Monthly e-Newsletter

SCRS InFocus

Welcome to the December issue of InFocus, where we provide insights and solutions to help sites and other stakeholders ensure site sustainability.

SCRSCurrent: News and information about SCRS.

SCRSConnects: Exclusive interviews with industry leaders.

MetricsThatMatter: Unique and current metrics supporting your success.

ACROUpdate: Insights from influential industry stakeholders.

SCRSCurrent

Preparations for 2018's European Site Solutions Summit in London March 26-27 continue! The full agenda, with topics ranging from moving beyond randomized trials, innovative patient recruitment methods, and e-Technology, is now listed online. Register for the EU Summit to secure your spot.

Global Site Solutions Summit planning activities are also underway. Earlier this month, the Summit Steering Committee met to identify innovative topics and fresh ways to present the information that drives our industry forward. The 2018 agenda promises to be even more robust and pioneering than last year's! Register today for the 2018 Global Site Solutions Summit.

SCRSConnects

Deirdre BeVard has made a career out of connectivity. Her work in the industry began through a position as a clinical research associate, and blossomed to leading, at an executive level, the development operations of clinical research at small- to mid-sized sponsor companies.

However, it wasn't until she began working to provide opportunities for clinicians to get involved on the healthcare side of industry that her perspective shifted. "I thought, naively, I suppose, that I really understood what sites were contending with", she said. "But it wasn't until I started working on behalf of sites that I understood how we as an industry were interacting with sites."

It was this direct interaction with sites that directed Ms. BeVard's career toward developing deeper connectivity and access to clinical research. "My main motivation is getting much needed medical therapeutics to patients," she said. "In this industry we have opportunities to contribute even without being health care providers." She explained that the best way she can make a difference is by ensuring that medical therapeutics are advancing in a way that increases access.

This is why she joined Elligo Health Research as their chief operating officer this August. At Elligo, Ms. BeVard saw an opportunity to create change by more intimately engaging patients and clinicians in the clinical development journey. "Creating close connections with clinical sites vastly improves understanding and awareness", she said. "It's so easy to gloss over the importance of connectivity when pushing up against deadlines and the general pressures of the workplace. But, arguably, there is nothing more centric to the success of a trial than thorough communication with both the care providers and the patients."

Ms. BeVard identified four main resources to deepen connectivity and awareness for clinicians and patients. First, she talked about data and information, explaining that providing access to patient health information in one central location in a way that protects confidentiality would put an end to duplicative data gathering. "With this real-world data, we could get drugs vetted with fewer interventions."

SCRSConnects

Next, she talked about conversation and education. Many patients don't know what clinical trials are, or that they exist as a treatment option; and many clinicians don't know how to identify the best clinical trials for their site. Clinicians should be supported in evaluating opportunity to determine whether a particular clinical trial is the right fit for their site. "Patients should have all of the facts available to make the best-informed decision possible," she said. "We need accessibility that's next door, not halfway across the country."

"In the end, what our industry is working toward is developing a process that respects and acknowledges both the clinician and the patient", said Ms. BeVard. "This includes improving access to and understanding of clinical trials, and the data associated with them." From this perspective, it is clear that connectivity is the foundation that unifies the entire industry.

MetricsThatMatter

We asked sites to share with us what ways they are most deeply impacted by the winter holidays. Responses were spread equally across vendor, shipping, and staffing schedule issues; but one pain point stood out among the rest: more than 53% of respondents said that patient schedules cause the biggest disruption to sites' activity around the holidays.

Respondents noted a variety of measures that they implement to prepare for these scheduling issues:

- Schedule more aggressively- allow more time to receive responses from sponsors, vendors and patients
- Encourage patients to get flu shots so that they don't miss visits due to illness
- Avoid public transportation; include taxi costs for patients in the budget
- Pause enrollment on studies if visits would take place over the week between Christmas and New Years
- Get schedules from PIs and other staff early

ACROUpdate

Congress Looks At 21st Century Cures

Having provided CRO input during the two-year process of the drafting of the legislation, ACRO is closely following implementation of the 21st Century Cures Act. And now, one year after passage of the bill, so is Congress.

Intended to give new direction and latitude to the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) in accelerating the discovery, development and delivery to patients of new biomedical products, overseeing the progress of 21st Century Cures is high on Congress's agenda, and recently two committees have held hearings on the bill, questioning FDA Commissioner Scott Gottlieb and NIH Director Francis Collins about their agencies' commitment new options for clinical development.

At a November 30 hearing of the House Energy & Commerce Committee and a December 7 Senate HELP (Health, Education, Labor & Pensions) Committee hearing, both Republicans and Democrats were keen to hear how FDA and NIH are adhering to the deadlines set out by the Cures Act.

Much of the conversation revolved around what FDA is doing to spur modernization of today's clinical trials and those of the future. While acknowledging there is still much work to be done, Commissioner Gottlieb said that Cures has given the Agency a solid platform upon which to build, with the FDA committed to encouraging new innovative trial designs, like adaptive and seamless trials, and to using more flexible regulatory processes to get treatments to patients faster. He indicated that FDA is looking to rework its policy frameworks to encourage greater use of innovative trial designs and to match the increased focus on gene therapy development. Commissioner Gottlieb also spoke about the inclusion of real-world evidence in clinical trials going forward and disclosed the fact that real-world evidence has already been accepted by the FDA in the drug review process to supplement clinical trial data, mostly in post-market, label extension studies so far. Further, he discussed how the FDA is working with NIH and the Centers for Medicare and Medicaid Services (CMS) to develop better tools to evaluate products to ascertain their safety and effectiveness more efficiently. Additionally, Dr. Gottlieb expressed his hope that, although the IRB provisions of Cures – mandating the routine use of single/central IRB review in normal circumstances – have not been fully implemented as yet, he expects this change to help reduce administrative barriers to research and for the use of a single IRB for multi-site trials to become the norm.

Members of Congress were also concerned with ensuring that increased efforts are made to include minority and other populations that are typically underrepresented in clinical research; a position both Dr. Collins and Dr. Gottlieb recognized as very important.

ACRO will continue to follow implementation of the 21st Century Cures Act and will continue to report on FDA activities to the research community. For those who are interested in tracking the 21st Century Cures Act, you will find updated information here.

AboutSCRS

Founded in 2012, SCRS is a global trade organization that unifies the voice of the clinical research site community to create greater site sustainability. Representing over 9,000 sites in 47 countries, SCRS membership provides sites with a community dedicated to advocacy, education, connectivity and mentorship. SCRS is an influential voice for sites and an active partner in industry-wide initiatives and dialogues focused on improving the clinical research enterprise. **Our Voice. Our Community. Your Success.** Join the community.