Monthly e-Newsletter

SCRS InFocus

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

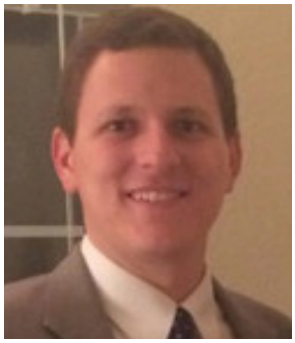
SCRSConnects: Exclusive Interviews with Industry Leaders. This month: Charlie Jordan.

ACROUpdate: Organizations share updates and perspectives on topics that matter most.

MetricsThat**Matter**: Unique and current metrics supporting your success.

SiteSpotlight: Site stories of innovation and success. This month: Meridian Clinical Research.

SCRS**Connects**



A career in clinical research was not on Charlie Jordan's radar coming out of college; he was a history major and had a different professional path in mind. However, his job search led him to pursue accounting work at PMG Research and, like many others, he tumbled into the clinical research industry and fell in love with it.

Clinical studies have to be closed out eventually, and this is where Charlie started his career. As he gained proficiency in study close-out, he helped the site switch from cash to accrual accounting, refine how they recognize revenue, and better understand their accounts receivable. As he learned more about what is required to bring a clinical study to fruition, Charlie developed an interest in areas extending beyond the financials. "By managing the finances of clinical studies, I became more familiar with what is required to negotiate a clinical trial agreement (CTA) and a budget within a CTA," Charlie said. He spent two years as PMG's primary budget negotiator.

Charlie's interests extended still further. Known for his friendly demeanor at PMG, he wanted to engage in some of the outward-facing work to improve communication practices with the site's sponsor partners. "I wanted to be able to work on building these relationships from the ground up so that when issues arise, sponsors knew exactly who to call to navigate the issue," Charlie said. Poor communication has been identified as one of sites' primary pain points, so attention to the quality and consistency of communication is vital. By delineating a primary contact, PMG Research was able to begin the process of decreasing study start-up timelines and navigating issues as soon as they were identified.

Charlie has been the manager of business development at PMG Research for almost two years. In this role, he is able to focus on both sponsor negotiations and communication. "The start-up process has the potential to be streamlined, but it is often one of the biggest elements that holds us back from study success," he shared. Delayed study start-up often results in hundreds of thousands – if not millions – of dollars in delays, and while site employees are very capable, no employee is able to maximize their effectiveness by working as fast as possible to meet deadlines. "We cannot improve the start-up process without bringing focus to managing our relationship with sponsors," Charlie said. Sites are highly motivated to work quickly, but when sponsors tell sites that they are not working fast enough, the quality of work suffers and it becomes impossible to think smarter about start-up processes.

"I see my job less as finding one particular study for the company, and more about talking with the sponsors we work with the most to determine how satisfied they are with the quality of work we provide and how we can build upon that," Charlie commented. "Sponsors that have demonstrated commitment to timely and efficient study start-up are willing to have conversations that might extend beyond the normal scope. When these conversations happen early on in the study process, all involved end up benefiting." To date, Charlie has been able to facilitate increased quality in relationships with five primary sponsors that PMG Research works with. As a result, both the sponsor and the site are able to utilize candid feedback to adjust protocols and approaches as needed. "We all benefit," he said, "including the patients."

"Clinical research as a care option is our mantra at PMG," said Charlie. The organization focuses intently on the patient experience and how patient's lives are impacted by trial participation. The clinical research industry is trending toward patient-centricity, and conversations with PMG's investigators about what they want to achieve for their patients helps Charlie advocate for that.

From turning a degree in history into a career in clinical research finances, Charlie has demonstrated the importance of the guidance he offered to help sites amplify their success: "Be flexible and fast. In this ever-changing landscape, sites have to be open to considering alternative approaches to start-up, communication and even to the types of studies your site considers taking on." When a site's ability to start up and enroll quickly is the sponsor's primary motivator for site selection, it is easy to understand the value of this piece of advice.

