Monthly e-Newsletter

SCRS InFocus

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

SCRS**Connects**: Exclusive interviews with industry leaders. This month: Casey Orvin.

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

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

SiteSpotligh: Site Stories of innovation and success. This Month: Medical Oncology Research

SCRS**Connects**

Ultimately, the success of a clinical trial starts and ends with the patient. "I learned very early in my career that when patients have a positive experience participating in a trial, other aspects of the trial are much smoother," said SCRS' newly appointed president, Casey Orvin. A patient's experience is created by the site, so the industry as a whole benefits when sites' needs are prioritized."

Casey began his clinical research journey working for a site management organization in 2001. The organization had 30-40 sites in six states, and Casey was responsible for finding appropriate studies for all of them. By the time he left in 2007, he'd grown the number of sites to 65 and developed standardized processes to efficiently manage them. He then moved on to other BD roles with Clinical Research Advantage, Radiant Research, and Synexus, which merged with Radiant Research under Casey's leadership to create the world's largest network of clinical trial sites.

"Working in the field of business development helped me understand early on what sponsors and CROs need from sites to ensure a positive patient experience, and that is good, qualified patients for trials," said Casey, who has had the unique opportunity to utilize this knowledge to support the success and sustainability of hundreds of sites for nearly 20 years.

"Our industry's purpose is to bring better medicines to patients faster, and the primary keys to this are quality sites that produce quality data and providing patients with a clinical trial journey they enjoy being on," Casey commented. "When sites have internal practices and relationships with sponsors that enable them to create a positive clinical trial experience for their patients, the industry as a whole benefits. It is so important that clinical staff and PIs connect with patients and leave them feeling like they are the most important person they saw all day. This is what inspires patients to participate in additional trials. It is one of the most important aspects of success on the site level."

Casey worked closely with SCRS' late founder, Christine Pierre for many years. "When Christine told me that she wanted Casey to be her successor, it really demonstrated her belief in his ability to impact real and lasting change in the site community," said Allyson Small, VP of operations for SCRS. Casey attended his first Site Solutions Summit in 2011, then produced by Christine's first-founded company, RxTrials. "She approached me and said that she believed we could have a powerful impact on the site community together, and I agreed," said Casey. He joined the Summit Planning Committee and eventually the Leadership Council and other related committees to help promote SCRS' mission to unify the voice of the global clinical research site community for greater site sustainability. "The Site Solutions Summit has always stood out to me as the only conference that really focuses on representing the voice of the sites," Casey said. "Before Christine dreamed up the Site Solutions Summit and SCRS, the sites' voice was faint, and I knew they needed to be heard loud and clear in all aspects of the conversation. It quickly became the one conference I wouldn't miss each year."

Casey has learned throughout his career that sites need a prominent seat at the table when sponsors are at the forefront of the decision-making process: "I wanted the sponsors I worked with to understand site pain points and barriers to success, and I recognized that this was the only way all parties involved in the trial could succeed. We didn't necessarily want our voice heard so that we could get what we wanted; we wanted our voice heard so that together, we could be successful."

Casey's presidency was announced at the inaugural SCRS Global Oncology Site Solutions Summit in Austin, TX on February

2. "Being at the Oncology Summit really brought everything together for me," he said. "It was a time to celebrate Christine's legacy, the culmination of her last big dream in her career, and the incredible people in the oncology clinical research field whose work extended Christine's life and gave her more time with family and friends." Attendees approached Casey and other SCRS staff members throughout the conference, invigorated by the Summit and expressing their excitement to celebrate Casey's joining SCRS at the helm. "The outpouring of encouragement, enthusiasm, positivity and commitment was overwhelming. I left the conference feeling rejuvenated," Casey said. "What we do at SCRS makes an incredible difference in the lives of patients, and when industry comes together at a conference focused on solutions, our collective ability to help patients inevitably improves."

When asked what one piece of advice he would give to sites to maintain sustainability, he replied, "Continue focusing on the patients' journey and remain teachable. Whether you're a stand-alone site, a network of 5 sites or a network of 500 sites, serving the needs of patients and remaining teachable in an ever-changing industry are our main keys to success."

