Monthly e-Newsletter

SCRS InFocus

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

Articles in this issue include:

SCRS Current: SCRS launches new webinar series for sites around the globe.

SCRS Connects: As recruitment lead on an LMC | Manna Research type I diabetes project, Nazneen Qureshi brought home the SCRS Site Patient Recruitment Innovation Award (SPRIA).

Listen Up: Site leaders are unsure what monitoring changes are driven by "risk-based monitoring."

Metrics that Matter: More research is needed on how risk-based monitoring affects site staff time.

CTTI Update: CTTI presents research on mobile technology.

Site Focus: Send us your news!

SCRSCurrent

SCRS staff are busy preparing for the 2018 EU Site Solutions Summit to be held in London on March 26th and 27th. European-specific topics including BREXIT and General Data Protection Regulation (GDPR) will be discussed. Don't miss your opportunity to attend the European conference focused on sites - register now.

We've also prepared a webinar series featuring topics for the European region and the Asia Pacific region which are presented at times convenient for attendees in those regions. The webinars start December 2017 and will continue every other month throughout 2018. Go to the webinars section of the SCRS website to find out more. A full listing of webinars will be available soon.

Join us at the 2018 Global Site Solutions Summit to hear from next year's finalists. This is the only global conference dedicated to sites. Register now for the 2018 Global Site Solutions Summit to be held October 12-14, 2018 in Boca Raton, FL.

SCRSConnects

Nazneen Qureshi's enthusiasm for patient communication overflows, and has brought accolades to LMC | Manna Research. As the Manager of Patient Engagement on a Type I Diabetes project, she gave an impassioned presentation that won the 2017 SCRS Site Patient Recruitment Innovation Award (SPRIA).

Her accomplished career all started by accident - Ms. Qureshi answered an LMC | Manna Research advertisement for what she thought was a position in human resources recruitment. At the interview she was asked how she would educate the public about clinical research and realized she wasn't where she expected to be; but it soon turned into a passionate mission, leading up to her present accomplishments.

Ms. Qureshi remembers that as she learned about clinical research, she understood the power of what she was doing: "I saw how I could change people's lives by simply informing them about their clinical research choices that allowed them to expand the therapeutic horizon. It's about understanding their needs, what is important to them and how you can help them find the solutions."

Ms. Qureshi also learned how to communicate with diverse groups: "No matter what patient group you're talking to, you need to understand their phase of life and utilize plain language to explain complex conditions, therapies and devices," she explains. This flexibility was challenged when the type 1 diabetes study that was awarded to LMC

SCRSConnects

| Manna Research was unexpectedly changed to a pediatric study. While the team has over 20 years of clinical research experience, they had never worked with children before.

"Working with children was different because there are many more variables to be mindful of, most importantly understanding how to have these conversations with a parent," explains Ms. Qureshi. "Why would a teen with a busy school schedule and social life enroll? What are the parents looking to gain from this experience? We surveyed type 1 diabetes pediatrics and their parents prior to enrollment to better understand the population and their motivation, asking why would they participate in the study and what were reasons that would prevent them to do so?"

What she found was that teens are different from other groups she had worked with, but they are also similar. "The teens we interviewed wanted to learn more about how they were contributing to something larger than just themselves, and were excited to have the opportunity to meet people just like them. They also wanted to minimize their time spent away from work and school."

Another finding was that parents turn to the internet to gather information to protect their children before showing any commitment. "We had to make sure that we were known to the community and that we were well represented in online discussions. We adjusted our marketing style since parents were skeptical in reaching out without adequate study information, such as purpose and procedure, presented to them at first interaction."

Ms. Qureshi built these community relationships by reaching out to smaller organizations who focused on type 1 diabetes. "When w reach out to large organizations, they go into it thinking that getting any sort of response, that is not automated, would be rare," she explained. "But when we reach out to organizations that are similar to us in size, we often find that we can communicate more effectively. While these groups are smaller in size, the level of engagement from their members is unsurpassed. "

At study start, Ms. Qureshi through social listening, identified a patient advocate to share her research journey on social media, giving her free reign to blog about her experience. Potential participants were more receptive to her transparency, allowing her to also be available to current and future patients for support and inquiries.

By collaborating with these smaller organizations, LMC | Manna Research was able to set up an outdoor educational event for the organizations where people could learn about the study. They even brought in US Ski Cross Athlete and Type 1 Diabetic Lauren Salko, to speak to her experience of living in a world where people with Type 1 are perceived to live with restrictions.

Ms. Qureshi has found that sponsors are accepting of educational events. "If you outline your plan early enough, I've never faced a problem with a sponsor. I think it is a misconception that sites feel that the sponsor will say no, but if you outline how these events support study awareness and enrollment, they're willing to experiment with their advertising budget."

