Financial Barriers to Site Sustainability, Patient Experience & Overall Trial Success

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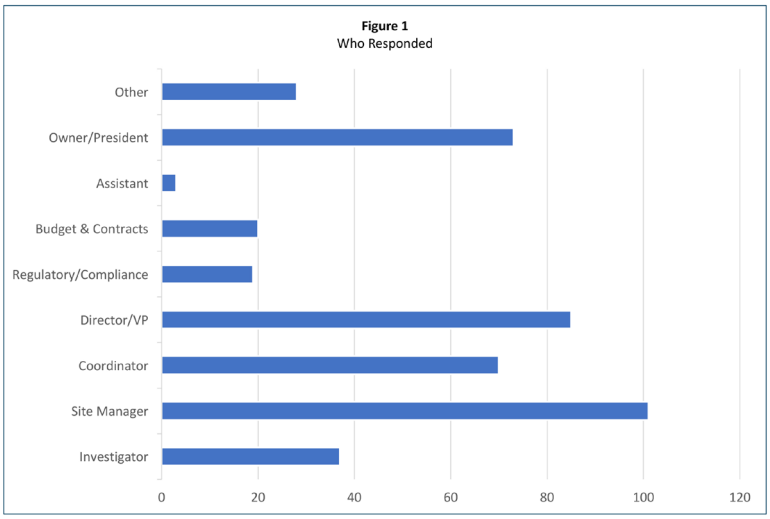
SCRS WHITE PAPER

FEBRUARY 2019

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

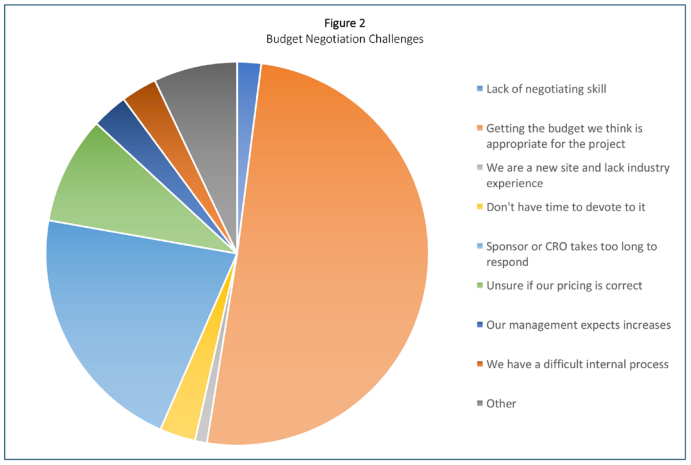
Sites globally face challenges at every stage of the payment process that impact the quality and speed of their work. Recent survey findings show that while progress is being made, the major challenges identified previously require further action.

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

Streamline Budget Negotiations and Study Start-up

The process of negotiating a study budget is burdensome for all parties involved. Access to meaningful data is often limited, and the processes for target budget creation, communication between contracting parties, adjustments, adjudication and confirmation are often manual and time-consuming. This creates multiple challenges in negotiating budgets, resulting in administrative burden and overall delays to study start-up. As one respondent noted, "Sponsors take too long to respond (and) full details of what is involved are not provided to the site to adequately determine the costs." On top of the manual burden, 50% of survey respondents said the biggest challenge in budget negotiations was getting an appropriate budget for the study (figure 2). Sites are faced with significant burdens before a trial is even initiated, including resource constraints and limited data, just to be in a position to support a given study.



"Sponsors take too long to respond [and] full details of what is involved are not provided to the site to adequately determine the costs."

What can be done?

There is an opportunity for sponsors and CROs to introduce transparency, quality and efficiency into their budget and contract negotiation phases. Technology solutions that streamline the negotiations and automatically populate contracted rates into payment tools can be used to improve the contracting process and accelerate study start-up.

Increase Automation of Site Invoicing Processes

Once contracting is complete and research-related activities begin, the site is faced with the burden of the invoicing process. 43% of respondents in 2018 reported that they create invoices manually. While this percentage has decreased from 50% in 2016, there is still significant improvement to be made in this area.[1]

74% of sites surveyed spend a minimum of one hour compiling and creating invoices per study per month. More than one-third of all sites and 40% of OUS sites dedicate at least four hours per month, per study to this activity. Even more staggering, one in four OUS sites spend seven or more hours per month, per study creating invoices (figure 3). One respondent stated they outsource invoicing activities and are forced to pay a 2% charge on monies recovered. Another respondent said, "Payment frequency effects our ability to meet financial needs and our ability to operate as a company."