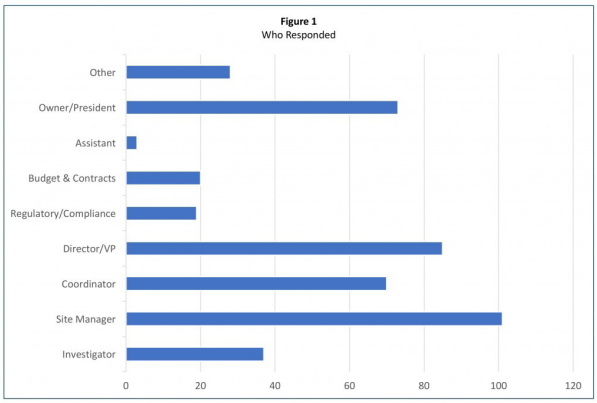
MetricsThatMatter

White Paper Preview: Financial Barriers to Site Sustainability, Patient Experience and Overall Trial Success

It is well-known and frequently documented that financial stress is one of the primary issues negatively impacting clinical research site success. Previous data collected by the Society for Clinical Research Sites (SCRS), in partnership with Greenphire, identified four major challenges affecting clinical trial success: limited operating cash, manual invoicing processes, untimely payment frequency and lack of financial transparency are all top of mind for sites globally. These findings are reported in a joint white paper entitled Site Payments and Reimbursements: A Global Perspective.1 However, it is important to understand that the barriers to success are not exclusively correlated to site payments. In fact, the challenges are evident throughout the life-cycle of a clinical study, as early as the study budget negotiation processes and all the way through patient engagement and payments.

The 2018 Site Financial Challenges Survey

Recognizing the importance of understanding and addressing the financial challenges of sites more holistically and the impact of such challenges on trial success, SCRS and Greenphire recently joined forces again to conduct another survey that evaluates site realities and needs related to the full spectrum of budget negotiations, invoice generation, payment frequency, and patient needs. Survey responses were collected from 527 site respondents between September 5 and November 20, 2018, with almost one-third of responses coming from sites residing outside of the US (OUS). Approximately 60% of respondents hold high-level positions such as site manager, director, owner, president, and vice president; the remaining 40% were investigators, coordinators, assistants, and individuals working in regulatory/compliance and budgets/contracts (figure 1).



Although almost everyone involved agrees on what improvements are needed in the clinical research industry, only a small percentage take the action required to improve sites' realities in terms of these key areas of burden. It is time to stop talking and begin acting to bring about meaningful and lasting change in these areas.

Call to Action

Sites globally face challenges at every stage of the payment process that impact the quality and speed of their work. Recent survey findings show that while progress is being made, the major challenges identified previously require further action.

SCRS has identified the following specific action areas of improvement for sponsors and CROs to implement in order to improve their relationship with sites, the patients' experience and ultimately the success of the trial:

1. Streamline budget negotiations and study startup
2. Increase automation of site invoicing processes
3. Continue work to develop and execute a plan to pay sites monthly
4. Support sites in meeting patient needs

CTTIUpdate

New CTTI Recommendations: Enhancing the Use of Mobile Technologies in Trials by Incorporating Site and Patient Perspectives

Many site investigators agree that the future of clinical research is in mobile technology due to its potential to help sites reach more participants, conduct research more efficiently, improve data quality, and decrease participant burden. At the same time, they voice concerns about usability issues and operational challenges posed by new technology. Addressing these perceived benefits and barriers will drive the successful adoption of mobile technologies in clinical research and advance the development of new medical products.

This week, CTTI is releasing new recommendations that encourage incorporating the perspectives of investigators as well as potential research participants in trials using mobile technology. These recommendations will be unveiled during a free public webinar on Thursday, February 21 at 12:00pm EST and will provide practical tools for planning and conducting more efficient mobile trials by involving sites and patients throughout the process—from trial design to data dissemination.

CTTI's new solutions, developed in partnership with leaders and experts across the clinical trials enterprise, address key challenges for clinical research sites involved in mobile clinical trials including contracting, budgeting, training, and technical support. In addition, they have the potential to maximize value and minimize burden for study participants by offering recommendations for setting participant expectations early, protecting privacy, returning individual data, and enhancing patient-site interactions.

