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.

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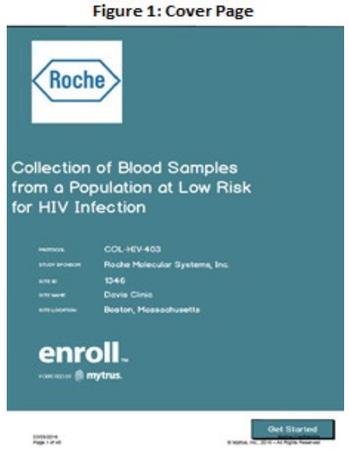
Table 1. Vendor Selection Criteria
21 CRF Part 11 compliant
ICH/GCP guidelines for automated clinical systems
Types of hardware and the platform
Web-based, app-based
Securities in place – access based on role, sponsor, subjects, and study staff
Web-based encryption
Location tracking of the iPad
Time and date stamp
Limited access to outdated consents
Connect to eCRF and EMR
Promote for re-consenting of subjects when necessary

Figure 1: Cover Page



Method

The Enroll eConsent solution was implemented at 10 sites with total 34 clinical site staff. The study enrolled 2726 participants. At the completion of the study, a survey with 10 questions was sent to the clinical site staff to assess their experience with the eConsent. Additionally, the sponsor discussed the benefits and challenges of implementing the eConsent.

Figure 2: Site status and Add New Subject

Figure 3: Signature Page

Result

Clinical site staff (94.11%) stated that eConsent improved assessing the participant's understanding of the study. In addition, 86.36% of the site staff stated eConsent improved the management consent tracking (e.g., remote monitoring, re-consenting, consent withdrawal, and expired consent).

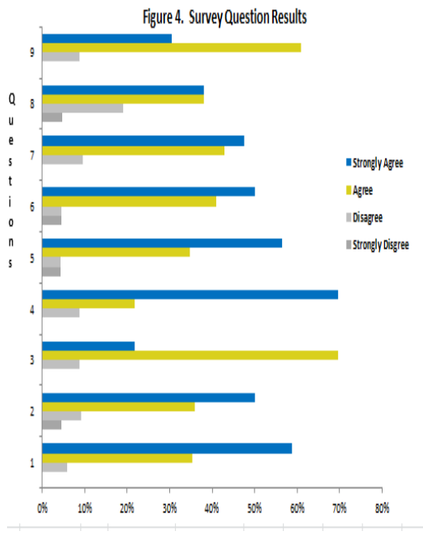
Table 3: Some Benefits of eConsent		
Benefit for Sponsors	**Benefits for Sites**	**Benefit for Participants**
Streamlines monitoring activities	Reduce paperwork and quality risks	Increase compliance
Reduce audit and inspection findings	Reduce audit and inspection findings	Multimedia components Increased readability
Increase quality and consistency	Lowe burden on site staff	Help special population
Improve productivity	Less administration time	Engagement with consenting process
Automated reporting	Improves management of consent tracking	Attractiveness of new technologies
Increase retention	Provide information about study participants	Increase readability

Result

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

Table 2: Survey Questions
1. eConsent improves patients understanding of the study
2. eConsent improves management of overall consent tracking (e.g., re-consenting, consent withdrawal)
3. eConsent increases participant compliance
4. eConsent reduces paperwork and quality risks
5. eConsent lowers the burden on site staff, allowing a focus on high-value activities, including specific study participant questions and concerns
6. eConsent reduces administrative burden of onsite monitoring activities by providing an increased amount of information with eConsent to the study participant and also enabling some activities to occur remotely
7. eConsent provides less administration time (e.g. automated reminders for consent amendments, potential for paperless systems)
8. eConsent reduces the need for complex and time-consuming and supplementary study explanation tools
9. eConsent provides information about study participants level of understanding during the consent process
10. Do you have any other comments, questions, or concerns?

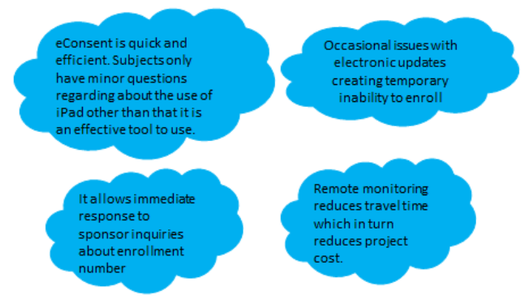
Figure 4. Survey Question Results



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

Figure 5: Some of the sponsor and site comments



Reference

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