## Site Payments and Patient Reimbursements: A Global Perspective



INANCIAL STRESS AT CLINICAL RESEARCH SITES negatively impacts the success of clinical trials. This has been well-researched in the United States: Approximately 40% of sites indicate that slow payments are a primary operating concern.<sup>1,2</sup> In 2016, 66% of sites globally reported having less than three months' worth of operating cash.<sup>3</sup>

Past analysis of how site processes interact with sponsor and contract research organization (CRO) payers has been based on assumptions; until now global information about these processes has not been available. The Society for Clinical Research Sites (SCRS) and Greenphire conducted a global survey of sites focused on their financial operational processes for handling study payments as well as patient reimbursements, and how the payment processes and systems used by sponsors and CROs interact to impact site financial stability.

This survey demonstrates that sites globally all have the same expectation to be treated as valued business partners, and the same need for four key improvements from payers:

- Timely payment (30 days)
- Electronic payment (electronic funds transfer)
- Site access to their financial information in payers' electronic systems
- Automatic payment with reduced need for manual invoicing

Survey findings also demonstrated that payment processes interact with patient payments in multiple ways, and that these interactions directly impact the patient.

SCRS has advocated for each of these key improvements and is 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, hasbeen a core element of SCRS advocacy.

To validate these long-standing advocacy positions, survey responses were collected from 760 site respondents between December 20, 2016 and February 7, 2017. Approximately three-quarters of the respondents were from sites located in the United States (US). Approximately three-quarters were part of

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a hospital or clinical practice, while the remaining respondents worked at a freestanding clinical research site or an academic medical center. Threequarters of the survey respondents had been involved in clinical research for more than 10 years.

Sites spend a considerable amount of resources on accounting tasks. Most sites use paper or spreadsheet software such as Microsoft Excel to manage accounts receivable, and most of

the employees performing accounting tasks also perform patient care. Managing patient stipends and reimbursements is another accounting burden these employees take on, including organizing the information required for tax reporting in many regions. Site staff face challenges at every step in the process of getting paid: creating invoices to receive payment, maintaining operations while waiting for payment, reconciling the payment once it arrives, and meeting the needs of patients who also require reimbursement.

Sites placed a high value on every improvement in accounting processes and information presented to them. Sites value access to information that makes accounting tasks easier. As reported in SCRS Site Landscape Surveys and other industry surveys spanning almost a decade, sites especially value timely electronic payment within 30 days. Payment delays create financial stress that impacts sites' ability to perform study functions. This is the first survey to demonstrate that delayed payments are not only a burden in the US, but worldwide.

Digging deeper into why payment processes and optimization have such a profound impact at sites, sites were asked about their accounting practices. Sites expend significant resources to maintain accounts receivable records, generate invoices, and manage reimbursements. Only 35% of sites use accounting software such as a clinical trial management system (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. Sites outside of the US are almost twice as likely as sites within the US to use a paper accounts receivable system and three times as likely to not have an accounts receivable system at all.

The contents of site invoices vary considerably inside and outside of the US. Most sites in the US, 78% of US

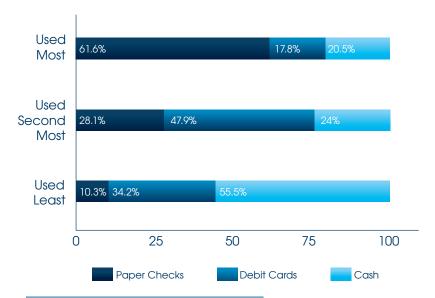


Figure 1. How Study Stipends are Paid.

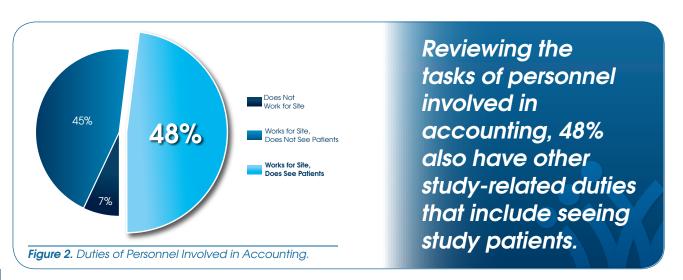
respondents, only invoice for pass-through items. Outside of the US, 77% of sites invoice for every study item, including study visits. Sites outside the US are often required by local regulation to create an invoice for every payment they receive, resulting in increased administrative and reconciliation burden on both sites and payers.

It is important to note that though the invoicing burden is lower for US sites, significant inefficiency remains in the invoice processes that do exist for US sites. These inefficiencies are often focused on reimbursement for pass-through costs. A large portion of clinical research budgets is paid through manual invoicing, even when invoicing is limited to pass-through

costs. SCRS advocates for automated payment systems for as much of the clinical trial budget as possible.

For patient stipends and reimbursements, paper checks or cash were reported as most common. (Figure 1) While debit cards may offer more efficiency, sites were mixed in whether they felt their patients would be receptive to them. In the US, sites reported that debit cards were more accepted by patients, but more than half of non-US sites indicated that patients prefer cash. Debit cards can be an important component of a collaborate effort to reduce the accounting burden on sites and payers. Where cash is required, sites must be reimbursed promptly and accounting must be automated as much as possible.

When asked if they are required to provide information about patient payments to tax authorities, 61% of sites stated they were required to provide information either directly or by providing the information to the



patient. Only 52% of sites indicated that they use a system that is "somewhat" or "extremely" effective in generating the required information.

