EmpiraMed
Digital Clinical Technology for RWE

Beyond Consent Forms:

eConsent's

Role in Simplifying Decentralized Clinical Trials

Decentralized clinical trials (DCTs) have gained popularity in recent years as a remote alternative to traditional study approaches. Leveraging digital technologies and remote processes, DCTs can facilitate increased participation from people in diverse geographical locations. These types of trials offer several advantages: heightened patient convenience and flexibility, cost reduction, and accelerated timelines. Despite the benefits of their structure, DCTs face the common challenge of obtaining informed consent from participants. The consent process traditionally involves paper forms and in-person discussions with investigators, which can be time-consuming and inconvenient for patients.

In recent years, eConsent has emerged, offering a digital solution designed to simplify and streamline the informed consent process for DCTs. Modern eConsent platforms enable participants to review and electronically sign consent forms at their convenience, eliminating stress and the need for clinic or site visits.[1] eConsent tools are now playing a pivotal role in reshaping clinical trial methodologies within the decentralized framework.

Electronic Informed Consent Forms - How They Work

Electronic Informed Consent (eICF) tools can help ensure participants' safety and research integrity with the added potential to reduce participant burden and trial costs.[2] To illustrate how eConsent features work, we'll explore an example using EmpiraMed's eConsent process for DCT projects.

The initiation of EmpiraMed's eICF can occur in three different places: the MED Portal (EDC), EmpiraMed API, or a straightforward participant enrollment workflow using an operations-based intake form. Using any of these methods, clinical coordinators can enter participants into a study and trigger the 21 CFR Part 11 compliant eICF based on enrollment or other specified actions.

Upon study entry, participants receive a personalized email containing a unique code and a clickable button. Clicking the button leads to an account verification page where they confirm their identity by entering a unique code and email address. Once verified, they are redirected to the eICF to sign consent documents digitally. Participants can request a PDF copy of all signed forms for their records. EmpiraMed's eConsent is backed by a rules engine, which allows for the triggering of standard actions (e.g., notifications) upon a participant's eSignature, enhancing overall functionality and communication throughout a study.

Benefits of eConsent for DCTs

Patient Convenience and Flexibility

Patients can experience the entire clinical trial process, including recruitment, screening, and enrollment, from the comfort of their homes. This convenience is especially advantageous for individuals residing in remote areas or facing challenges traveling to trial sites.

