ICON Launches New Drug Safety Reporting Solution that Ensures Compliance through Automation

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Developed on platform deploying rule-based automation for timely delivery of drug safety information

DUBLIN--(BUSINESS WIRE)--Feb. 5, 2019-- 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 a new drug safety reporting solution based on an innovative cloud-based system, featuring automated and configurable business rules. The solution ensures compliance in an increasingly complex regulatory environment and enables the sponsor to gain visibility into the safety profile of an investigational product throughout its lifecycle.

Using regulatory intelligence from 80 countries, the system is configured with date-stamped decision rules. This facilitates the required safety information to be submitted and distributed automatically to all relevant stakeholders including Investigator Sites, Ethic Committees, Institutional Review Board and Competent Authorities within due dates. Safety information is submitted in the mandated format in each case and a fully auditable distribution trail is provided. Overall, this leads to higher quality, increased speed and regulatory compliance. In addition, compound level reporting removes duplication of notifications to those sites participating in multiple studies investigating the same compound, thereby reducing investigator burden.

The solution also features reporting functionality and a dashboard showing both individual and aggregate submissions at a study and portfolio level. This provides the sponsor with increased transparency to monitor and manage drug safety.

“The regulatory landscape is continually evolving which makes drug safety reporting increasingly complex,” commented Andy Garrett, Executive VP Scientific Operations, “Combining our drug safety and regulatory expertise with innovative automation elevates ICON’s safety reporting by reducing the burden on investigator sites whilst showing clear benefits in terms of regulatory compliance”.

The system used in delivering this enhanced service to sponsors is built on the Pega 7 cloud platform, a market leader in AI and business process management software. It can be deployed with any pharmacovigilance safety database, including the option to use as a stand-alone solution, avoiding additional sponsor technology expenditure.

ICON’s Automation Centre of Excellence is dedicated to streamlining processes using Artificial Intelligence (AI) and Robotic Process Automation (RPA) to maximise human capital to accelerate clinical trial delivery.

About ICON plc

ICON plc is a global provider of outsourced drug development and commercialisation solutions and services to the 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 currently, operates from 93 locations in 37 countries and has approximately 13,680 employees.

Further information is available at www.iconplc.com

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