Reviewing the tasks of personnel involved in accounting, 48% also have other study-related duties that include seeing study patients. (Figure 2) When asked how much time is expended on accounting activities, 74% percent of sites report that personnel spend more than 15 minutes per patient visit and 46% reported spending more than 30 minutes. (Figure 3)

It is in everyone's interest to have site resources focused on patients. When resources are wasted on inefficient accounting procedures, time is taken away from patient

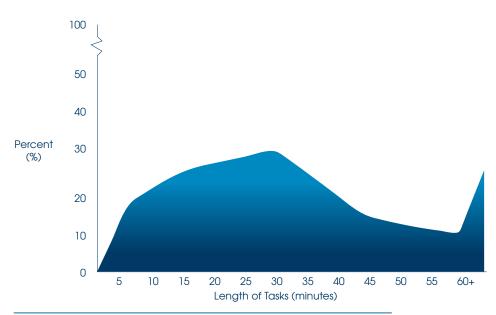


Figure 3. Time Spent On Accounting Activities Per Patient Visit.

identification, recruitment, retention and care. This survey identified site receptiveness to key improvements that could be implemented by sponsors and CROs which would improve both financial success and accounting efficiency at sites.

Sites were asked about the impact of timely and electronic payment, access to their financial information housed in payers' electronic systems, and automatic payment that reduces the need for manual invoicing. Sites were asked about the impact of these key improvements on their financial sustainability, their

efficiency, and their patients.

## Sites are clear that prompt electronic payment is required for study success.

Sites are clear 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. This preference is consistent around the world. 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. More than three-quarters of sites reported that reimbursement timelines have an impact on their ability to pay stipends and reimbursements to patients.

Payments that are delayed

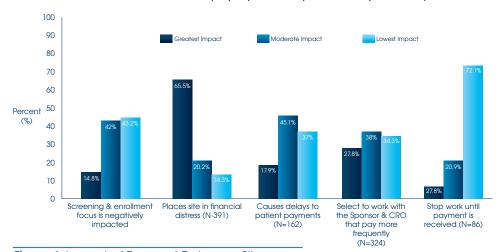


Figure 4. Impact of Payment Delays on Sites.

Sites outside the US responding to questions about delayed payments are more likely to report a higher negative impact on screening and enrollment, more financial distress, and greater likelihood of stopping work.

have a cascade of negative effects on sites and their studies. (Figure 4) In an environment where 66% 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 simply cannot pay the patient immediately and wait for a reimbursement that may be delayed several months. In addition, payment delays affect the ability of a site to devote resources to screening and enrollment activities.

Sites use payment timeliness as a factor in determining which sponsors and CROs to accept studies from, and occasionally sites make the decision to stop work when they have not been paid. Sites outside the US responding to questions about delayed payments are more likely to report a higher negative impact on screening and enrollment, more financial distress, and greater likelihood of stopping work.

Sites are equally clear that they value help with their accounting burden. Site 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." Sites were asked about four areas of accounting information they might value: account currently due, expected date of payment, payment details, and record of what has been

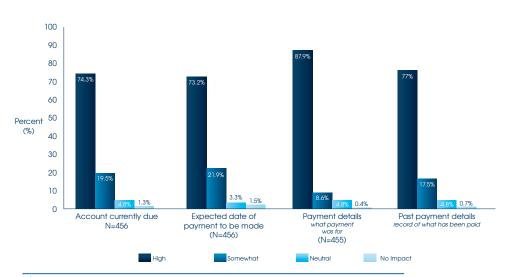


Figure 5. Impact of Making Accounting Information Available.

paid. More than 70% of sites rated the impact of the availability of all of this information as "high." (Figure 5.) Non-US sites reported even higher impacts than US sites.

An information system which made accounting information that is already maintained by sponsors and CROs transparent to the sites would increase site accounting efficiency and return staff to patient care. Information that helps non-US sites generate required invoices would be equally helpful. Sponsor and

CROs have this information available to them using the electronic data capture (EDC) systems that prompt payment for most studies. Reducing the need for manual invoicing is a key improvement that helps site efficiency.

Likewise, a system that could generate patient stipend and reimbursement information as required by regional tax authorities would free up site staff for other value-added tasks. These results clearly indicate an opportunity for sponsors and CROs to affect the efficiency of sites' financial systems and processes.

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. The need for payment within 30 days is all the more important in light of the fact that sites believe it is important to patient satisfaction to pay patients at the

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time or immediately after the visit. 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. The legacy system of paying sites on a quarterly basis is a carryover from when data were written on triple

carbonless paper, verified by the monitor, and then pulled and entered into a system at a data entry center. This system has been replaced with immediate electronic data capture and central monitoring. While it is heartening to note that some sponsors and CROs have started committing to making monthly payments for sites, 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.

Meeting these four goals of timely payment within 30 days, electronic payment, site access to their financial information and reducing manual invoicing will improve site sustainability around the world. The barriers to providing these improvements are significantly lower than they once were. SCRS calls on industry to remove remaining barriers to payment and accounting efficiency for sites.

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This paper produced by SCRS in collaboration with



<sup>&</sup>lt;sup>1</sup> Neuer A. Budget Woes Stall Clinical Trials and Stymie Sites. Clinical Informatics News. February 2012. Available at <a href="http://www.clinicalinformaticsnews.com/ecliniqua">http://www.clinicalinformaticsnews.com/ecliniqua</a> article.aspx?id=113005. Accessed: March 5, 2017

<sup>&</sup>lt;sup>2</sup> Klein, J. Benchmarking Investigator Payments. December 2012. <a href="http://www.appliedclinicaltrialsonline.com/benchmarking-investigator-payments">http://www.appliedclinicaltrialsonline.com/benchmarking-investigator-payments</a>. Accessed: March 7, 2017

<sup>&</sup>lt;sup>3</sup> SCRS. Site Landscape Survey. 2016

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