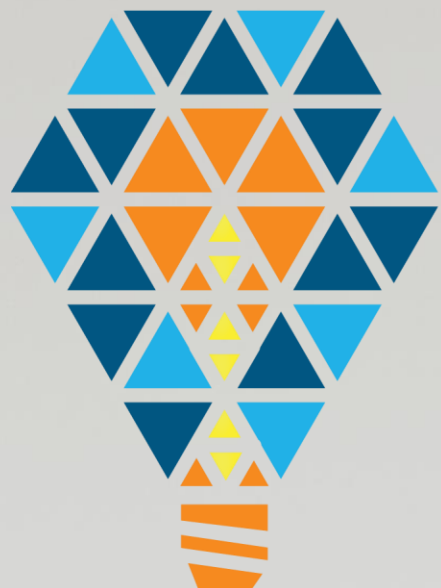




SCRS WEST

Site Innovation Summit

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The New Era of Site Quality: Compliance to Innovation

June 1, 2026

PARTNERING FOR SUCCESS



Faculty Disclosure



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I do not have financial or other relationships with the
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this educational activity.**

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Criteria for Awarding Contact Hours



Applicants must be present during the “live” event; contact hours are not issued for recordings.

Applicants must attend the activity for the entire duration, missing no more than 10 minutes.

Applicants must complete the post-meeting survey with a score of at least 70%.

Applicants must complete the post-meeting survey.

Society for Clinical Research Sites, Inc. is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center’s Commission on Accreditation.



The New Era of Site Quality: Compliance to Innovation



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Agenda



- **Welcome & Introductions**
- **Why We're Here. Setting the Tone**
- **Evolution of Quality Frameworks**
- **Defining Site Quality: The Five Domains**
- **INTERACTIVE: Whiteboard on the Five Domains**
- **Examples of Quality Indicators**
- **Key Takeaways & Close**

Clinical Research Sites at the Center of Quality Innovation

- Transform protocols into consistent, high-quality execution
- Embed participant safety into every process and decision
- Integrate regulatory compliance into streamlined workflows
- Ensure data integrity through standardized and scalable processes
- Leverage innovation (technology, analytics, and workflows) to improve quality and efficiency



Operational Responsibilities = Quality Risk Points



- ***Patient Recruitment & Informed Consent***
 - Risk of misunderstanding, enrollment delays
- ***Protocol Implementation***
 - Risk of deviations and inconsistency
- ***Data Collection & Reporting***
 - Risk of errors, missing or late data
- ***Safety Monitoring***
 - Risk of delayed or incomplete reporting

Innovation in quality processes focuses on reducing variability and mitigating these risks.

Traditional Evaluation of Clinical Research Sites



Historically, site performance has been measured by:

- Enrollment speed
- Start-up timelines
- Participant recruitment numbers

But...

- Limited focus on data quality and protocol adherence
- Minimal visibility into process consistency and deviation risk
- Reactive vs. proactive quality oversight



Operational metrics alone cannot measure:

- Regulatory compliance
- Data integrity
- Staff competency
- Patient safety practices



*How do you elevate the importance of quality at your site?
What challenges are you experiencing?*

Regulatory Oversight



Multiple layers of oversight ensure compliance:

- **FDA and global agency inspections**
- **Sponsor audits and quality reviews**
- **Routine and triggered monitoring visits**
- **IRB / Ethics Committee oversight**

Layers of Oversight

FDA & Global Agencies

Sponsor Audits

Monitoring Visits

IRB / Ethics Oversight

Defining Site Quality



Site quality is multidimensional:

- **Operational performance**
- **Regulatory compliance**
- **Data integrity**
- **Patient safety**
- **Staff training and competency**



Whiteboard: Operational Performance

Beyond enrollment numbers, what does operational excellence actually look like at a high-performing site?

- *What signals tell you a site is well-run?*



Whiteboard: Regulatory Compliance

What separates a site that's compliant on paper from one that's truly compliance-driven?

- *What does a compliance-first culture look like?*



Whiteboard: Data Integrity

What are the biggest threats to data integrity at sites today?

- *What does “good” look like?*



Whiteboard: Patient Safety

How do you measure a culture of patient safety?

- *What signals tell you a site genuinely puts the patient first, not just on paper?*



Whiteboard: Staff Training & Competency

What does a meaningful training program look like, not the annual checkbox version?

- *How do you know it's actually working?*



Investigator Perspective on Quality

“Quality at the site begins and ends with the patient’s safety.”

— Dr. Bruce Corser



Industry Initiatives Supporting Quality



Organizations advancing quality frameworks include:

- **TransCelerate BioPharma**
- **Clinical Trials Transformation Initiative (CTTI)**

Organizations advancing site and workforce excellence:

- **Society for Clinical Research Sites (SCRS)**
- **Association of Clinical Research Professionals (ACRP)**

Audience Questions:



Which of these factors is an indicator of quality for a site?

- a) The percentage of enrolling studies that have met their contracted enrollment goal.
- b) The number of certified coordinators(CCRC/CCRP).
- c) If the site has a locked/secured dedicated drug storage?
- d) The number of FDA audits in the last 10 years with NAI (No Action Indicated)?
- e) All of the above.

Audience Questions:



Which of these factors is an indicator of quality for a site?

- a) They collect demographic information (race, gender, ethnicity).
- b) The site has a dedicated pharmacist on site.
- c) The site is ADA (Americans with Disabilities Act) compliant.
- d) The site engages in community outreach efforts.
- e) All of the above.

Audience Questions:



Which of these factors is an indicator of quality for a site?

- a) The site has a dedicated recruiter(s).
- b) The site uses a CTMS.
- c) The site has SOPs in key areas like SAE reporting, informed consent process, temperature monitoring, etc.
- d) The site has a formal internal education/training process.
- e) All of the above

Key Takeaways

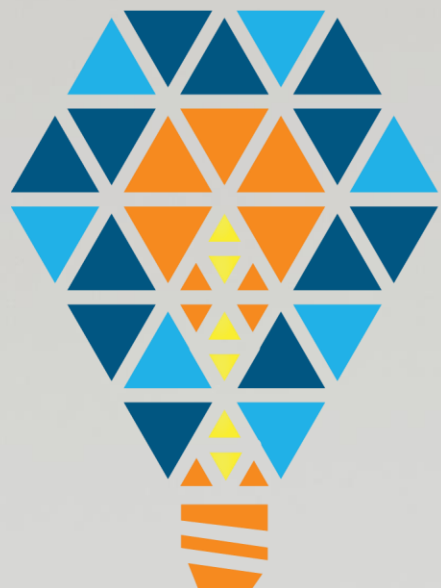
High-quality research sites require:

- Strong regulatory compliance
- Reliable data management
- Operational efficiency
- Patient-centered safety practices

Looking ahead:

- Emerging tools and frameworks are helping standardize quality measurement across the clinical research industry.





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