



# **THE SITE ACCREDITATION AND STANDARDS INSTITUTE**



**The "North Star" for Clinical Research, and  
the Standard for Site Quality and Safety**

# The SASI-QMS: 2023-2 Global Standard for Clinical Research Site Quality and Safety

The [SASI-QMS: 2023-2](#) is grounded in GCP and focused on QM fundamentals that deliver high-quality trial data. When properly applied, it creates a quality management system with a "Keeping the Promise®" supporting culture of competence and conscience.



# **The SASI-QMS: 2023-2 Aligns with Essential QM Global Standards**

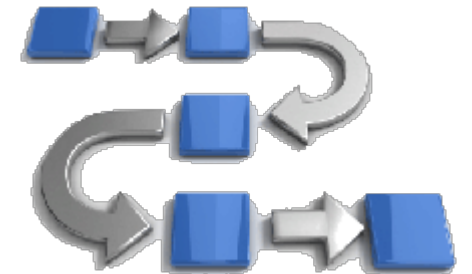
*Easy to learn and apply with incremental steps of marketable staff and process certifications leading to full Accreditation*

- **ISO 9000: 2015, Quality Management Systems - Fundamentals**
- **ISO 9001: 2015, Quality Management Systems - Requirements**
- **ISO 9004: 2018 Quality Management - Quality of an Organization**
- **ISO 27500: 2016, The Human Centered Organization**
- **ICH 6E R3: 2025, Guidelines for Good Clinical Practice**
- **Quality Management Institute, KTP Complete QM**



# Quality Management 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 errors and 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 improvement 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 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  
Chair and Executive Director  
Site Accreditation and Standards Institute**



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

## **HOW IT WORKS**

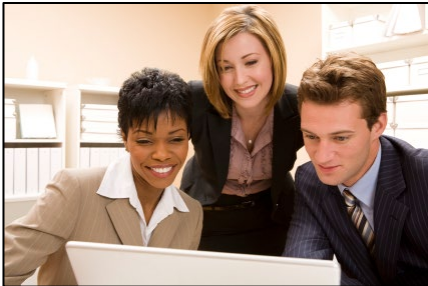


## **3-STEPS TO SASI ACCREDITATION**



# 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  
increase Site income while you  
prepare for accreditation

## Step 3: Get Accredited



Request the official  
conformity assessment and  
complete the accreditation

# STEP 1: Test-Drive the Road to Accreditation with the SASI QM Framework Program

- An engaged, educational, online, and manageable process with a SASI liaison
- Expert instruction on the SASI Standard and its Accreditation Protocol
- Guided site-scoping and gap analysis to map your Site's path to accreditation
- Emphasis on site growth, marketing, leadership development, and profitability
- Self-paced online study to certify two Clinical Research Quality Managers (CRQM) to manage the task of building a profitable, accreditable, culture<sup>1</sup>

\$5495 Per Site. (Less than the costs associated with attending one conference with tuitions and travel expenses.) The purpose of the QMFP is to learn about the SASI Standard, experience and evaluate the requirements and benefits of accreditation, identify the Site strengths and gaps; equip two leaders to forge the way, and then create a profitable plan to pursue and achieve accreditation.

Explore

<sup>1</sup> Online training and certification by the [Quality Management Institute](#)

## STEP 2: Take the "SASI Pledge" to Improve, Increase Income, 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 QM Framework Program that fits your financial and human resources.
- Improve your quality culture with additional QMI Certifications<sup>1</sup>.
- Expand the QM Framework 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

<sup>1</sup> Online training and certification by the [Quality Management Institute](#)

# **STEP 2-Plus: Improve Where it Produces Income with Staff and Process Certifications**

SASI has partnered with QMI to deliver specialized training that immediately creates positive impact with smoother operations, efficiency, and profitability.

Clinical Research Quality Manager (CRQM) Certification<sup>1</sup>

Clinical Trial Enrollment Professional (CTEP) Certification<sup>1</sup>

Clinical Research Staffing Professional (CRSP) Certification<sup>1</sup>

Keep pressing toward the North Star of Clinical Research, the SASI-QMS: 2023-2 Standard. Focus on the growth, strengthening, and marketability of your business by delivering quality services.

**Improve**

<sup>1</sup> Online training and certification by the [Quality Management Institute](#)

# **STEP 3: Set a Course to the SASI North Star. Grow Your Business and Get Accredited**

- When ready, the CRS staff will submit the documents demonstrating conformance to the Standard via the Accreditation Management Directory.
- SASI Surveyors and CRS leaders will collaboratively review non-conformances that must be addressed to achieve SASI Accreditation.
- After the 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.
- Following approval, the site's SASI Pledge Page will be updated from "Candidate" to "Accredited" with a unique serial number; and the "SASI Accredited" icon can be added to your website.



*For More Information Click the Links on Each Slide and Below*

- [Visit the SASI Drill Down Page](#) for a Wide Variety of Information
- [Contact Us](#) to Enroll in the QM Framework Program

