

ACRES Testing Clinical Research Site Accreditation Process

The Alliance for Clinical Research Excellence and Safety has begun the process of validating the first global standard for clinical research sites and testing the process for voluntary accreditation of sites. The first test case is with ActivMed Practices and Research Inc.

CAMBRIDGE, Mass. ([PRWEB](#)) October 02, 2018 -- The Alliance for Clinical Research Excellence and Safety ([ACRES](#)) announced this week that teams have initiated validation of standards and testing of procedures for voluntary accreditation of clinical research sites. The first evaluation effort, under the direction of Dr. Larry Kennedy, ACRES VP for Quality Management Systems and Chief Quality Officer, is underway in association with [ActivMed Practices](#) and Research, Inc.

ACRES is a global non-profit working with nearly 150 strategic allies worldwide to build a global system to enhance quality and safety of clinical research and accelerate new medical products development. ACRES released the first global standard for clinical research sites at the end of June for public review and comment ([access here](#)).

ActivMed, founded in 1994 and headquartered in Methuen, Massachusetts, operates 3 clinical research offices north of Boston. It has successfully completed nearly 720 clinical trials and received numerous awards, including the CorporateLiveWire International Award for Excellence in Clinical Research Services for 2018.

ActivMed president and CEO Terry Stubbs, CCRC, who also co-chairs the ACRES Site Accreditation and Standards Initiative (SASI), notes that “Our goal at ActivMed is to offer a compassionate, friendly, and positive research experience for our patients while gathering information to benefit everyone. A culture of excellence has always been a goal for our site. The idea of site accreditation is an important one--we are sure that both our site and ACRES will learn more as we move through the beta-testing of the standards. After all, research IS a learning process and I am delighted that our team is participating in development of this “first of its kind” accreditation process.”

The systems testing at ActivMed is being led by Dr. Mary Westrick, University of Wisconsin-Madison and Dr. James Riddle, Vice President of Client Services at Kinetiq, a consulting and technology division of QuorumReview, a Seattle-based independent ethics and regulatory review board that assures the ethical integrity of clinical research.

Riddle notes “Quorum IRB strongly supports ACRES efforts in bringing improved quality and safety to clinical research through voluntary site-accreditation. At Quorum, we have seen first-hand the positive impact accreditation can have on performance and quality of Human Research Protection Programs at academic institutions, hospital systems and private research organizations. We expect the ACRES SASI effort to have a similar transformative impact on clinical research worldwide.”

Dr. Kennedy, CEO and founder of Florida-based [Quality Management Institute](#) and leader of the ACRES effort since 2015, explained that the release of the standard for public comment and “pressure testing” now underway are important milestones along the path to implementation of a robust, voluntary global site-accreditation process. “We have a superb, well-qualified team that is committed to getting this done! Based upon the comments we receive from stakeholders and the results of this field testing, we expect to make necessary adjustments and prepare for pilot implementation—we are on target to begin accreditation in January 2019.”



Dr. Greg Koski, ACRES CEO and co-founder, recognized Kennedy and the SASI team, noting “Today we have industry and academic leaders calling for voluntary site accreditation and sites getting in line to be first. This is truly a transformational moment; a job well done!”

After the pilot program, ACRES will commission an independent study to evaluate the impact of accreditation on site performance and research quality, both of which dramatically impact cost and time required to develop a new medical product. Concurrent with testing and impact assessment, a working group is developing a technology-assisted process known as “Dynamic Accreditation™”, an innovative approach that will provide real-time feedback to sites, sponsors, CROs, regulators and patients about site-performance and recognize sites that fulfill their commitment to excellence.

Kennedy, whose background includes work on the Apollo space program, brings more than 35 years of quality systems engineering to the ACRES effort. “This is all about quality—about building a culture of quality and a system to support it”, said Kennedy. “What we do in clinical research is important to everyone, and we have a responsibility to ensure that it is done right--and that is precisely what this system will do.”

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. For more information, please contact Mary F. Tobin, PhD, Chief Strategy Officer and Special Advisor to the President/CEO, at [mtobin\(at\)acresglobal\(dot\)net](mailto:mtobin@acresglobal.net).



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