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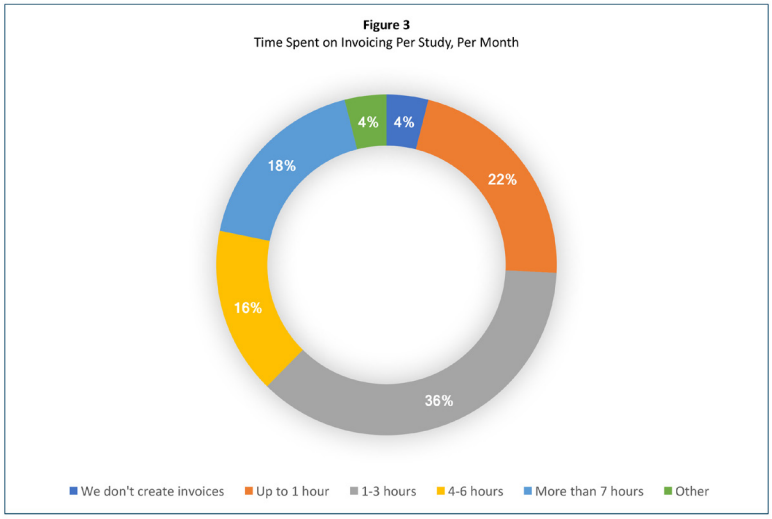
On top of the time creating and compiling invoices, sites spend considerable effort communicating back and forth with the sponsor or CRO.

"Payment frequency affects our ability to meet financial needs and our ability to operate as a company."

Figure 3
Time Spent on Invoicing Per Study, Per Month



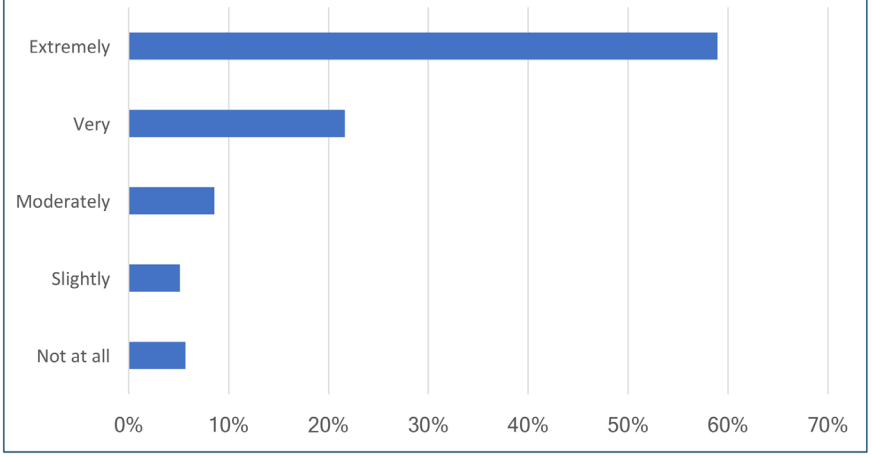
A time-intensive invoicing process inevitably takes away from time that could be dedicated to recruiting patients and conducting research.

What can be done?

While CTMS solutions provide many benefits to sites, the survey data indicate that sites that utilize CTMS to assist with invoice generation are spending more time than those who utilize manual processes. Four out of five respondents indicated that reducing the need to create invoices manually in favor of a more automated invoicing process would be extremely or very beneficial (figure 4). Reducing this administrative burden is important to ensure financial sustainability for sites globally. Utilizing automated invoicing technology specifically designed for clinical trial research is one means to reduce this burden.

Continue Work to Develop and Execute a Plan to Pay Sites Monthly

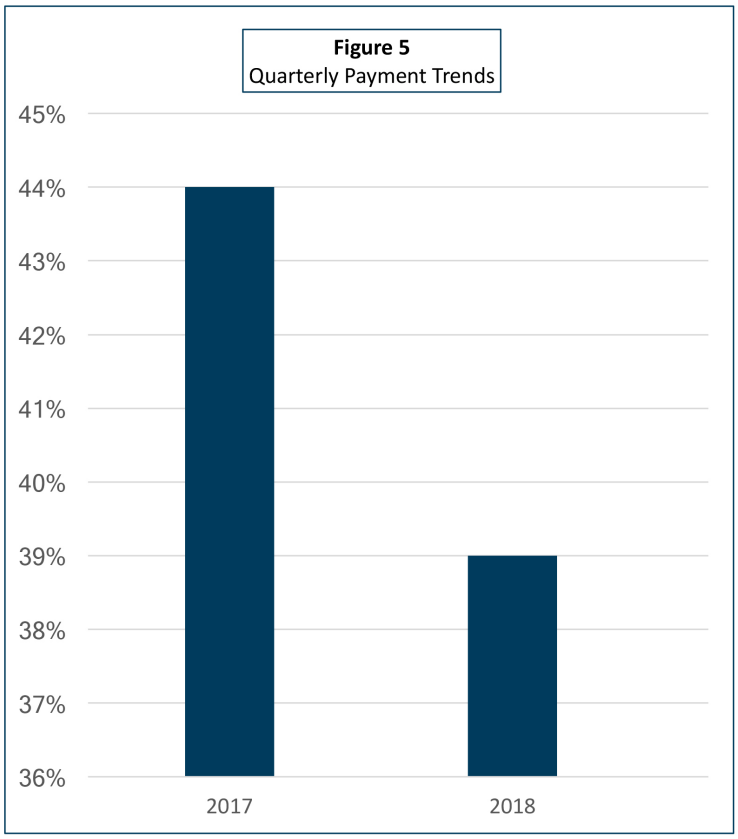
Figure 4
How beneficial would it be if your site could reduce or eliminate the need to create an invoice, and instead receive payment based on a trigger from your data capture?



