

## ACRES and QMI Launch Quality Management Continuum for the Clinical Research Enterprise

A new partnership between ACRES and Florida-based Quality Management Institute (QMI) is rolling out a comprehensive professional quality management system to provide a global framework for ongoing safety-focused performance improvement initiatives in healthcare, research and medicines development.

CAMBRIDGE, Mass. (PRWEB) December 12, 2017 -- The Alliance for Clinical Research Excellence and Safety (ACRES) President and CEO, Dr. Greg Koski, and Dr. Larry Kennedy, Founder and CEO of the Quality Management Institute (QMI), announced that the two organizations will unite efforts to build and deploy a comprehensive professional quality management systems environment to enhance performance, safety, and efficiency across the health care and sciences ecosystem. The approach is modeled after similar highly successful efforts in the aerospace and air transport industries.

The new initiative, expanding upon their existing strategic alliance agreement, will bring QMI's extensive expertise, online training programs and professional certifications in quality management into the ACRES Quality Continuum, providing a unifying framework for ACRES' multiple system-building initiatives, in particular the ongoing Site Accreditation Standards Initiative (<u>SASI</u>).

Under the terms of the new partnership, Dr. Kennedy will join the ACRES management team as V.P. for Quality Management Systems and Chief Quality Officer (CQO). As V.P., he will assume broad responsibility for the development, testing and implementation of global consensus standards for high-performing sites of clinical research excellence while retaining his role as CEO of the Quality Management Institute (QMI). He will also serve as liaison between ACRES and the British Standards Institution (BSI), which is partnering with ACRES to create standards and processes for accreditation of clinical research sites.

Dr. Kennedy, who brings more than 30 years of systems engineering and quality management expertise from aerospace, business and nonprofit enterprises to ACRES, will provide QM leadership to support ACRES overall vision. He has been instrumental in the development of the ACRES Quality Continuum and will Chair the Site Accreditation and Standards Initiative (SASI) with support from co-chairs Terry Stubbs and Beth DiGiulian and advisors Amir Kalali and Arti Bajpai.

ACRES, a global non-profit collaborative working to build a comprehensive shared system for clinical research, has adopted QMI's 2QR® Curriculum for a High-Performing Work Culture as the foundation for the development of the SASI team and to assist Site Leadership in effectively deploying standards. The online, state-of-the-art 2QR® curriculum will be made available to all ACRES constituencies and will enable the broadening of ACRES collaborations across the health sciences and medicines development enterprise.

"The pursuit of high-quality outcomes is the common thread that runs through every effort to improve healthcare, research, and medicines development and it provides the framework for achieving excellence. But significant improvement means that quality management must be recognized as a professional discipline and as a cultural imperative within the ecosystem that is clinical research," said Kennedy.

Under Kennedy's leadership, the leaders and members of the 10 domain teams currently working to develop standards within SASI are obtaining professional certification in quality management. Terry Stubbs, President



and CEO of ActivMed Practices & Research, Inc, and Administrative Co-Chair of SASI team agrees "This is such a positive move for the industry. The training programs will teach and then reinforce important business practices, helping research sites thrive when they apply what they learn and pass on this information to all members of their team. This will embed the new approach firmly within their day-to-day operations."

"These developments come at a critical moment, when global leaders from industry, academia and government are calling for voluntary accreditation of clinical research sites as an effective means of enhancing and accelerating safe development of new medicines—ACRES remains at the forefront of these efforts as we continue to push forward", said Koski.

ACRES objective and ensuing efforts to realize global accreditation of clinical research sites began 5 years ago. ACRES and BSI expect the initial version of standards to be ready for public comment by the 2nd quarter of 2018. Efforts to concurrently develop processes for "dynamic accreditation" are also underway. Pilot testing is expected to occur in 2018 with initiation of the accreditation process as early as 2019.

Alliance for Clinical Research Excellence and Safety (ACRES)

The Alliance for Clinical Research Excellence and Safety (ACRES) is a non-profit alliance working in the public interest. Bringing together stakeholders spanning the clinical research ecosystem to build an open, integrated global system based in principles of Accountable Research<sup>™</sup>, ACRES adapts lessons from industries successfully implementing principles of systems and safety engineering, such as transportation, communications and information technology. For more information, please contact Mary F. Tobin, PhD, Special Advisor to the President and CEO at mtobin(at)acresglobal(dot)net.



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