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For immediate release

CIRS receives grant to help strengthen the regulation of medicines in low- and middle-income countries

London, UK 29 March 2016 – The Centre for Innovation in Regulatory Science, Ltd (CIRS) today announced that it has been awarded a 4-year grant from the Bill & Melinda Gates Foundation to develop and implement a performance metrics programme to assess, measure and strengthen systems for the regulation of medicines in low- and middle-income countries (LMICs).

Many national regulatory agencies, especially those in LMICs, have limited resources to effectively regulate the quality, safety and efficacy of medical products. These limitations result in an increased likelihood of poor-quality medicines in these jurisdictions as well as delays in the review and approval of critical new therapies. Having a process for assessing their performance against international standards for product assessment metrics is a tool many agencies in high-income countries have found helpful in improving their regulatory performance.

This grant

- provides support to convene forums for regulatory agencies in low- and middle-income jurisdictions to learn about performance metric tools that will build their regulatory performance
- underwrites the development and implementation of a metrics collection process through which
 - regulatory agencies in low- and middle-income countries can assess their own regulatory process performance metrics
 - the use and effectiveness of regional cooperation initiatives that support work-sharing and referencing can be gauged
 - objective information can be garnered for use by agencies to justify funding from their governments and other stakeholders for capacity building and further implementation of international regulatory best practices
- funds the development and implementation of mechanisms to communicate results back to regulatory agencies to provide a continuous learning feedback loop

Initiation of interactions with national regulatory agencies and regional cooperative groups across Asia, Latin America and Africa will begin over 2016-2017. CIRS envisions that the project will embed a culture within regulatory agencies of tracking and measuring review performance to promote continuous improvements including potential reductions in review and approval times without compromising product safety, efficacy, or quality. Executive Director Lawrence Liberti said “CIRS is proud to collaborate with the Bill & Melinda Gates Foundation in this programme to measure progress and facilitate change that will promote best practices and enhance the predictability, transparency, timeliness and quality of regulatory review and ultimately increase the availability of vital medicines.”

About CIRS

CIRS - The Centre for Innovation in Regulatory Science - is a neutral, independent UK-based subsidiary company, forming part of the Intellectual Property and Science business of Thomson Reuters. The mission of CIRS is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science. It is governed and operated for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities and grants. For more information, go to www.cirsci.org.