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ICON Launches Electronic Informed Consent

New Firecrest eConsent Solution part of ICONIK Informatics Hub designed to enhance patient engagement in the trial process and in line with recent FDA guidelines

DUBLIN, Ireland--(BUSINESS WIRE)-- ICON plc, (NASDAQ: ICLR) a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries, today announced 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a next-generation electronic informed consent solution that incorporates key recommendations from the [FDA's recent draft guidance](#) on informed consent.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 to 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," commented Frances Abeton, Vice President, Firecrest. "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."

Request a demonstration of Firecrest eConsent and learn more about ICON's Firecrest solutions at www.iconplc.com/technology/firecrest.

About ICON plc

ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 83 locations in 38 countries and has approximately 10,600 employees.

ICON/ICLR-G

This press release contains forward-looking statements. These statements are based on management's current expectations and information currently available, including current economic and industry conditions. These statements are not guarantees of future performance or actual results, and actual results, developments and business decisions may differ from those stated in this press release. The forward-looking statements are subject to future events, risks, uncertainties and other factors that could cause actual results to differ materially from those projected in the statements, including, but not limited to, the ability to enter into new contracts, maintain client relationships, manage the opening of new offices and offering of new services, the integration of new business mergers and acquisitions, as well as economic and global market conditions and other risks and uncertainties detailed from time to time in SEC reports filed by ICON, all of which are difficult to predict and some of which are beyond our control. For these reasons, you should not place undue reliance on these forward-looking statements when making investment decisions. The word "expected" and variations of such words and similar expressions are intended to identify forward-looking statements. Forward-looking statements are only as of the date they are made and we do not undertake any obligation to

update publicly any forward-looking statement, either as a result of new information, future events or otherwise. More information about the risks and uncertainties relating to these forward-looking statements may be found in SEC reports filed by ICON, including its Form 20-F, F-1, S-8 and F-3, which are available on the SEC's website at <http://www.sec.gov>.

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