
20TH
Site Solutions Summit™
ANNIVERSARY

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SCRS Site SPARK AWARD

Site Spark℠

Sponsored By:

Pfizer

October 16, 2026

PARTNERING FOR SUCCESS

SCRS Society for Clinical Research Sites

2026 Judges

SCRS Site SPARK AWARD



Greg Adams

Pfizer



Joshua Carey

Emeritus Research



Kerry Gorman

IQVIA

2026 Finalists

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Crystal Gann
Centricity Research



Michelle Mack
Duke University School of Medicine



Nicole Stiff
Revival Research Institute

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Faculty Disclosure

In compliance with ACCME Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.

Crystal Gann, Centricity Research

Michelle Mack, Duke University School of Medicine

Nicole Stiff, Revival Research Institute

Lauren Stockwell, SCRS



Criteria for Awarding Contact

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

Applicants must attend the activity the whole time, missing no more than ten minutes of the activity.

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

Applicants must complete the post meeting survey evaluation questions.

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.



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Duke Office of Clinical Research

- Central Support Office for all clinical research units.
- In FY26, Duke had 2000 active clinical trials, enrolling ~ 25,000 Duke patients.

WHAT WE SOLVED

- Start Up timelines for Industry sponsored trials averaged over 250 days in FY25.
- Activation delays reduce enrollment windows and access for our patients to clinical trials
- Rapid Study Start Up (RSSU) was created as an initiative to open industry sponsored trials in 90 days and to identify institutional processes that can be improved for all clinical trial start up.
- In the Pilot Program, start up timeline was reduced to 112 days.

INNOVATION OVERVIEW

- A dedicated team for Study Start Up, independent of the Clinical Research Unit (Department).
- Process improvement through the application of project management principles
- Primarily Academic Research centers, or any group interested in streamlining study start up.
- Significant reductions in the average start up timelines.

Key Takeaways

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1

WHAT YOU LEARNED

- A project manager leads start up, serving as the primary point of contact, establishing the timeline, and solving delays. This format reduces delays encountered when start up relies on busy study coordinators.
- Process mapping coupled with clear communication and alignment with sponsor/CRO minimizes delays and repetitive communication.
- Alignment and partnership between site, sponsor, IRB and internal teams is necessary to streamline.
- Not all protocols are the right fit for rapid start up.

2

HOW OTHERS CAN IMPLEMENT

- Mapping of study start up with a reflection on known delays and opportunities to engage with central support offices
- Ensuring effective communication, and connection to the study team to minimize delays with implementation.
- Discuss with internal stakeholders opportunities to reduce delays
- Planning and timeline adherence critical to success
- Consider use of central IRBs

3

FINAL NOTES

- Unanticipated delays were encountered, but with consistent intervention and directed problem solving, the impact was minimized.
- Discussions with key internal infrastructure teams have lead to overall process improvement for all studies
- Staffing can be optimized by using a central start up team
- The number 1 factor in success - COMMUNICATION

RAPID STUDY START UP PROGRAM

Aligned People. Accelerated Processes. Earlier Impact.

FROM PROTOCOL TO PATIENTS FASTER.

THREE KEY PROCESSES. ONE COORDINATED PATH.



PROJECT MANAGEMENT PRINCIPLES DRIVE SUCCESS

STAKEHOLDER MANAGEMENT

- Engage early and often
- Align goals across sponsors, sites, vendors and regulatory authorities
- Proactively manage risks and expectations

CRITICAL PATH FOCUS

- Identify and prioritize critical activities
- across all processes
- Remove bottlenecks quickly
- Maintain cross-functional visibility

TIMELINE ADHERANCE

- Set clear milestones and accountabilities
- Monitor progress with real-time tracking
- Implement corrective actions early
- Deliver on time, without compromising quality

FASTER STARTS | GREATER COLLABORATION | LOWER RISK | MORE PATIENTS. SOONER.

Pilot Study Start Up

Study	Start Up timeline	Comments
Ph1/2a Diabetes	111 days	
Ph1 Diabetes	107 days	
Ph1 Autoimmune	101 days	
Ph2 Angioedema	91 days	
Ph2 Atrial Fibrillation	231 days	Delays due to updated required contracting language
Ph1 Bladder Cancer	143 days	~ 3 week delay due to holidays and board reviews
Pneumonia	119 days	
Ph 3 Heart Failure	83 days	
CAR-T MS	142 days	Upgrade to CTMS delayed final approval
CAR-T PGA	118 days	Submitted simultaneously
CAR-T SLE	119 days	Submitted simultaneously
CAR-T SSc	119 days	Submitted simultaneously
CAR-T IIM	117 days	Submitted simultaneously

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MEET REVIVAL

A multi-site clinical research network with 25+ sites across Illinois, Michigan, Nebraska, New Jersey, North Carolina, Texas and Poland.