Ms. Qureshi noted that centralized advertising campaigns take a lot of burden off of the site, but also reduce the direct relationship between patients and sites. "Even with centralized advertising, there should also be room in the budget for outreach by the sites, to continue to build relationships and awareness for clinical research."

From community outreach, online marketing and patient engagement, LMC | Manna Research was able to recruit and randomize 36 participants within 6 months for this study, meeting all sponsor deliverables.

ListenUp

"Risk-based monitoring" is often defined to site personnel in different ways by sponsor and CRO representatives. As a result, site personnel are unclear what changes in monitoring tasks are related to risk-based monitoring, leading the term to become a catch-all for alternative monitoring practices. How these practices impact the site drives discussion linked to site leader perceptions about risk-based monitoring.

Over the last year, these discussions have focused on changes to query rates and practices, investigational product accountability, and remote monitoring. As these monitoring changes occur, site managers are rushing to evaluate the risks to their own operations. Increased communication about alternative monitoring practices and the reasons for their implementation is needed in order to empower sites to be partners in clinical research process improvements.

For more on what site leaders had to say about their perceptions about risk-based monitoring, Global Impact Partners can join mySCRSsolutions *online community and members can join the online forum created for them –* mySCRScommunity *for investigators, owners, directors, and managers or* mySCRShuddle *for site staff.*

MetricsThatMatter

We asked sites whether risk-based monitoring (RBM), on average, increases or decreases site personnel time spent conducting monitoring activities. The results in our small sample were mixed. While RBM is primarily about focusing monitoring efforts in the most efficient way to increase quality, research on other measures of efficiency remain in the e early stages. We do not have a lot of information about how RBM affects study coordinator time, partly because other changes to study design are happening at the same time. Nonetheless, the perception of site leaders is that RBM is driving increases in study coordinator burden. More research is needed.

The discussion continues on the SCRS LinkedIn Group: What effects have you seen on study coordinator time due to risk-based monitoring?

CTTIUpdate

A Key to Fueling Mobile Clinical Trials: Knowing What Patients and Investigators Want

The fact that mobile technology holds great promise for clinical trials is evident. However, the research enterprise is currently sitting at a crossroads of realizing technology's benefits, but not fully knowing how best to use it for data capture in trials.

One of the many reasons why our field has been slow to adopt mobile technology is because information is sparse on the receptivity and needs of key stakeholders—namely, clinical investigators and trial participants. Understanding these groups' familiarity with mobile technology, as well as their concerns with using such technology, is critical to reaping the many benefits of mobile clinical trials (MCTs), which potentially includes reducing the burden of participation, increasing participant satisfaction, and improving protocol adherence.

The Clinical Trials Transformation Initiative (CTTI) is currently working on a project to better understand the possible barriers and facilitators of using mobile technology in clinical trials from the perspectives of investigators and patients.

As part of the MCT Stakeholder Perceptions project, CTTI recently conducted a survey with 193 patients to identify their attitudes, preferences, and concerns related to using mobile technology in clinical trials and, among many interesting results, found that:

- 76% preferred to participate in a mobile trial, after being asked to compare to an equivalent traditional trial.
- 47% indicated that, for trials using mobile technology, they would prefer to see the trial doctor only at the start and end of the study.
- A majority preferred site involvement both in new device training and troubleshooting that device during the trial.

To understand the experiences and perspectives of investigators who have conducted trials involving mobile technology, CTTI has also conducted a series of in-depth interviews with site investigators and is currently analyzing the results. The research addressed topics such as the advantages and disadvantages of running a MCT as compared to a traditional trial, site training needs and experiences, and unique budgetary and resource considerations for trials using mobile technology. We anticipate the findings will provide insights for investigators, as well as sponsors who are considering conducting a trial using mobile technology.

Collectively, these research efforts will lead to the development of new recommendations for integrating mobile technology into clinical trials in a way that truly meets the needs of all stakeholders, and embrace the many benefits that may come with this new approach.

We look forward to sharing those recommendations with you in 2018. In the meantime, if you are interested in hearing more about the results from CTTI's MCT Stakeholder Perceptions research—including findings from our research with investigators who have conducted mobile trials—please join us at SCRS's upcoming webinar "Mobile Technology in Clinical Trials: New Research from CTTI on Patient and Investigator Perspectives" on Tues., Dec. 5 at noon ET.

SiteFocus

Do you have a celebration at your site? Did you expand into a new building or launch a new program? Send us your news!

Site Focus is a new section in the SCRS InFocus Newsletter. You are invited to send your news to Jessica Knott: Jessica.Knott@mySCRS.org

AboutSCRS

The Society for Clinical Research Sites (SCRS) is a global trade organization founded in 2012 which represents almost 9,000 research sites in over 45 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. Sites, as well as companies that sponsor or support clinical research sites, benefit from membership and partnership. **Our Voice. Our Community. Your Success.** Join the movement and Become SCRS Strong.