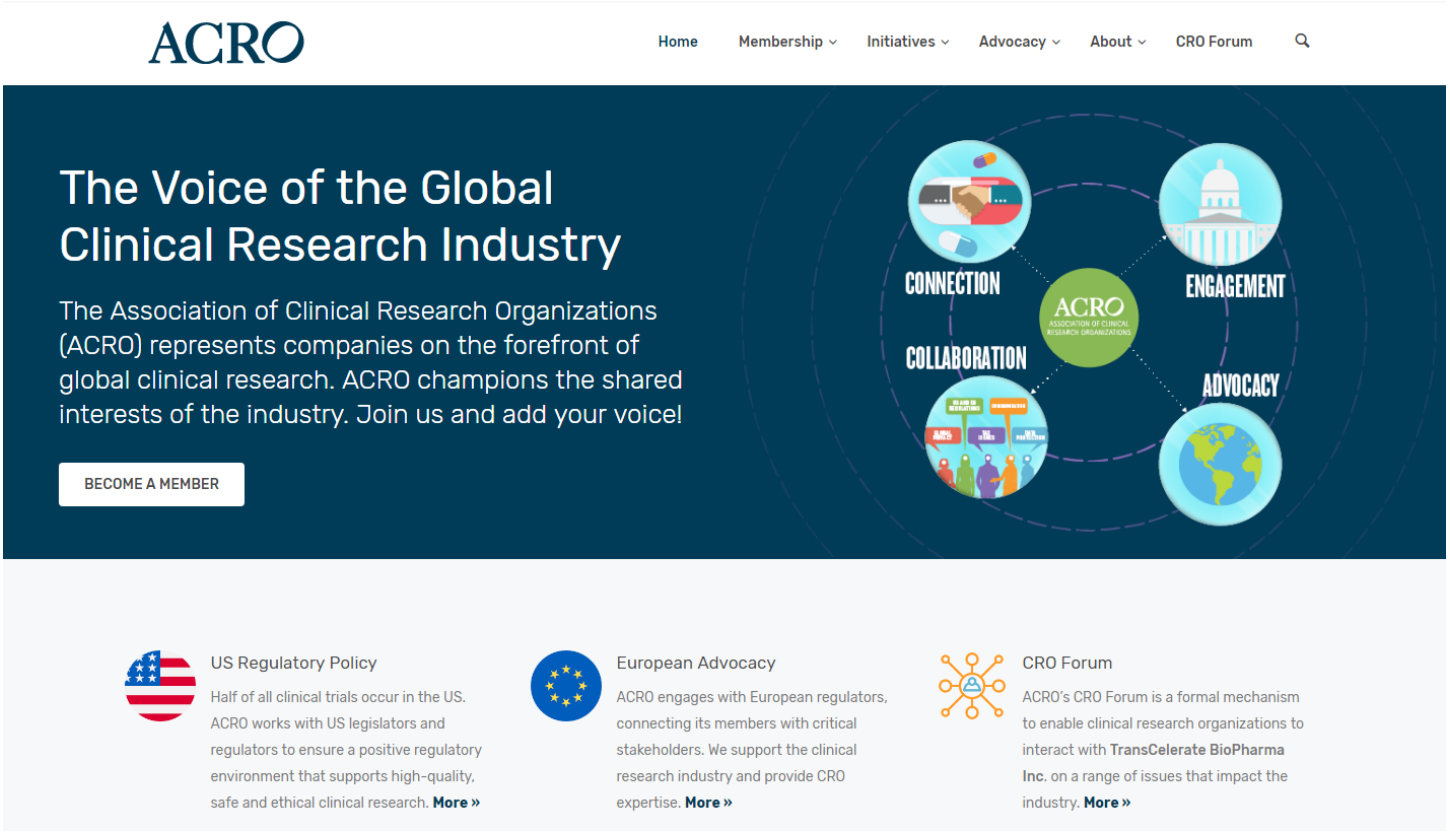
ACROUpdate

ACRO launches revamped website

It's here! The Association of Clinical Research Organization (ACRO), has launched a new website. Redesigned in the context of growing membership and innovation in the clinical research industry, the new website is focused on delivering useful information about ACRO's activities and impacts on the industry.