THE eSOURCE BOTTLENECK

- eSource for every protocol was built manually and took up to 2-3 weeks, from protocol to approved build.
- Each source builder worked differently, so quality varied by person and by site.
- Small build errors surfaced later as data queries.

MEET PROTOSCRIBE

- ProtoScribe builds a protocol-specific eSource from the protocol and eCRF guidelines in minutes.
- A second, independent AI reviews each build and flags items for human review.
- Built for sites and site networks running many studies at once.

SCAN ME

The ProtoScribe Workflow

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01

UPLOAD

Add the protocol and eCRF guidelines. Choose your formats and instructions.

CLINICAL TEAM

02

BUILD

Saved templates build the visit schedule, forms and edit checks in minutes.

PROTOSCRIBE

03

AI CHECK

A second, independent AI rates each item and flags what needs a closer look.

PROTOSCRIBE

04

HUMAN REVIEW

Your team reviews the flagged items, then approves, edits or regenerates.

CLINICAL TEAM

05

EXPORT

Export the approved build, including a structured file to set up in your CTMS.

CLINICAL TEAM

Not quite right? Regenerate a whole form or just specific questions.

Protocol to approved build: 2–3 weeks →about 2 business days

The ProtoScribe X-Factor

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01

BUILT ON YOUR RULES

- Rules layer from company to site to therapeutic area, so every build follows the same standards.
- Upload past eSources and the tool learns your team's preferences.
- Rules and logic are easy to build and edit.

02

WORKS WITH YOUR TEAM

- Ask it questions and give feedback in real time until the source is complete.
- Regenerate a whole form or just specific questions on a form.

03

FITS YOUR ENVIRONMENT

- Runs on a local LLM, so no data is passed to external AI.
- Works seamlessly with Revival's pre-CTMS.
- Part of a bigger AI support system: feasibility questionnaires, pre-screening, marketing prep and subject screening.

Key Takeaways

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LEARNINGS FROM PROTOSCRIBE

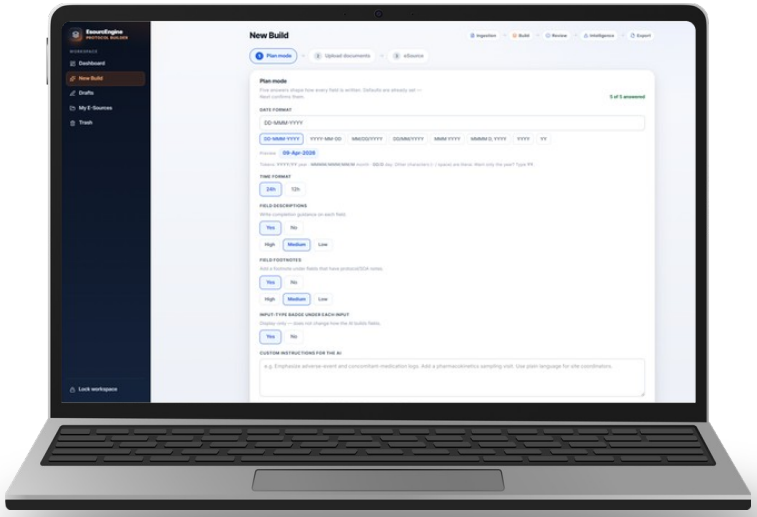
- The AI's first draft isn't always right. A second AI check before human review catches mismatches between the protocol and the eCRF.
- Each therapeutic area needs its own template, and the tool improves as each area is tuned.
- Consistent builds mean fewer queries caused by build errors.

TRY IT AT YOUR SITE

- Start with your pain point: Map how your eSource gets built today and where the time goes.
- Write down your build standards, and what your CTMS needs to import the result, before any tool gets involved.
- Bring in a technology partner to build against those standards.

ADVICE AND WHAT'S NEXT

- Let your team's daily pain pick the technology, not the other way around.
- eSource was our first step. Query review is next.




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LOOKING AHEAD

Networking Break

ThermoFisher SCIENTIFIC

Therapeutic Area Roundtable

Summit Kickoff Reception

rt RealTime eClinical Solutions



SUMMIT KICKOFF RECEPTION

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