New Safety Regulations Drive Greater Need for Resources and Expertise at Every Stage of Clinical Development

Study Examines Impact of Regulatory Changes on Pharma Industry

DUBLIN, June 18, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- According to a report issued today, drug safety leaders in pharmaceutical and biotechnology companies recognise the need to increase resources, either internally or through partnerships, to comply with the safety regulations recently issued by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMEA). The report - Safety First: The Impact of New Regulations on Clinical Development - is based on a survey of 140 industry safety specialists, including heads of medical, drug safety, pharmacovigilance, and regulatory departments within large and mid-sized pharmaceutical companies and biotech firms. The survey found that more than three-quarters (77%) of respondents believe that new safety regulations have had a considerable impact on the industry as companies implement drug safety regulations throughout the clinical development process.

The FDA and EMEA have recently introduced more rigorous safety regulations, with a particular emphasis on post-marketing surveillance, to ensure that medications are monitored for their safety and effectiveness over the long term, across wide populations, and in real-life settings. The survey findings also highlighted regulatory departments in particular as having a pressing need for greater resources, with more than half of those surveyed (53%) requiring resources within the next six months.

"The transition from performing passive post-marketing surveillance to active safety monitoring using Phase IV studies, safety registries and comparative effectiveness programmes, is to ensure that benefit/risk re-assessment continues as safety information on the real-world use of products is revealed. Although initially resource intensive, this more rigorous approach to obtaining and analysing post-approval safety data will better ensure the public's confidence in a product's true safety profile. The real challenge will be to find better tools and novel approaches to implement the requirements of regulations efficiently and cost effectively," says Dr. Suzanne Gagnon, Chief Medical Officer, ICON Clinical Research.

The report was commissioned by ICON plc, a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, and developed by IMS Health, the world's leading provider of market intelligence to the pharmaceutical and healthcare industries.

Phase IV activities, including observational trials or "safety registries" that gather data on the use and effectiveness of medications in the real world are expected to be particularly impacted by new regulations, according to the survey. Eighty percent of respondents anticipate the number of Phase IV trials to grow over the next five years, while 58 percent indicated that safety registries increasingly will be used to monitor drug safety at every stage of the clinical trial process.

"The move toward greater transparency around drug safety remains a regulatory and political priority worldwide," says Nigel Burrows, Senior Principal, Management Consulting, IMS. "The pharmaceutical industry has and continues to respond to this challenge, both in drug clinical development and commercialisation. These efforts have the potential to go beyond simply satisfying regulatory requirements, leading to more clinically effective and commercially viable advances that improve outcomes and set new standards of care."

Notes to editors

Survey methodology

ICON commissioned IMS Health to conduct a survey that explored global trends in drug safety issues, and to evaluate the impact of recent safety regulations on the industry. A total of 140 people were questioned via a telephone interview, and included the heads of pharmacovigilance, safety and clinical research functions among pharmaceutical and biotechnology companies. Respondents included 59 from large pharmaceutical companies, 56 from mid-size pharma companies and 25 from biotech companies. All respondents have global or regional-level responsibilities. Analysis and insight are based on interview responses. Confidence levels of 90% were applied to analyze statistically significant differences within the results.

About ICON

ICON plc is a global provider of outsourced development 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 71 locations in 38 countries and has approximately 7,100 employees. Further information is available at http://www.iconplc.com

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