From the blog with updates about the organization's work, to a full archive of comments to regulators, the website offers a deeper look at how ACRO is collaborating with diverse stakeholders to advance the clinical trial enterprise.

We encourage everyone to visit the new website, sign up for the free quarterly newsletter, read about ACRO's work and be in touch.



MetricsThatMatter

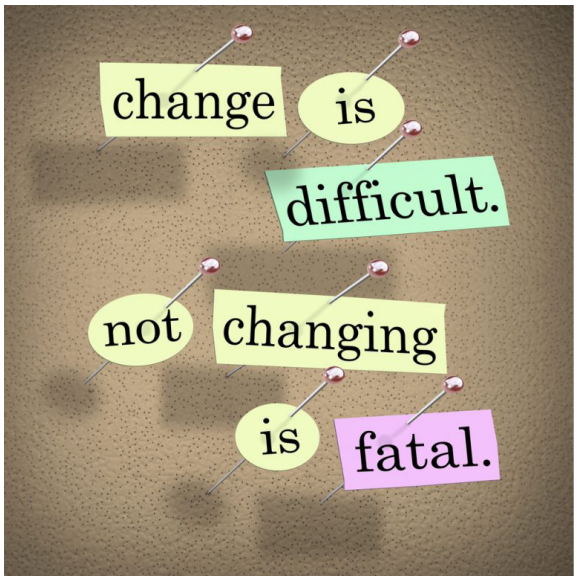
Site Payments and Patient Reimbursements

It is no secret that financial stress at clinical research sites has a negative impact on the success of clinical trials. This has been well-researched in the United States: according to a survey conducted jointly by SCRS and Greenphire, approximately 40% of sites indicate that slow payments are a primary operating concern.

In 2016, 66% of sites reported having less than 3 months of operating cash in the bank. 2017 Site Landscape data showed an improvement: approximately 60% of sites globally reported that they have no more than three months of operating cash in the bank.

The survey also demonstrated that sites globally have the same need for four key improvements from payers:

1. Timely payment (30 days)
2. Electronic payment
3. Site access to their financial information in payers' electronic systems
4. Automatic payment with reduced need for manual invoicing



Digging deeper into the problems and solutions surrounding these matters, SCRS asked what is needed for sites to obtain success in clinical trials. Sites clearly shared that prompt electronic payment is required for study success, with 63% of sites indicating preference for electronic payment and 83% of sites indicating preference for payment to arrive in thirty days or less. Prompt payment is particularly tied to patient stipends and reimbursement, in that 77% of sites rank "very important" or "extremely important" the ability to provide patients' their stipend and/or reimbursement during or immediately after the visit.

As shown in Figure 1, in an environment where more than 50% of sites have less than three months of operating cash, delayed payments can drain a site's bank account. This adds financial strain to the sites that cannot pay the patient immediately and wait for a reimbursement that may be delayed several months.

Sites expend significant resources to maintain accounts receivable records, generate invoices, and manage reimbursements. Only 35% of sites use accounting software such as a CTMS to manage accounts receivable. Most sites are not using a CTMS: 60% are using paper or spreadsheet software such as Microsoft Excel, and 5% do not track accounts receivable at all. Half of the respondents indicated that their site generates invoices by hand.

As shown in Figure 2, for patient stipends and reimbursements, paper checks or cash were reported as most commonly used. While debit cards may offer more efficiency, sites were mixed in whether they felt their patients would be receptive to them. Where cash is required, sites must be reimbursed promptly and accounting must be automated as much as possible.

Sites use payment timeliness as a factor in determining which sponsors/CROs to accept studies from, and occasionally sites make the decision to stop work when they have not been paid. Sites are equally clear that access to their financial information in payers' electronic systems is a key improvement sites desire. When asked to characterize a sponsor's system or process that would assist the site in reconciling payments, 72% of sites ranked it as "valuable" or "very valuable".

