

▶ Global Trade Organization Amplifies Sites' Voice

CHRISTINE PIERRE, President of RxTrials, takes the helm of the Society for Clinical Research Sites (SCRS) after forming the organization to help sites raise their voice with sponsors, CROs, and other clinical stakeholders.



Christine Pierre

➔ **PV: What was the impetus behind founding the Society for Clinical Research Sites?**

PIERRE: The Society for Clinical Research Sites (SCRS) was founded in 2012 in response to the growing need for a trade organization to represent the global voice of research sites. The actual formation of SCRS was a natural progression from the Site Solutions Summit, which, for many sites and industry leaders, had become the de facto trade organization for sites.

As sites represent the largest number of providers to the industry, their impact on the clinical trials process cannot be underestimated. Sites, which have long been the silent partner in the research enterprise, will no longer be passive participants. Now is the time for sites to become part of the dialogue and solutions through the voice of SCRS. I am confident we can attain operational excellence while, at the same time, ensure safety for study volunteers.

➔ **PV: Why do you believe the voice of sites was not being heard?**

PIERRE: The inability to hear the true signals from the noise was due to a lack of unity among the sites. Because of their fragmented status, sites have often been viewed as the bottom rung or the smallest denomination in our industry. They have also been pegged as the silent or just complaining partner in this enterprise. The truth is the sites are the closest to the nucleus of this industry — with the center being the volunteers. Without sites there are no subjects, no data, no research, and no advancement of medicine. It is extremely encouraging to see the response SCRS has received in this short time from all of the industry wanting to ensure the site's voice is considered. SCRS is committed to working tirelessly on behalf of and for the sites.

➔ **PV: What is the biggest challenge sites face?**

PIERRE: Cash flow is the biggest challenge. More than 50% of studies are still paid on a quarterly basis, which translates into payments being re-

ceived by the site about 135 days after its completed the work, coupled with 10% of that being withheld until database lock. The cash flow issue is quickly followed by lack of consensus of what defines fair market value (FMV) for study budgets. Currently, systems are referencing FMV from prior study budgets that sites would argue do not actually reflect their true costs.

As we witness sites closing their doors regularly, including experienced sites and not just the 74% of the one-and-done sites, we need to learn why. Stated reasons include lack of adequate reimbursement, poor payment terms, and increasingly difficult protocols, which they're unable to enroll.

PV: What are the biggest opportunities that sites can bring to bear as part of development?

➔ **PIERRE:** With more than 20 initiatives currently ongoing within the industry, it is clear that everyone is seeking to find solutions to the inefficiencies in the current system. For any given study, the site is expected to interact with between seven and 11 different organizations. Whatever these groups are discussing, I can assure you that at some point, their ideas will be something that will directly or indirectly interface with the site. For those discussions to continue without the input of sites would be very shortsighted.

Sites are the linchpin in the clinical research process. Some may think this is an overstatement, but sites are the only place in the research ecosystem that have the responsibility and privilege of interfacing with volunteers that provide the data that allow us to advance medical options to our patients. I am, therefore, hopeful the resources currently being expended on all these initiatives will not be made without the site's input, as this would be a true travesty.

➔ **PV: Seven months after forming SCRS, how is it doing in terms of achieving its mission?**

PIERRE: SCRS currently represents 1,300 sites in 12 countries, which conservatively represents more than 6,000 professionals involved in research

at the site level. To represent such a significant membership in such a short period of time truly speaks to the need and enthusiasm of our community's desire to have SCRS represent and unify the sites.

Equally as impressive has been the response from the industry. We routinely receive calls from sponsors, CROs, and vendors that also want to participate in SCRS and show their support of the sites. Their participation is welcomed in a number of membership opportunities; many have already shown their commitment by becoming a Global Impact Partner. While SCRS is the trade organization for the global site community, we know it is a process done in concert with others.

➔ **PV: How does the Site Solutions Summit complement the organization's goals?**

PIERRE: The Site Solutions Summit, now in its eighth year, and having grown from 12 to more than 500 attendees, is now the annual global meeting of SCRS. The summit will continue to allow the noncompetitive conversation among sites and other industry stakeholders and to continue to work toward setting site standards, creating efficiencies, and ensuring the highest level of protection for our subjects as they so generously give of themselves to participate in our studies.

➔ **PV: You are recognized as a role model and innovator. What message would you like to convey to those who are just entering the industry?**

PIERRE: Follow your passion. Those fortunate enough to be engaged in research, and especially at the site level where the volunteers are engaged and trust you, need to understand that dishonesty is very transparent. Life is short, so make the most of every day and of the choices you make for others and yourself. **PV**

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