



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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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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ICON Media Contact:
Lucinda Sandon-Allum
Weber Shandwick
+44 (0)20 7067 0548
lsandon-allum@webershandwick.com