Implementing eConsent

To date few Australian sponsors and sites have taken advantage of informed consent software and are continuing to use the paper based systems even though take up in the USA and elsewhere is growing substantially. The FDA fully supports eConsent and the FDA see it as the next logical step in extending the electronic data collection in research projects. FDA and EU guidelines state that the environment needs to be patient centric, and that eConsent must effectively manage patient privacy, while providing the patient with relevant educational information whilst recording their consent to participate in the clinical trial or study.

Like all technologies the more you use them the greater the benefit and eConsent is no different. As each clinical trial potentially has different stakeholders, it is essential that eConsent is included as part of the clinical trial project plan. This will ensure that both ethics and sites are onboard from the start. The plan should clearly define the roles and responsibilities in the eConsent implementation.

There has been some discussion about eConsent technology selection, that can range from the FDA open source system, in-house development, out-sourced or self-service. Signant Health research indicates that in their experience the preferred options are out-sourced or self-service, with self-service providing the greater long-term benefits. There has also been a lot of concern around security, privacy and traceability, the good news is that all major eConsent vendors that provide EDC, eCRF, CTMS, and eCOA products already have security, privacy and traceability built into their systems. Best practice indicates that all patient personal and identifiable data must be encrypted, and the eConsent system must have built-in privacy management functions. One of the main benefits of the eConsent process is the ability to report on the trial site's consent status, so it is essential that the eConsent system has user friendly reporting tools.

The eConsent approach uses an educational paradigm to inform the participant. The eConsent systems should be capable of delivering multi-media that can be tailored to the clinical trial processes, confirm the participant's knowledge, let the participant raise queries or issues and explicitly collect the participant's acceptance and consent to participate in the trial processes.

Having selected the eConsent system the next step is defining the eConsent form/documentation. This usually consists of reviewing the protocol to identify the educational information that a participant will need to comprehend. The documentation needs to be broken down into a number of educational topics that will be delivered to the participant. Having identified the educational topics, the designers can then prepare the content. Videos are a great educational tool and there are lot of videos covering many trial procedures and processes already available or they can be custom made or rented from organisations such as Healthily or Praxis. It should be noted that videos can usually be reused.

The design of the eConsent page will be many cases be similar to developing interactive CRF pages. Once your eConsent content has been designed, it needs to be reviewed by the ethics committee. As the system is interactive, ethics will need to see the system from the participant's perspective, i.e. does it easily and fully inform the participant and is it easy to understand. Bringing the ethics stakeholders on board early will ensure that the ethics team have input into the eConsent design, which should steam-line the approval process.

When ethics have approved the eConsent system, the recommended next step is to pilot the eConsent system with one or two lead sites, to verify that the workflow is operating, and that the sites have the appropriate reporting and analytical tools. By piloting the eConsent at one of your sites, it should be possible to run eConsent devices over the clinic's WIFI network. When you have completed the pilot and resolved any issues your eConsent system will be ready to be rolled out.

While implementing eConsent will be an initial upfront additional cost for the trial, international experience indicates that effective eConsent systems substantially improve recruitment and retention allowing trials to meet the recruitment targets quicker while significantly reducing the subject dropout rate. According to the international experience, sponsors will start to see a financial benefit after the second or third eConsent implementation.