SITE ACCREDITATION AND STANDARDS INSTITUTE

3-STEPS TO ACCREDITATION

(Landscape Mode (Horizontal) Recommended for Mobile Phones)

NEED FOR CLINICAL RESEARCH SITE QUALITY ACCREDITATION

The NEW ENGLAND JOURNAL of MEDICINE

October 12, 2017

- "Site-to-site variability in start-up time, recruitment, and protocol adherence is substantial and contributes to the cost of trials and the reliability of their findings — and ultimately slows the pace of innovation and improvements in health."

- Proposal: "a voluntary site-accreditation system could encourage the creation of a higher-quality system that could speed the development of new therapies."

A GLOBAL STANDARD FOR QUALITY AND SAFETY

A Vision to Write, Test, and Accredit

ACRES created the SASI "Initiative," engaged the British Standards Institute and the Quality Management Institute, to write and test the Standard; and then spun-off the independent, first of its kind accreditor, the Site Accreditation and Standards "Institute."

- A Clinical Research Site Standard grounded in GCP, and focused on QM fundamentals that creates a quality system and a culture of competence and conscience that delivers high-quality trial data.
- Announced on June 28, 2018, in NEJM article.

WHAT IS A QUALITY MANAGEMENT SYSTEM?

- A system with methods for planning, executing, assessing and improving quality
- Enables proactive quality management
- Establishes clear process owners
- Addresses all aspects of an organization's work-flow
- Increases customer satisfaction
- Improves operational efficiency and reduces waste
- Lowers defects and errors
- Ensures a more engaged workforce

QUALITY MATTERS TO CLINICAL RESEARCH SITES

- **Increase Sponsor's Trust** that your site produces reliably consistent data
- **Secure More Studies** as sponsors prioritize accredited sites
- **Engage and Retain Your Best Staff** by supporting a quality culture
- **Reduce Process Errors and Risk** with consistent quality standards
- **Minimize Costs** associated with poor quality
- **Improve Recruiting and Retention** of Study Participants

QUALITY MATTERS TO CLINICAL RESEARCH SITE LEADERS

“The emphasis on "QM culture" in the Standard resonated with our staff. They loved the training and appreciated the new QM credential earned on their CV's. Throughout the SASI process we enjoyed how the Standard confirmed what we were doing right as well as what systems needed tweaking to implement better quality management."

Terry Stubbs, Vice President
ActivMed Practices and Research, LLC and
ALLCUTIS Research, LLC

QUALITY MATTERS TO CLINICAL RESEARCH SITE STAFF

“With Sponsors and the FDA putting pressure on sites to better manage their quality, the SASI Standard provided a way for us to demonstrate we are doing just that. The CRQM staff certifications pointed the way and created a new career ladder."

Michael Ellis, CEO
Avanza Medical Research

QUALITY MATTERS TO SITE-SPONSOR RELATIONSHIPS

“The SASI Standard and QMI training were critical in getting our site recognized for excellence. We have seen significant increases in study volume and revenues, as we publicized our preparations for accreditation and Sponsors took a closer look."

Kurt Zimmerman, Senior Director
Office of Biohealth Industry Partnerships,
School of Medicine and Public Health,
University of Wisconsin-Madison

QUALITY MATTERS TO SPONSORS

“Sponsors get all of the benefits of higher quality research, and additionally, I believe they can decrease their site oversight efforts and costs by at least 30%.”

Briggs Morrison MD
CEO of Crossbow Therapeutics
Former Chief Medical Officer at AstraZeneca
Former SVP (Head of Global Clinical Development) at Pfizer

QUALITY MATTERS TO ADVARRA

“Supporting clinical research sites in conducting safe and efficient research is key to delivering quality therapeutics and devices to market. We are encouraged to see so many sites stepping forward to validate the quality of their programs through SASI accreditation."

James Riddle, MCSE, CIP, CPIA, CRQM
SVP, Global Review Operations
Advarra
SASI Accreditation Council Founding Member

QUALITY MATTERS TO WCG

“Quality and safety are reciprocal essentials in providing a secure environment for clinical trial participants and efforts to produce reliable data. A SASI accredited quality management system increases the comfort level of all parties in a clinical trial."

