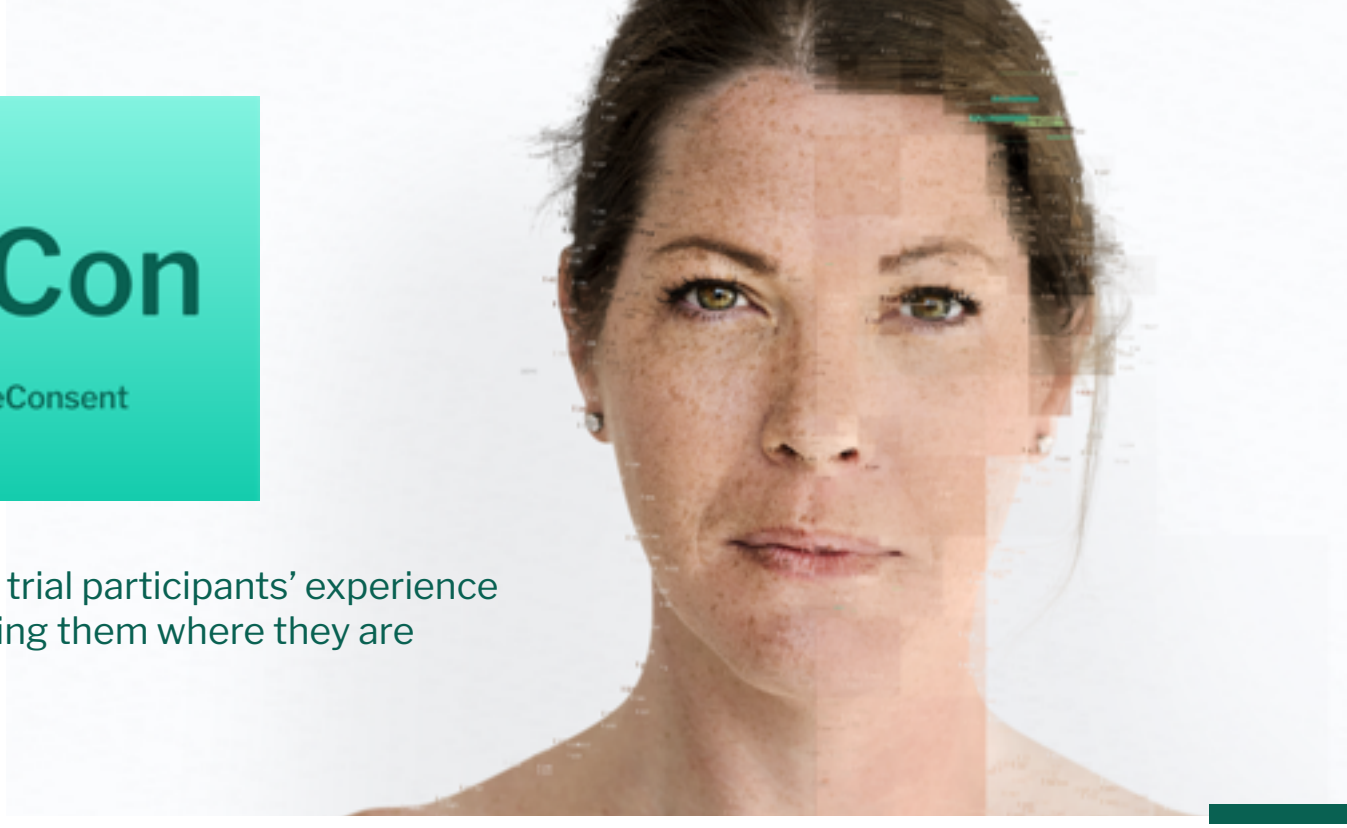
eCon

eConsent



Improve trial participants' experience by meeting them where they are

OVER THE PAST YEARS ECONSENT SOFTWARE, WHICH HELPS TRIAL PARTICIPANTS TO READ AND SIGN INFORMED CONSENT DOCUMENTS ONLINE, HAS EXPLODED IN POPULARITY.

Paper informed consents do not promote consistent dialogue and informed decision-making. They have become increasingly complex, technical, and more difficult for patients to understand clinical research objectives. Adding the variability in literacy levels and cultural diversity, the development of ICFs has become overly intricate and an inefficient means for conveying information about a trial to the patient.

Studies conducted by the FDA have shown that 20% of eligible patients do not enrol due to **lack of understanding regarding the study specifics** and 5% of eligible patients drop out due to **misunderstood expectations**. At the same time, informed consent is required in most medical settings. Specifically on clinical studies the study can't start until the document is signed, hence the importance of having an easy and fast way of accessing that.

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Of eligible patients do not enrol due to a lack of understanding regarding study specifics.

5%

Of eligible patients dropout due to misunderstood expectations.

Paper informed consents do not promote consistent dialogue and informed decision making.

Electronic informed consent (eConsent) provides the same information as traditional paper, but in an **electronic format that may include multimedia components** such as images, audio, video, diagrams, reports and a digital signature which may aid the consenting process.

EvidentIQ's **eConsent solution offers new avenues and goes** beyond what traditional eConsent solutions offer. It leverages EvidentIQs **500+K patient community** scattered across the US and Europe to accelerate enrolment in a hybrid or decentralized trial setup.

Depending on the trial, **the patient can use any connected device**, review materials related to the trial, and schedule a live consultation with the study personnel to ask further questions. During that time, **the patient can be seen**, and **the study personnel can share all media interactively** and respond to any questions the patient submitted during the initial material reviews. At the end of that process, a 21 CFR Part 11 compliant eSignature can be collected, and the patient will be enrolled into the EDC system.

01 **eConsultation**
Trial participants have the ability to have a video consult during the consent process – meet them where they are.

02 **eConsent**
Unique Live Informed Consent with the study personnel.

03 **eEnrollment**
Leverage EvidentIQs Patient Community to automate EDC enrollment (500.000 members based in Europe and the US).

04 **Full Control**
Patient details can be seen during the consultation and study personnel can share all media interactively.

05 **Compliance**
21 CFR Part 11, EU Annex 11, HIPAA, GDPR

06 **eSignature**
Via screen or code.

07 **Media Support**
Videos, PDF and PowerPoint.

08 **Compatibility**
Fully browser based, works with any device.

EVIDENTIQS ECONSENT CAN BE TAILORED TO THE INTENDED AUDIENCE, TAKING INTO CONSDERATION THE SUBJECT'S AGE, LANGUAGE, AND COMPREHENSION LEVEL.

An important part of this tool is the authentication feature, which in this case is provided by a **multiple layer of authentications**, whether it be in the form of an OTP or an email verification. **A secure solution** also provides various methods of document authentication by requiring participants to upload multiple forms of identification such as a state ID, driver's license, and/or a health card.

EvidentIQs eConsent will help increase transparency via remote control, give the ability to focus on patient's targeted questions and areas of concern, avoid on-site ICF versioning issues and enable DCT and Hybrid trials while reducing trial costs.

FOR FURTHER INFORMATION:
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