Why you should implement eConsent

Informed or electronic consent, "eConsent" is a hot topic in the clinical research world right now as sponsors and sites continue to grapple with cumbersome paper-based consent forms while looking for more efficient solutions. To date few Australian sponsors and sites have taken advantage of informed consent software and are continuing to use the paper-based systems. Understanding the benefits of making the transition to eConsent can help overcome one of the last paper-based bastions in clinical research.

We all agree that the paper-based consent process is daunting to potential participants who are often faced with up to 30 pages of documentation to read, which results in participants electing not to enter the trial or study or enrolling in the trial and later withdrawing. eConsent is a more effective way of communicating with participants while increasing trial recruitment and retention.

The key drivers for moving to eConsent include increased recruitment, reduced participant attrition, increased regulatory compliance and the enablement of remote monitoring of the eConsent process. International experience demonstrates that effective eConsent processes provide participants with educational content in an easily digestible format and language, while also validating comprehension and providing a method of raising and resolving queries.

In order to transition from a paper-based environment to eConsent we must re-imagine the entire eConsent process by making it an educational and participant focused experience from start to finish. Industry best practice indicates that we should maximise the multimedia content delivery, with a combination of videos, animations or diagrams describing the consent process, combined with a simple user friendly interface to assist the participant to navigate through the consent and confirming both their knowledge and progressive acceptance of the trial procedures and processes. At the completion of the process the system collects the participant's legal consent to enter the trial using an eSignature.

The availability of digital technology is rapidly encouraging users to take advantage of technology to collect and store an ever-wider variety of personal health information, including electronic medical and health records and patients are now recording their own outcomes after a medical intervention. This technology is rapidly changing healthcare delivery and eConsent is extending this into clinical trials. A number of well-designed eConsent platforms are being introduced into the continuum of technology advancement to provide participants, their families and caregivers with the ability to consume consent material in their own time and on their own device. FDA and other regulators around the world have published guidelines on eConsent implementation to ensure that the technology both informs the participant while meeting the regulatory requirements.

Adopting eConsent provides benefits for all of the stakeholders in the clinical research world. Sponsors and service providers can provide a streamlined process around collecting participant informed consent. Sites are able to monitor the status of all participants. eConsent can substantially reduce the time needed to consent a participant. The outcome of the consent process can be used to induct participants into the relevant clinical trial management systems. Participants benefit by having a greater understanding of the trial and their involvement and, once consented, they are much more likely to remain in the trial.

Industry figures published in February 2019 based on the analysis of customer trials across the world, indicated that on average 69% of identified participants are pre-screened out of the trial. While this may appear high, it is dependent on the therapeutic area, disease and the trial's acceptance criteria. 58% do not consent, 32% are screened out and 18% fail to complete the trial, leaving just 7% of identified participants completing the trial. Based on these figures a trial would need to identify 2,758 potential participants, in order to have 200 participants to complete the trial. If an eConsent environment could increase the number of consenting patients by 10%, the trial would only need 2,226 potential participants providing a saving of 19%.

eConsent has the potential to provide significant benefit to the entire industry. There are many case histories of the technology being successfully implemented overseas. eConsent is relatively simple to implement and has the potential to substantially improve trial recruitment, retention, significantly reduce trial costs and enhance patient involvement and knowledge. Best practice indicates that sponsors and sites consider a pilot implementation eConsent technology before undertaking a site wide implementation.