



ICON Launches FIRECREST Safety Letters and Site Question Management Supporting Regulatory Compliance and Increasing Site Support

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New solutions enable enhanced delivery, tracking and management of drug safety reporting and medical questions from sites

DUBLIN--(BUSINESS WIRE)--Feb. 8, 2021-- ICON plc, (NASDAQ: ICLR) a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries, today announced the release of two new digital solutions supporting clinical research sites and sponsors. The FIRECREST suite of digital clinical solutions are now integrated with the ICON Safety Reporting solution to enable electronic acknowledgement of safety letters by principal investigators, with full compliance tracking and dashboard reporting. The FIRECREST Site Question Management solution automates, accelerates and tracks medical questions from the site for quicker resolution.

The pharmaceutical regulatory landscape is continually evolving, making safety reporting increasingly complex. FIRECREST Safety Letters is supporting sites to manage safety letters and increasing transparency for sponsors. It enables faster sponsor reconciliation of safety letters, both on-site and remotely, that are stored and accessible in one location with single sign-on. The solution also features compound level management, reducing duplication and empowering the principal investigators, or assigned user, to acknowledge safety letter receipt ensuring pharmacovigilance regulatory compliance.

FIRECREST Site Question Management provides medical query routing according to region and role, facilitating faster responses to medical focused questions and providing governance of the process. A record of the interactions and metadata are held centrally in the site portal for oversight purposes and an exportable excel document can be filed in the eTMF.

"The COVID-19 pandemic has highlighted the value of remote clinical management including the use of digital tools. We are delighted to announce the availability of two new FIRECREST solutions that are increasing speed of process and regulatory compliance." commented Alison Liddy, Senior VP Site & Patient Solutions at ICON plc. "FIRECREST Safety Letters and Site Question Management are part of a range of digital solutions from ICON focused on automation to help improve the efficiency of site activities.

FIRECREST digital solutions drive measureable efficiency and quality in clinical trials and are deployed by 18 of the top 20 pharma with 540,000 users across 233 different indications.

About ICON plc

ICON plc is a global provider of outsourced drug and device development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. 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 employed approximately 15,250 employees in 94 locations in 40 countries as at September 30, 2020.

Further information is available at
www.iconplc.com/firecrest

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