Monthly e-Newsletter from SCRS
InFocus
Our Voice. Our Community.
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Committed to Change: INC Research Launches SCRS Site Advocacy Group

SCRS Circle of Sustainability Sponsor INC Research recently kicked off its Scientific and Operational Site Advocacy Group (SAG), focused on psychiatry. INC Research is the first CRO to launch a SAG, and join the landmark industry initiative which enables clinical investigators and site professionals to interact directly with senior industry leaders and provide their perspective on critical phases of clinical research. The newly-launched SAG started with a May 28 face-to-face meeting held at INC's offices in Austin, Texas.

"The focus of this SAG is to leverage our highly experienced and therapeutically focused SAG members to evaluate protocols for scientific merit and operational success," INC CEO Jamie MacDonald wrote in a letter welcoming members of the SAG to the landmark event. "This effort will better position us to provide our sponsors with a comprehensive protocol review that includes the site perspective on the ability to conduct the proposed study. Ultimately, the goal is to embed efficiencies in the planning phase to increase the quality and speed of clinical research."

During the meeting, members, who are practicing physicians conducting clinical trials and interacting with patients, reviewed and discussed a protocol for a study that evaluated the efficacy, safety, and tolerability of a drug to treat patients with bipolar depression. The real-world feedback the members provided will improve the protocol, making it more implementable.The SAG will work to ensure that sites have the opportunity to bemore involved in protocol development so that it is more aligned with current practices. This effort strives to improve the process for everyone involved and SCRS is pleased to offer such support to INC and other stakeholders.

"The meeting was a tremendous success," said SAG member Dr. Thomas Apostle. "We created a framework to enhance protocol development for more efficient, successful trials. The ultimate goal of this process is to provide more effective medications for our patients." Added SAG member Dr. Angelo Sambunaris: "The proactive effort on

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the part of INC Research and SCRS to improve clinical trial methodology is one in which the entire industry should pay attention and emulate. This is a difficult time in CNS drug development and without changes in our methods these difficulties will not only persist but most likely worsen."

"Through this forum, INC Research will collaborate with clinical research sites that have direct experience in psychiatry studies to gain their insights into the most common challenges and operational efficiencies that can be implemented for future studies," said Clare Grace, Vice President, Site and Patient Access. "We will leverage these expert insights to incorporate the site and patient voice in the evaluation of psychiatry study protocols for scientific merit and operational success."

The dialogue between SCRS members and INC executives that occurred at the Austin meeting marked a strong start for the Scientific and Operational SAG. SCRS' mission, to unify the voice of clinical research sites globally for greater site sustainability, is wholly manifested in the SAG initiative and will continue to be propelled through the activities of the INC Research SAG.

About SCRS

The Society for Clinical Research Sites (SCRS) was founded in 2012 in response to the growing need for a trade organization representative of the needs of clinical research sites globally. SCRS currently represents over 2,600 research sites; this includes 30,000 research professionals in 42 countries. SCRS' mission is to unify the voice of the global clinical research site community for greater site sustainability. SCRS has become an active partner in industry-wide initiatives and dialogues focused on improving the clinical research enterprise.

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Your Sustainability.
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You Heard it from SCRS

A Closer Look at Contract Language

While many argue that the clinical trial process is ripe for disruption – and scientific advances and new technologies are hastening this change - several initiatives are currently underway to chip away at the inefficiencies imbedded in the process.

One such project is the SCRS-led effort to develop a model Clinical Trial Agreement between sites and sponsors to accelerate the clinical research process and reduce study start-up costs. The Association of Clinical Research Organizations (ACRO) is pleased to be working with SCRS, TransCelerate and other sponsors to jumpstart this process. Ultimately, every day saved in the contracting process benefits sponsors, sites, CROs and, let's not forget our most important constituent: patients in need of new treatments and cures.

Much the same can be said, for instance, about efforts to encourage the use of central Institutional Review Boards to accelerate study start-up.

The project kicked-off earlier this year and the plan is to have model language drafted by the end of year. The initial focus is on the United States with other countries to be targeted in the next phase. The working group is first tackling five often troublesome clauses:

- Indemnification
- Intellectual Property
- Publication
- Subject Injury
- Confidentiality

Of course, use of the model language would be voluntary but the collaborative approach to developing this template bodes well for widespread adoption.

ACRO is being represented in this working group by INC Research, PPD and Quintiles. This is one of several initiatives where CROs are lending their broad expertise to help bring greater efficiencies to the clinical research process.

To capture the central role CROs play in the drug development process, and the industry's commitment to innovation, ACRO has produced this short, animated video: https://www.youtube.com/watch?v=MDOfyW2ITFE

SCRS Members Speak Up

"I found the second webinar in the SCRS Inspection Readiness Series, 'Day of Call – In the Door,' to be excellent and highly informative. Even after 17 years of experience in clinical trials, I learned more useful information!"
Kathy Stuples, LPN, CCRC
Research Coordinator II
Charlottesville Medical Research

SCRS On The Move

Model CTCL Charter Kicks Off

In early June, SCRS convened with the Model Clinical Trial Clause Language Charter Work Stream for a face-to-face meeting in Ellicott City, Maryland. The Model CLA Work Stream, composed of representatives from TransCelerate, ACRO, non-TransCelerate sponsors, non-ACRO CROs, and sites, was assembled to address critical contract clauses that inhibit the pace of study start-up. The multi-stakeholder effort is focused on streamlining universal language in identified clauses to expedite the time in which critical, life-saving drugs and devices can be brought to market. Significant progress was made at the kick-off meeting, as the group discussed what members identified as the five most contentious clauses in contracts between sponsors and sites – those that involve cross indemnification, intellectual property, publications, subject injury and confidentiality. The group now will focus its efforts on developing model clinical language clauses for each of the areas that will be acceptable to stakeholders.

Sites Are Talking

Protocol Training Turbulence

When a monitor informed an SCRS member site that their training methodology was inadequate, the director took to the Listserv for advice. "Our training method is spelled out in our SOPs," the director elaborated, who was told continuation of training with the sites' methods would need to be submitted as a deviation to the IRB. SCRS members relayed similar experiences. "This has been a pain point for us also," commented one director. "Rarely are we provided a list of third-party vendors and required training per portal," they elaborated. One member cited the SCRS white paper on this topic, "The Approach of Protocol Training on Clinical Trial Quality," in which sites confirm that the "protocol training approach has a significant impact on their ability to successfully implement the trial, and that the "ultimate responsibility for ensuring adequate training resides with the investigator." Direct, solution-focused communication with the sponsor related to protocol training was encouraged. "Training is not about checking a box," one director summarized. "It is about giving people the critical information needed to do their jobs well."

Site Survey

What percentage of your site's patient recruitment comes from social media efforts?

1. 0-10%
2. 11-25%
3. 26-50%
4. >50%

Please select the response that most closely fits your site's position.

Your Voice. We Advocate.