The use of Electronic Informed Consent (eConsent) in a Blood Collection Study – Pilot Study

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Purpose

Informed Consent is a process for providing education and obtaining permission before conducting a healthcare intervention on a person. Health care practitioners engage in dialogue with potential participants of research studies about a proposed medical treatment, consequences, harms, benefits, risks, and alternatives. The International Conference on Harmonization (ICH) Good Clinical Practice (GCP) defines informed consent as a process by which a potential participant voluntarily confirms his or her willingness to participate in a particular study after having been informed on all aspects of the study.

Currently, most informed consent forms are presented in paper format which have become increasingly complex, long, and difficult for patients to understand. In addition, paper informed consent can pose a risk to compliance and regulatory requirements. To address these challenges, technology companies have partnered with industry to introduce patient-centered Electronic Informed Consent (eConsent) that is interactive, easy to use and on multimedia platforms. eConsent is governed by FDA regulations. 21 CFR Part 11 establishes the criteria for FDA acceptance of electronic records, electronic signature, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signature executed on paper.

The purpose of this study was to assess the benefits of an eConsent solution from the sponsor and clinical site staff perspective.

Method

The sponsor selected Mytrus, Inc.’s, Enroll® eConsent solution to implement as a pilot for the study. Enroll is an innovative, patient-friendly solution for electronic informed consent and patient enrollment for clinical trials. Enroll was presented to the participants using iPads and the data was collected in a hosted database where clinical site staff were able to access it online. Enroll enables the sponsor to conduct 100% remote monitoring.

Result

The survey revealed that eConsent improved the overall management of obtaining informed consent.

Conclusions

The eConsent solution can be beneficial to the sponsor, clinical sites, and study participants. The eConsent solution is centralized where the sponsor and the clinical site can manage participant’s informed consents remotely. Additionally, eConsent may improve a participant’s understanding of the informed consent.

Reference

1. Implementing e-Consent for Clinical Trials, Pitfalls and Practical Considerations, FDANEWS
2. eConsent-Implementation Guidance, Transcelerate Biopharma