# ICON Selected by the FDA to Validate Patient-Reported Outcome Endpoints for Antibacterial Drug Trials

***Research is being conducted in collaboration with the FNIH Biomarkers Consortium***

**Dublin, Ireland, 20 February 2017 – ICON plc, (NASDAQ: ICLR)** a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries, today announced that it has been awarded a project by the US Food & Drug Administration (FDA) to validate three Patient Reported Outcomes (PRO) instruments that will measure clinical endpoints in antibacterial drug trials. The conditions in which the endpoints will be validated are Acute Bacterial Skin and Skin Structure Infections (ABSSSI), Community-Acquired Bacterial Pneumonia (CABP) and Hospital-Acquired Bacterial Pneumonia (HABP).

HABP is the second most common hospital-acquired infection and is the primary cause of death in intensive care units; ABSSSI has high rates of morbidity and other associated medical conditions whilst CABP is a major cause of mortality and morbidity worldwide, particularly among people over 65 years of age. Sponsors engaged in clinical trials for these conditions are currently using different methodologies to assess the primary endpoint as there is no qualified PRO instrument.

ICON's Clinical Outcomes Assessment (COA) group, in collaboration with the Biomarkers Consortium of the Foundation for the National Institutes of Health (FNIH), will create an electronic platform to validate key PROs, allowing investigators to assess the symptoms of ABSSSI, CABP and HABP at various time points over the course of the infection and measure the effects of antibacterial drugs. The PROs will be implemented on CRF Health's TrialMax® eCOA platform, allowing patients to use the application on a handheld device during the course of the trials. These PROs will continue to be validated and developed in accordance with the FDA guidance for PRO measures used to support labeling claims and will follow the Drug Development Tool (DDT) Qualification Program.

The collaboration brings together scientists from ICON, FNIH, the FDA, the National Institute of Allergy and Infectious Diseases, the Infectious Diseases Society of America, pharmaceutical and biotechnology companies and the academic research community, to develop new approaches for evaluating the efficacy of antibiotics in future clinical trials of therapies for ABSSSI, CABP and HABP.

*"This project builds on our previous work with the FDA and FNIH to develop a new PRO measure for HABP trials and we're proud to continue our support in this area of great unmet need,"* commented Ramita Tandon, Executive Vice President, ICON Commercialisation & Outcomes. *"Bacterial infections are becoming harder to treat as drug-resistant strains emerge at an increasing rate. ICON's COA group has extensive experience in all areas of outcomes research to validate these important endpoints for antibacterial trials, speeding up the drug development process and delivering effective antibacterial medicines to patients."*

**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 87 locations in 38 countries and has approximately 12,500 employees. Further information is available at www.iconplc.com.

**About the FNIH**

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world's premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate key issues of scientific study and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1996, the FNIH is a not-for-profit 501(c)(3) charitable organization. Further information is available at www.fnih.org

**About the Biomarkers Consortium**

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to develop, validate, and/or qualify biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis and treatment of disease and improve patient care.
Further information is available at www.biomarkersconsortium.org

**About CRF Health**

CRF Health is the leading provider of patient-centered eSource technology and service solutions for the life sciences industry. With experience in more than 800 trials, over 100 languages and across 74 countries, CRF Health's TrialMax® platform consistently demonstrates the industry's highest data accuracy, patient and site compliance, and patient retention.

CRF Health's eSource solutions improve trial engagement by fitting into the lives of patients and seamlessly integrating into sites to maximize protocol compliance. The integrated TrialMax® platform includes eCOA solutions for collecting PROs (Patient Reported Outcomes), ObsROs (Observer Reported Outcomes), ClinROs (Clinician or Rater Reported Outcomes), and PerfOs (Performance Outcomes), and features TrialConsent™, an electronic solution for collecting informed consent in clinical trials. More information is at http://www.crfhealth.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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