

## Sites NOW Highlights Issues Impacting Site Operations in September Launch

“Our main goal here is collaboration towards information.” With these impactful words, the first-ever SCRS Sites NOW session was launched. In a dynamic session that attracted more than 80 clinical executives, unreleased data and industry perspectives were shared freely in a virtual environment that emulated the face-to-face energy of past Site Solutions Summits.



**Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners face in 2020.**

Over the next 12 months, Sites NOW will provide a forum for content-sharing, open discussion, and networking among industry stakeholders, to include sites, sponsors, CROs, and solution providers. At each session, subject matter experts provide a 30-minute presentation focused on providing meaningful metrics and invaluable insight into one central theme impacting research today. Following the presentation, attendees participate in team breakout sessions to discuss industry standards, best practices, and pressing questions related to the presentation with the overall objective of providing information for site success.

While advancing site sustainability is the underlying mission of SCRS, Sites NOW delivers a platform to meet, share, and explore solutions that advance thoughts, best practices, and – most importantly – relationships.



The initial session tracked different industry perspectives on one central theme: why sites matter. Industry leader David Vulcano, vice president of clinical research at HCA Healthcare, kicked off the meeting by presenting new data from a recent SCRS Site Survey to convey the rich and varied perspectives on why sites matter in 2020. Mr. Vulcano provided a comprehensive overview of the evolution of the site and how its function has changed congruently with clinical trial format.

### WHO OWNS A STUDY?

With the evolution of research, particularly in 2020, the answer could be “everyone involved.” While the pharmaceutical sponsor is arguably the owner, the site provides certain elements that the sponsor does not: the physical location of the study, the coordination of the study itself, the interface with patients. And those elements, Mr. Vulcano acknowledged, are more important than ever. According to Mr. Vulcano, the value of the interface opportunity provided by the site is at an all-time high. With patients at home in quarantine, face-to-face interactions are welcome – even when the average patient has to travel more than 25 miles to get to the trial site.

For patients and subjects, the site is indisputably essential; it is the central source to which the personal relationship is tethered. It is a trove of answers, help, and knowledge. Mr. Vulcano averred that with different stakeholders funding and managing the study, responsibilities become fragmented such that the concept of ownership is challenging. Who owns the patient experience when the patient experience is so incredibly multifaceted that patients have their EKGs taken at home? And in such a situation, should the sponsor or the site be responsible for oversight?

## **VIRTUAL IMPACT**

The concept of a virtual and/or decentralized trial amplifies the challenging question of “who owns a study”? Mr. Vulcano disclosed that the primary concerns sites expressed were related to the unknowns associated with a study, such as patient safety and the lack of comfort level at the site. Another pressing concern is a straightforward one: the budget for this type of trial is simply too low.

While the complexities of study ownership are vast, the importance of the site remains paramount. Mr. Vulcano explored the unparalleled importance of sites to sponsors, CROs, communities, and patients/subjects. For sponsors and CROs, Mr. Vulcano reported that protocol feasibility and “hands-on” assessments available to the site are vital. Having hands-on assessments available at the site eliminates the guesswork inherent in telemedicine and reduces the likelihood of adverse events. Sites also have exclusive access to volunteers and unique understanding of local diversity and inclusion.

As for the importance of the site within the community, Mr. Vulcano revealed that sites are a rich resource of knowledge for experimental care options and regulations. Further, what the population considers to be a “new” therapeutic is something with which the site already has considerable experience. Clinical research sites also exert a positive local economic impact.

## **SITE FUNCTIONS**

Prior to the meeting, SCRS queried its membership on the level of importance of site functions in clinical trial progression and completion. In order of “extremely” to “very” important, members identified:

- (1) Subject recruitment and retention;
- (2) Access to targeted subject populations;
- (3) Promoting clinical trial awareness; and
- (4) Providing feedback on study design

These metrics were discussed by Sites NOW breakout teams, who reached the consensus that these four items are preeminent among important site activities.

**The site and its important functions have become the focus of global attention. Clinical research has taken center stage this year in a way that the industry could not have foreseen.**

While the fruits of clinical research dictate, prolong, and save our lives, the focus is not on the process itself but on the product. For those who are not a part of the clinical research world, access to the drugs and devices that treat and cure is simply an expectation, and they have minimal interest in their development. This year, that completely changed as clinical research was thrust into the spotlight. News articles, tweets, and press conferences are all focused on tracking the answer to the most important question: “When?”

Sites NOW discussions reflected and embraced this new normal. Attendees agreed that the site workforce has the potential to improve study outcomes when there is collaboration among stakeholders and when training is developed by sites and sponsors working in concert. “Collaboration is key.”

## **POST SUMMIT GLOW**

Year after year, SCRS scrutinizes each post-Summit survey carefully and sees the same sentiment expressed by attendees: “I wish I could go to the Summit every month.” The “post-Summit glow” is a phenomenon known to all Global Site Solutions Summit attendees. After days spent absorbed in content-rich sessions and forging invaluable relationships, attendees leave with renewed energy and passion for clinical research. There is a burst of momentum that follows the Summit as participants leave with refreshed commitment to their work and to each other. It is a reminder that the clinical research community is vast and useful in its vastness for the ideas, research, and best practices that abound, yet also close-knit. After all, the research community is comprised of individuals who care: care about the survival and advancement of humanity, care about science, and care about each other.

The Sites NOW format was carefully crafted to capture the substance and energy of the Summit and share it each month. Clinical research has taken the global spotlight this year in a way that none of us could have planned for, and opportunities to engage with one another are imperative.

SCRS Sites NOW will be convening each month. For details, visit <https://myscrs.org/scrs-sites-now/>.

7250 Parkway Drive, Suite 405  
Hanover, MD 21076

Phone: +1 410.696.5080  
[info@myscrs.org](mailto:info@myscrs.org)