This is the fourth and final set of recommendations from CTTI's Mobile Clinical Trials (MCT) Program. Recommendations for developing novel endpoints generated by mobile technologies were announced in 2017 by CTTI, and in 2018 we unveiled new solutions for using mobile technologies for data capture in clinical trials and for planning and conducting decentralized clinical trials. The recommendations build on previous work—including CTTI's Quality by Design and Patient Groups and Clinical Trials recommendations—that emphasizes the involvement of multiple stakeholders, including patients and sites, in trial design and throughout every step of clinical research.

By implementing CTTI's new recommendations, researchers can design mobile trials that work better for everyone involved, streamlining the research process and accelerating the development of critical new therapies.

SiteSpotlight

Celebrating Research Milestones

Being a trials unit based outside of a major metropolitan city comes with many challenges, but over the last 30 years we have patiently built a team of enthusiastic researchers who are dynamic, science-based, and patient-focused.

The secret of our unit's overall success comes from thee simple principles:

First, all protocols are reviewed by all our clinical research team members prior to a final decision to undertake or decline a trial. We have a dedicated meeting where all aspects of the trial are examined and discussed – the investigational drug and its mechanisms of action, objectives, scientific merit, eligibility criteria (and any likely impediments to recruitment), schedule of assessments, current and projected trial staff and investigator workloads, unit capability, budgets, level of interest, and suitability within the known characteristics of a patient population. This "strength in numbers" approach has yielded some impressive trial recruitment numbers, as evidenced by our investigators receiving authorship in trial manuscripts and, more recently, being the inaugural 2018 Asia-Pac Site Solutions Summit Site Patient Recruitment Innovation Award (SPRIA AP) recipient.

Secondly, we do not conduct competing trials; we have learned through past experience that it is divisive within the research team and often counterproductive to achieving enrollment targets. Adopting a consensus-based policy of conducting only one trial in any given patient population at any given time maximizes accrual potential to that trial by eliminating potential investigator biases and facilitating more focused screening for potential participants.

Finally, we always look for ways to improve as a unit. From new practices to new equipment to restructuring staff and operational models, all possibilities are open to consideration and changes are made through team consensus and support. In recent years this approach has seen our unit develop and use:

- Staffing structured into specific task-based roles such as clinical trial coordinator, laboratory tech, data manager, regulatory and finance managers;
- A series of electronic trial templates for use in patient electronic medical records;
- A template for electronic Investigator Site Files/Folders (ISF);

- The NSW Oncology ClinTrial Refer App – a spin-off of ClinTrial Refer Australia – which connects doctors and patients to recruiting clinical trials across the state; and
- Our own branding for medical oncology research at the Mater, including a logo for use on uniforms, caps – a must in the Australian sun – and patient shoulder/tote bags given to our trial participants.

The decisions to undertake these changes have yielded improvements in staff appearance, patient recruitment, trial documentation, and ISF document filing and have garnered widespread support and praise from investigators, data managers, and pharmaceutical and CRO sponsors alike.

Our unit recently transitioned to a Clinical Trials Management System (CTMS) called MAISi. MAISi contains information for more than 70 trials, 700 patients, 60 sponsors and CROs and is integral to the daily workflow routines of all trial staff. MAISi has changed the way we prepare and manage trials, giving us more comprehensive data on trial activity, better reporting capacity, and ultimately more time to focus on both trial and patient needs.

As a result of these changes, Medical Oncology Research was the recipient of the inaugural SPRIA AP, and the other secrets to our recruitment success. Trials are by their very nature team-based, and investigators rely heavily on trial coordinators, data managers, administrators, and finance managers to efficiently and effectively run a trial. Reliable recruitment starts with understanding the trial needs and pain points and then overcoming the obstacles through planning and preparation, using strategies such as:

- Developing a recruitment or screening kit which can be placed in a convenient location in the outpatient clinic, including resources such as a printed eligibility check list, a participant information consent form and other relevant trial information;
- Screening all doctors' clinic lists on a weekly basis, identifying any potential trial candidates and flagging these patients with a Trial Alert entry in their electronic medical record and then following up with the doctor(s) after clinic;
- Regular communication with investigators (from simple one-on-one chats before or after a clinic to formal department presentations or email reminders of current recruitment status); and
- Establishing a good working model or workflow for the preparation, processing, and sending tissue and/or blood samples to central laboratories.

Finally, we've learned to look at each trial individually and be flexible in our approach to recruiting because ultimately you need the trial to be right for the patient just as much as you need the patient to be right for the trial.

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 52 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.