Sandra Smith, RN, MSN, AOCN
SVP, Clinical Solutions and Strategic Partnering
WCG
SASI Accreditation Council Founding Member

QUALITY MATTERS TO EVERYONE ON THE SASI QUALITY CONTINUUM

“From the participant in a clinical trial to the patient receiving treatment from a physician, the measures of "safe and effective" begin at the trial site. A SASI accredited quality management system reduces risk across the entire enterprise."

Larry Kennedy, PhD
Executive Director
Site Accreditation and Standards Institute

SASI-QMS:2023-2
STANDARD FOR THE
QUALITY MANAGEMENT
OF CLINICAL RESEARCH SITES

HOW IT WORKS

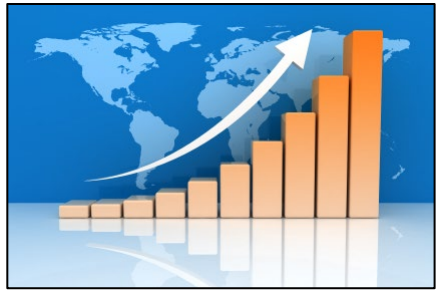
3-STEPS TO SASI ACCREDITATION

3-STEPS TO SASI ACCREDITATION

Step 1: Explore

"Test-drive'' accreditation with expert guidance and identify quality gaps

Step 2: Improve



Take the "SASI Pledge" and make the improvements necessary for accreditation

Step 3: Get Accredited

SASI ACCREDITED
KEEPING-THE-PROMISE QUALITY MANAGEMENT SYSTEM ™

Commit to the conformity assessment and steps to full accreditation

STEP 1: Test-Drive Accreditation in the SASI Exploratory Program

- An engaged and educational process with SASI liaison
- Expert instruction on the SASI Standard and its Accreditation Protocol
- Learn the value of creating a "Keeping the Promise" work culture and certify two Clinical Research Quality Management leaders to manage the task[1]
- Project scoping and gap analysis to map your Site's path to accreditation
- Role play the conformity assessment with a SASI Site Surveyor

$4944 Per Site. **Sites will not be accredited through the Exploratory Program.** The purpose of the Exploratory Program for Sites and Site-organizations is to learn about the standard, experience and evaluate the benefits of accreditation, and then decide on a course of action.

Explore

[1] Online training and certification by the Quality Management Institute

STEP 2: Take the "SASI Pledge" to Improve and Prepare for Accreditation

Taking the SASI Pledge will enable you to increase Site income as you publicly pledge your commitment to "Quality and Safety." You can promote your commitment to accreditation in your own words to sponsors, IRBs, or potential trial participants with a confirming link to your SASI Pledge page on our website.

- Create an improvement plan to resolve the gaps and risks discovered during the Exploratory Program that fits your financial and human resources.
- Improve your quality culture with additional QMI CRQM Certifications[1].
- Expand the Exploratory Program to additional sites.

"We have seen significant increases in study volume and revenues, as we publicized our preparations for accreditation and Sponsors took a closer look." University of Wisconsin-Madison

Improve

[1] Online training and certification by the Quality Management Institute

STEP 3: Complete the Accreditation Protocol

- The CRS begins the Accreditation process with accurate cost estimates based on the scoping of the CRS in the Exploratory Program.
- The CRS staff submits the documents demonstrating conformance to the Standard via the SASI Accreditation Management Directory.
- SASI Surveyors and CRS leaders will collaboratively review non-conformances that must be addressed to achieve SASI Accreditation.
- When SASI Surveyors have confirmed conformance to the Standard, and a site visit is successfully completed, the Surveyors will submit their report to the SASI Accreditation Council for review and approval.
- If approved, the site's SASI Pledge Page will be updated from "Candidate" to "Accredited" with its unique serial number and date of expiration.

Get Accredited

For More Information Click the Links on each slide and below.

- Visit the SASI Drill Down Page for a Wide Variety of Information, Including SASI History, Press Releases, Resources, FAQ's, etc.
- Contact Us to Enroll in the Exploratory Program
- Contact us for a Consultation. Email: admin@sasi-accreditation.org