Operational Efficiency

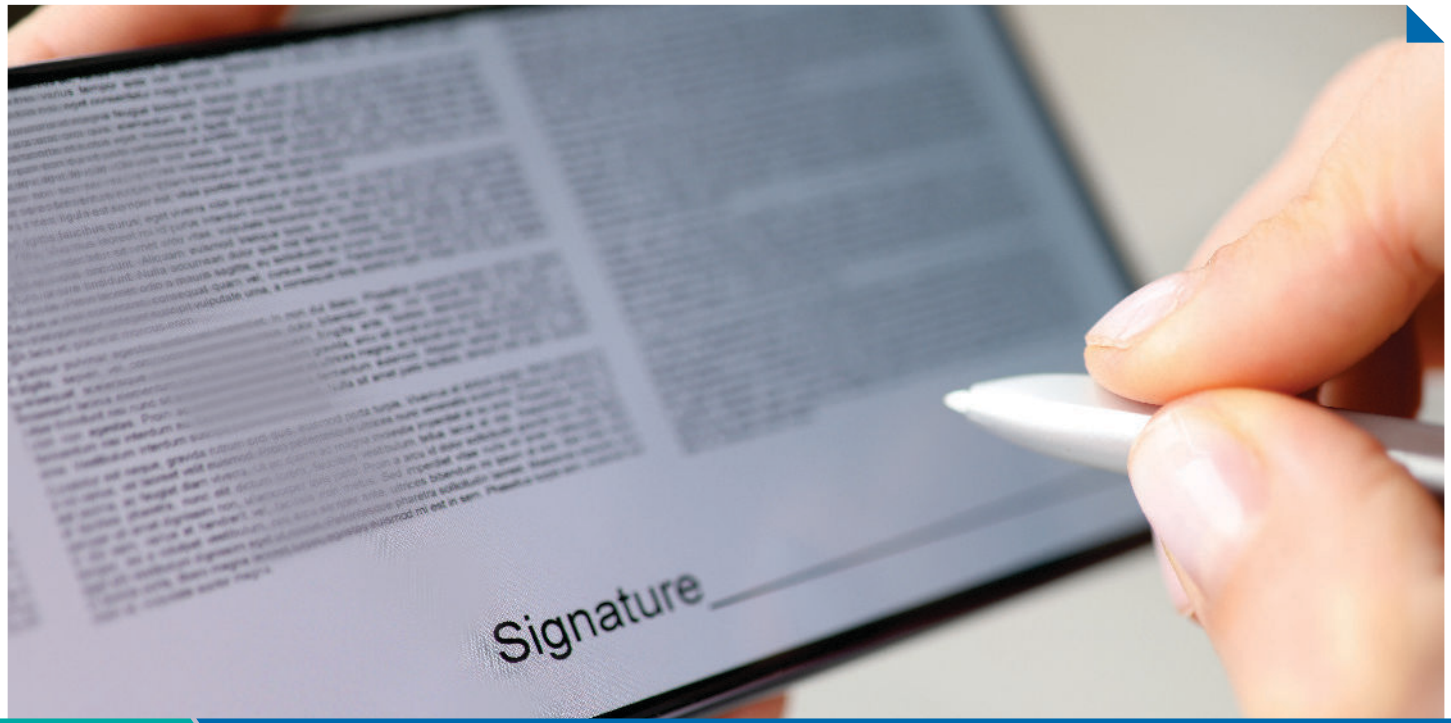
Deloitte's research underscores the remarkable impact of decentralized trials, with a 30-50% reduction in participant recruitment time. Additionally, these trials showcase a noteworthy 90% increase in retention rates and an impressive 97% surge in patient interest, demonstrating the operational efficiency gained through decentralized approaches.

Increased Enrollment

The implementation of eICF significantly contributes to the success of decentralized trials by making them more accessible and appealing. This approach addresses operational challenges and streamlines the enrollment process, facilitating a smoother experience.

Risk Mitigation

Higher loss-to-follow-up rates can directly affect the validity of the real-world evidence (RWE) derived from a study. Surveys conducted by the Center for Information and Study on Clinical Research Participation (CISCRP) emphasize a direct link between the failure to comprehend informed consent documents and the risk of increasing the loss-to-follow-up rate. eICF, with its participant-friendly design and reading levels, acts as a proactive measure, reducing the risk by ensuring clearer comprehension and promoting participant retention in clinical studies.[3]



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eICF Security and Compliance

Ensuring compliance is not just a recommendation but a fundamental necessity in eICF to safeguard patient data appropriately. EmpiraMed's advanced eConsent system adheres to the rigorous standards outlined in 21 CFR Part 11 for digital and electronic signatures, providing a secure framework for the consent process. For international studies, compliance with GDPR is seamlessly integrated into advanced systems, ensuring that data handling and privacy practices meet global standards.

eICF systems should go beyond mere compliance by offering clinical directors a comprehensive suite of features. In addition to adhering to 21 CFR Part 11 and GDPR, EmpiraMed's eConsent tools can incorporate medical releases and localized consent forms. These added forms enhance convenience for patients and coordinators while ensuring that specific regional requirements, such as the CA Bill of Rights or EU Data Use Agreements, are seamlessly integrated into the eICF process. This adaptability and thorough compliance provide a more holistic and secure eConsent experience.

Learn More About EmpiraMed's eConsent

eConsent is a valuable tool for pharmaceutical companies conducting DCTs. It can increase patient convenience and flexibility, reduce costs, and accelerate timelines. **EmpiraMed** is a digital health technology leader in virtual clinical studies for real-world evidence. EmpiraMed's stand-alone electronic informed consent module offers a secure, easy-to-use, and compliant solution to boost retention and support hybrid, site, or siteless projects.

References

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