ACRES Unveils Global Quality Standard for Clinical Research Site Accreditation

The Alliance for Clinical Research Excellence and Safety (ACRES), a multi-stakeholder non-profit public-interest collaborative building a comprehensive global system to accelerate medicines development, has released for public review and comment the first global quality standard for clinical research sites, creating a foundation for voluntary accreditation.

CAMBRIDGE, Mass. (PRWEB) July 17, 2018 -- The Alliance for Clinical Research Excellence and Safety (ACRES) announced in the New England Journal of Medicine the release of a global quality standard for clinical research sites. This release follows the recommendation for voluntary accreditation of clinical research sites to enhance quality and performance in multi-center clinical trials voiced by Clay Johnston, Dean, Dell School of Medicine, University of Texas; Chris Austin, Director, National Clinical and Translational Sciences program, NIH; and Freda Lewis-Hall, Chief Medical Officer and Executive Vice President, Pfizer.

This initial quality-focused standard is the product of a seven-year effort by multi-stakeholder teams convened by ACRES as part of its foundational Site Accreditation Standards Initiative (SASI). In 2014, a steering committee led by Tracy Blumenfeld (RapidTrials, Inc) and Linda Meyerson (formerly of GlaxoSmithKline) provided advice and direction for the standards development process, based upon results of a global survey. The effort advanced further under the guidance of Arti Bajpai (Quality Management Consultants) and Amir Kalali (CNS Summit).

Two-years ago, Dr. Larry Kennedy, CEO of Orlando-based Quality Management Institute (QMI) joined ACRES as Vice-President for Quality Management Systems and Chief Quality Officer. Kennedy, with 30 years of quality engineering experience from the aerospace industry, and assumed leadership of the effort, assembling a team of committed experts from every sector of the clinical research endeavor and partnering with Reginald Blake of the highly-respected British Standards Institution (London, UK) to draft the initial standard.

“To say this has been a team labor of love is an understatement. A whole lot of love for clinical research and the good that it does has gone into this effort and I believe our work product shows it!” Kennedy stated.

Greg Koski, ACRES CEO, congratulated the team and laid out plans for development and roll-out of the accreditation process. The draft standard is available for public review and comment from July 1 through October 31, 2018 after which an initial working standard will take effect. During the comment period, the standard will be “pressure tested” at selected sites expressing interest in accreditation. Details of the process will be released late this year and plans for pilot testing of the accreditation process are set for early 2019.

Koski acknowledged the progress made under Kennedy’s leadership. “Few initially had much confidence that a workable, consensus standard could be achieved in a reasonable timeframe, given the complexities of this environment worldwide. Impressively, Larry Kennedy, by focusing on quality as the essential common element for all responsible clinical research, has managed to do just that. Now, all stakeholders must to work together to realize value from effective application of the standard.”

“We are seeing enthusiasm for voluntary accreditation among sites committed to professionalism and high-performance as a way to be rewarded for their commitment to excellence,” said Koski. “Accreditation will benefit not only sites, but the entire medicines development enterprise from sponsors to patients. We are

working with sites to get this done in a way that meets their needs with minimal administrative burdens."

With an essential foundation for voluntary accreditation of clinical research sites now available, Dr. Freda Lewis-Hall, who launched the ACRES Global Consultation on Site Accreditation with her keynote address at the 4th Annual Assembly in San Diego in 2015 and recently joined Johnston and Austin in their call for action, greeted the ACRES announcement with enthusiasm, saying, "As a study sponsor, Pfizer seeks to hold all of our clinical trial site partners to high standards of excellence in conduct and execution. Accreditation of study sites is a useful tool to add to the methods sponsors may use to assess quality and reliability."

Concurrent with initial testing of the standard, ACRES Dynamic AccreditationTM Working Group is developing models and applications to integrate with ACRES technology-partners EXOCHAIN (Kennebunk, ME) and BlueCloud (Austin, Texas) to enable an innovative, real-time technology-assisted process that reduces the cost of accreditation while minimizing strain on sites. Dr. Michael Brown of Acesis, a Boston-based cloud solutions-provider that automates and improves healthcare administration by turning ad hoc administrative tasks into efficient technology-supported processes, expects to announce details later this year.

About ACRES

The Alliance for Clinical Research Excellence and Safety (ACRES) brings together all clinical research stakeholders to build an open, integrated global system. ACRES applies principles of systems and safety engineering, adapting lessons from industries such as transportation, communications and information technology.

If you would like more information about this topic, please contact Mary F. Tobin, PhD, Chief Strategy Officer and Special Advisor to the President/CEO, at mtobin(at)acresglobal(dot)net.

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