Improved budget negotiation processes and automated invoicing are only part of the solution: there must be a renewed directive for monthly site payments. Infrequent payments continue to be a primary problem for sites, negatively impacting their operating budget. This reality is a main cause of the one-and-done site dilemma in which a research site or investigator conducts only one clinical trial before ceasing operations. One site responded that slow payment frequency "cripples (their) site" causing them to "run at a deficit and have to let go of staff." Unsurprisingly, 90% of respondents prefer to be paid more frequently.

Payment frequency remains a significant problem worldwide.

SCRS advocacy has brought the importance of timely site payment to the forefront and begun a shift in the frequency with which sites are paid. However, payment frequency remains a significant problem worldwide. In 2018, 39% of sites reported being paid quarterly, down from 44% in 2017 (figure 5).[2] Though trending in the right direction, we must continue to advocate for monthly payments.



The impact of slow payments is magnified among sites outside of the US. 54% of OUS survey respondents receive quarterly payments, and only one in five receive monthly payments. Despite the common requirement to invoice for all services completed, which creates a higher invoicing burden compared to the US, only one OUS respondent said they preferred to be paid "less frequently".

What can be done?

When nearly eight out of ten of sites attempt to negotiate a monthly payment schedule every time or most of the time,[1] and nine out of ten sites clearly indicate a desire to work with sponsors and CROs that pay more frequently, it is crucial that the industry begin to treat monthly site payments as a need rather than a preference.

When using traditional manual processes or solutions not built specifically for clinical trial payments, it is nearly impossible to execute monthly payments: data compilation, appropriate contract rates, split payments (fixed and variable), auditability, invoice/tax compliance, transparency for sites and sponsors, predictability, approval workflows, foreign exchanges, and more all pose challenges to paying sites monthly; this reality increases when managing multiple studies. Purposefully-built solutions are available to automate and streamline not just invoicing, but payments as well which supports accurate, compliant, transparent and timely monthly payments. It is imperative that sponsors and CROS seek out such solutions to truly enable site sustainability and success by improving site payment practices.

Support Sites in Meeting Patient Needs

Alleviating the site's administrative burden related to invoicing and payments is a significant step in the right direction. Administrative burdens can be even further reduced by utilizing available patient reimbursement and travel technology solutions, allowing sites to focus on patients and their overall experience.

In today's clinical trial landscape, patient selection is becoming increasingly difficult. Rare disease trials, complex protocols, narrow inclusion criteria and other trends make it harder for sites to enroll and retain patients. Patients are required to travel further and stay longer, adding even more stress to an already stressful situation. Often, out-of-pocket costs prevent eligible patients from participating and have a negative impact on participant diversity. It is imperative that these barriers be removed to enable maximum participation.

Many trials require patient travel, and suitable transportation is a frequent concern among patients and sites alike. Currently, most sites are left to figure out this problem on their own. 76% of sites book travel for their patients, and 81% say quality transportation is important for recruitment and retention purposes – a top hurdle for sites.

Simply booking travel services such as flights, hotels, and car service is not enough. Even when patients are not paying out-of-pocket for their travel expenses, they still incur travel and participation-related expenses. Meals, parking, and time away from work are all examples of real expenses that create a significant burden for patients. When patients give their time and bodies to a clinical trial, they should not incur unnecessary inconvenience.

What can be done?

Sponsors and CROs must consider utilizing tools to reduce the administrative burden on sites related to booking travel and paying/reimbursing participants. However, it's not just the site's experience that needs to be improved – the participant's experience needs improvement as well. Payments and reimbursements must be immediate and easily accessible – including for the unbanked population – to participants around the globe. Providing travel accommodations specific to the local culture and modes of transportation with no out-of-pocket expenses for the patient or the site is recommended.

Summary

It is a well-known fact that site staff are hesitant to adopt another portal or application. Therefore, it is important to identify solutions that combine logical, similar processes into one technology and provide material value to sites. These technology solutions should enable streamlined payment processes, reduced administrative burden for the sites, and an improved experience for all stakeholders (patients, sites, and sponsors/CROs).

Increased focus on patient convenience and site centricity will position clinical research stakeholders globally for success.

While we have seen progress since SCRS first called attention to these matters, considerable work remains. SCRS calls on the industry to deepen their involvement and take meaningful, concrete steps toward addressing the above barriers, thus creating a better financial reality for sites and a barrier-free clinical trial environment for patients.

This paper was produced by SCRS in collaboration with greenphire®

References

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2. SCRS. Site Landscape Survey. 2017.

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