators, skip/add logic, derived calculations, among other.

Is Trial Online EDC compliant with FDA 21 CFR Part 11, EMA, and other regulatory requirements?

Yes. Trial Online EDC 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.

Is Trial Online EDC compatible with other devices and operating systems?

Yes. Our EDC supports all major web browsers such as Google Chrome, Microsoft Edge, Firefox, Apple Safari etc. The system includes responsive web design and works perfectly well on tablets, as well. The system can be used on smartphones; however, we do not include that in our testing.

Can the EDC system be customized to meet specific study requirements?

Indeed. Trial Online EDC allows easy configuration of trials according to each specific need from start to finish. The eCRFs in our EDC are created in a construction module, which allows for speedy and easy configuration, so easy that no prior programming skills are required. Our current version of EDC is capable to manage up to 90-95%of all clinical trials, but when it comes to most complex studies requiring multiple treatment arms and randomization steps, there are other solutions better suited, and we will gladly help you find yours.

How does Replior ensure the security of sensitive data in Trial Online EDC?

We are fully committed to data security and therefore, we have incorporated multiple layers of protection:

- **Strong authentication and 2-factor authentication:** Trial Online EDC requires not only a username and password but also a uniquely generated code, offering an additional layer of security. We provide the flexibility to configure password complexity and security according to the specific needs of each trial.

- **Dedicated hosting environment from redundant data centres:** Our products, EDC included, operate from two geographically separated data centres, ensuring resilience and reliability. Each client or study benefits from a dedicated hosting environment, including exclusive servers, networks, and security protocols. This setup, involving network segmentation and dedicated servers, is crucial for maintaining a secure production environment.

- **Encryption of data at rest and in transit:** We ensure the safety of your data by encrypting all stored data. Furthermore, all communication with our products is safeguarded by TLS 1.2 and SHA 256 encryption, setting a robust standard for data transfer security.

- **Multi-layered backup strategy**

- **Inter-data centre storage snapshots:** Hourly storage snapshots are taken and retained for 24 hours, creating a continuous backup between our two data centres. Additionally, daily snapshots at 12:00 CET are stored for 30 days, providing a rapid recovery solution in case of data centre outages or disasters.

- **Agent-based backup system**: A daily backup is conducted using professional backup software, with all backup data securely stored at an alternate physical location for 30 days. This system itself is backed up daily, ensuring a comprehensive disaster recovery capability.

What training and support does Replior provide?

Trial Online EDC is designed to be easy to use, which means that you don't need any prior experience as a Clinical Data Manager to set up your trial as the full process is self-explanatory. Our Data Management team can also assist you throughout your study journey, from co-building your first study to providing ongoing knowledge transfer and training. We offer continuous support throughout your study to ensure a smooth and efficient experience.

What is the average time for implementation and deployment of Trial Online EDC?

The implementation time varies on the complexity of the trial, but from the very beginning, a team is dedicated to your study specifically to ensuring a swift and efficient deployment process. The system setup and initial installation qualification process is performed **within 10 days**. If you would like the assistance from our Clinical Data Management team to configure the system according to your study protocol the lead-time varies on the study complexity and your specific review process. Usually, a study configuration is ready for your final validation after **4 to 6weeks.**

What is the pricing and cost structure for Trial Online EDC?

Our pricing model is transparent, and we offer flexible cost structures tailored to each trial needs. There are no current or down the road hidden fees, and we provide detailed pricing information during the consultation process.

Does Trial Online EDC integrate with other vendor' systems?

Yes, Trial Online EDC supports integration with other clinical trial systems and third-party applications, facilitating data exchange and enhancing overall trial interoperability. Some examples are of our partners are S-Clinica, Suvoda and Veeva RTSM.

Trial Online® by Replior

www.replior.com

info@replior.com

+46 8 601 13 30

Hammarby Kaj 18,
SE-120 30 Stockholm, Sweden