

Sites NOW December Session Spotlights

Diversity in Clinical Trials

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“Diverse patient populations have different responses to certain pharmaceuticals and ignoring this poses a significant community and global health risk.” These words from Diana Foster, Ph.D., SCRS’ Vice President of Strategy and Special Projects, launched and encapsulated the December 2020 Sites NOW session. Clinical executives convened to discuss the urgency of creating viable mechanisms to increase diversity in clinical trials in a content-rich forum focused on identifying solutions for sponsors and sites.

[SCRS 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 now face. Each session is centered around a singular topic; in December, the topic was diversity in clinical trials. Attendees benefit from an opening presentation hosted by an industry leader that provides a unique perspective and meaningful metrics on the topic at hand, then break out into groups for a dynamic discussion guided by relevant queries designed to identify areas of opportunity for participants in the clinical research pipeline.

In her presentation, Dr. Foster emphasized the importance of diversity inclusion and equity now and in the future. She shared the regulatory perspective - that the need to broaden eligibility criteria for studies starts with the sponsors, who must adopt best practices to ensure that the clinical trial participants reflect the diversity of the population who will be using the drug once approved. Dr. Foster identified objectives for sponsors in study initiating, to include listening to the site’s needs, understanding patients and their barriers to entry, and transparency with site partners on diverse recruitment aims.

One key initiative developed by the SCRS Diversity Project explored by Dr. Foster is the [SCRS Diversity Site Assessment Tool \(DSAT\)](#). The DSAT is a self-assessment instrument launched by SCRS designed to evaluate the extent to which best practices related to recruitment of diverse patient populations during clinical trials are used by the site. Once a site responds to the queries contained in the DSAT, the tool analyzes the information provided and scores the site on its effectuation of diverse clinical trials. The site can then understand and address the areas of opportunity identified by the DSAT; the site can also

provide its score to sponsors as a tangible indicator of its ability to execute diverse trials. Dr. Foster reported that over 400 sites have already used the tool to their benefit, and the information collected from these and forthcoming participants will aid SCRS in the development of resources targeted towards enhancing identified areas of improvement.

A singular theme emerged which characterized every proposed strategy and solution in the breakout sessions following Dr. Foster's presentation: trust. Trust between the sponsor and the site, trust between the community and the site, trust within the site, and trust between the patient and site. It was identified that trust must be implicit in every action and communication comprising the causal chain of study initiation, development, and execution. Trust is borne out of transparency, which begins with the sponsor being clear from the beginning with the site about diversity goals and desired timelines in a specific study. Transparency is also essential in the messaging used by the site during the enrollment phase in addressing patient questions and outlining expectations. Trust is additionally generated by relationships - it was emphasized that the site has a duty to establish and maintain relationships in its community at all times, and not only during phases of enrollment. Trust is further established through clear lines of communication, both between the sponsor and the site and the site and its patients. By session's end, it became clear that through the creation of resources, messaging, and training designed to generate and foster trust between all stakeholders, the future of clinical trials is limitless.

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

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