

ICON launches Electronic Informed Consent

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ICON has announced the launch of Firecrest eConsent, a next-generation electronic informed consent solution that incorporates key recommendations from the FDA's recent draft guidance on informed consent.

The e-Consent solution is a component of ICON's new informatics hub designed to enhance the engagement of patient populations in the development process. One of the critical parts to improving this engagement is improving the informed consent process.

Addressing the FDA's recommendation for a more patient centric approach for presenting clinical trial information, ICON's Firecrest eConsent employs videos and visual aids to assist in the explanation of complex scientific concepts and medical terms found in trial protocols. These educational techniques were developed based on research by Carnegie Mellon University, and have been systematically tested, to facilitate optimal patient comprehension and information retention. Firecrest eConsent enables patients to access materials via portals or through other online channels provided by the sponsor, giving patients more time to independently review and prepare questions for the physician before subsequently consenting to participate in the trial.

Conforming with the FDA's requirement for validating that e-signatures are written by the actual patient, Firecrest eConsent uses a new proprietary method to capture, confirm, encrypt, and store biometrics for each patient's signature.

Firecrest eConsent has also been designed to be compatible with sites' existing IT infrastructure, enabling sites to adopt the Firecrest eConsent solution quickly and efficiently.

"Electronic informed consent helps address one of the leading causes of regulatory findings - errors in the consent process in current paper-based processes. Firecrest eConsent simplifies and provides transparency in the entire patient consent process. It thoroughly and consistently explains the trial, which instils trust in the patient, and it also offers sponsors a secure and easy-to-implement solution to drive patient enrolment and reduce the opportunities for protocol violations," said Mr Frances Abeton, vice-president, Firecrest.