A central and essential finding from this survey is that sites prefer receiving electronic payment within 30 days. This finding is consistent globally and corresponds with prior studies which have repeatedly found that sites prefer monthly payments over quarterly payments. While certain aspects of how sites need to be paid vary by region, the need for prompt payment does not vary. It is evident from these findings that sites are looking forward to changes in the timeliness of payments. It is heartening to note that some sponsors and CROs have started committing to making monthly payments for sites, and SCRS encourages all sponsors and CROs to treat their sites as true business partners and pay for services received in standard business time, that is, within a month of data receipt.

SCRS has advocated for each of the above outlined key improvements and continues to be involved in a variety of initiatives to remove obstacles that have prevented these payment improvements from being realized. Payment to sites within 30 days, as is standard practice in most business relationships, has been a core element of SCRS advocacy.

SiteSpotlight

Q&A on Building Stronger Bonds with Investigators to Enhance Site Operations

Meridian Clinical Research has created a unique program to support the success and growth of its investigators. In this Q&A, Wes Bonner, vice president of strategic development at Meridian, shares how Meridian supports its investigators and why that support creates advantages and enhances site operations for the organization.

What makes your role at Meridian unique?

I'm responsible for ensuring Meridian's investigators are aligned and engaged with our organization and vice versa. My role is a unique position of investigator liaison, business development, and new site vetting and enhancement.

Meridian strives to minimize the administrative burden and overhead for investigators at our dedicated and embedded research sites across North America. To do this successfully requires constant communication with our investigators and, in some cases, existing clinical practice executives and managers.

As Meridian's investigator liaison, I also function as each investigator's advocate to the leadership team. This entails routine calls and face-to-face time with each investigator. We want our investigators to have every opportunity to voice ideas so we can address all issues strategically and consistently. From there, we leverage investigator feedback to strengthen the way we support them.

What does Meridian do differently when it comes to engaging investigators?

In the past decade, we've focused on providing resources that go well beyond the traditional embedded site model. We provide dedicated staff at each site in-house quality programs, centralized regulatory support, contact center and patient recruitment support, and other forms of training that increase investigator support and decrease liability for practices. This frees up more time for investigators to provide oversight and allows us to optimize working relationships.

One of the keys to sustainable growth has been the thoughtful vetting of sites. New sites are only added when 1) there's a viable study pipeline for the site and 2) we predict a healthy relationship with the potential investigator(s) and office administrator(s). This careful vetting increases and reinforces consistency, efficiency, and quality in conducting our future research and positions Meridian as a preferred partner with sponsors and CROs.

Does this help investigators become more invested in clinical research?

Absolutely. Beyond improving our organization's engagement with investigators, we aim to help connect them with the greater research community. We want to help investigators expand their personal networks and connect directly with sponsors and CROs.

Our team regularly attends industry events with our investigators and works to enhance their visibility. I also present or participate in panels at several conferences each year. When doing so, I use the opportunity to talk about investigator relationships and generate ideas for how Meridian can strengthen investigator engagement to improve trial conduct and service delivery. Much of this happens in sessions with representatives from sponsors, CROs and other site networks.

How else has this approach enhanced research conduct at Meridian?

One of Meridian's top assets is our ability to collaborate among sites. Our sites share best practices, standardize processes, and remotely support one another as needed. Our sites can also accept the same contract language and budgets. My role enables our investigators to have the same level of collaboration and continuity on a peer-to-peer level.

We hold training meetings and attend events so investigators and clinical personnel can meet in person and talk in structured and unstructured environments. Communication has improved companywide as a result, and investigator attendance and interest in these events has grown considerably.

Altogether, this brings investigators closer to their research while breaking down the silos that trigger disengagement. This approach improves the way we engage investigators, recruit and retain patients, communicate with practices, and deliver high-quality research.

Meridian is deeply invested in our investigators' success. We want them to feel supported and know that we go to great lengths to enable them to provide oversight with confidence.

About SCRS

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.