Site Payment

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Society for Clinical Research Sites

SCRS WHITE PAPER

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Site Payment

Site Payment Status Update

SCRS last published on site payment processes and their negative impact on sites in 2012 and today the issues surrounding site payments and their implications for the sites remain essentially unchanged. Recognizing issues related to site payments is a critical one for sites and, concerned about the lack of progress within the industry, SCRS decided to take on this topic as one of our 2015 initiatives. The purpose of the Site Payment initiative is to establish new industry standards for the frequency and process of how sites should receive payments for industry sponsored clinical research work.

For the last year, SCRS has supported a working group comprised of multiple stakeholders to evaluate the sources of burdens placed on sites by the current site payments practices and lead the way to solutions. Legacy, outdated processes related to site payments, places sites in an unfavorable financial position, adversely impacting site sustainability and the willingness of investigators to remain in clinical research. The working group for this initiative includes SCRS sites, sponsors, contract research organizations (CROs) and service providers. The initiative is co-chaired by Hospital Corporation of America, INC Research and Novartis.

This initiative is anticipated to span at least two years due to the complexity of the subject matter and the time that would needed to implement such significant process changes among large organizations. At this time the working group has focused first on establishing best practices pertaining to site payments in the United States. However, in 2017, the working group will address site payment issues for sites in the rest of the world. The working group has identified eight major areas of significant burden associated with the payment process that threaten site sustainability. Initial concepts have been identified to address the first five burdens identified. (Table 1) In 2016-2017 the working group will address the remaining three burdens identified.

Burdens Identified	Initial Recommendations
1. Contract Terms: Payment Frequency	Payment within 30 days
2. Contract Terms: Pay When Paid	In contracts where a "pay when paid" clause is included, the clause is limited to only cases were the sponsor has filed for bankruptcy
3. Payment Back-Up Information	Each payment will be accompanied by a report to include the protocol name and number, investigator name, details of each payment line item including subject initials, visit number, visit date and procedures outlined if the payment is for items outside the visit
4. Holdback Payments	Eliminate holdbacks
5. Dispute Resolution	All parties to the contract should include within their standard study documents an escalation process and contact information

Table 1 Identification of Significant Burdens on Sites by the Current Site Payments Practices

1 – Contract Terms: Payment Frequency

As was previously reported, 51% of all sites receive payment on a quarterly basis. While some would argue quarterly payments are inappropriate as a baseline, the reality is much worse than that: quarterly payments translate into sites being paid approximately 4 ½ - 6 months after the work is performed due to the internal processes of large companies actually getting payments to the sites. Additionally, sponsors and CROs that holdback portions of the sites' earned income further delay the sites being paid in full for work delivered.

Given this reality, it should not have been a surprise to learn that in 2011, 65% of sites reported having less than three months operating cash in the bank.[1] In a survey conducted by SCRS in 2016 the percent has increased to 66%. (Table 2) Additionally, in 2016 the average holdback of cash earned and paid to the site upon study closeout continues hovering right around 12%. In 2016, sites are reporting a profit margin of 13%, which has remained relatively unchanged over the last five years.[2] (Table 3) In addition to receiving payments well after they complete their work, holdbacks mean that more than the entire profit margin on a study may not be realized until months after the study ends. This fiscal paradigm imposes an unrealistic burden on the site to remain cash positive or even neutral. It is no wonder that guaranteed payment in 30 days is considered "very valuable" by 77% of research sites doing more than 5 studies per year. (Table 4) Yet only 28% of site payments are monthly.[1]

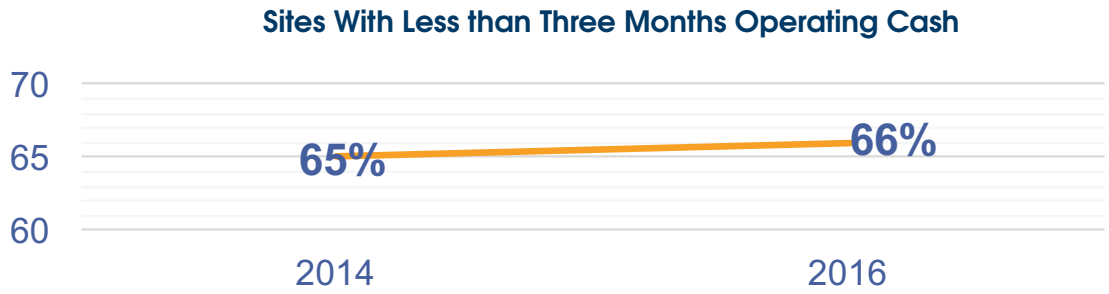

Table 2 Sites with Less than Three Months Operating Cash

From a different lens, recent data reveals that 80% of sites know studies that pay quarterly will incur a negative impact on the execution of the study.[3] This data supports similar results that SCRS identified in 2012. Sites, like any business, must have operating cash and that need will continue to drive them to prefer to work with sponsors and CROs that provide monthly payments.

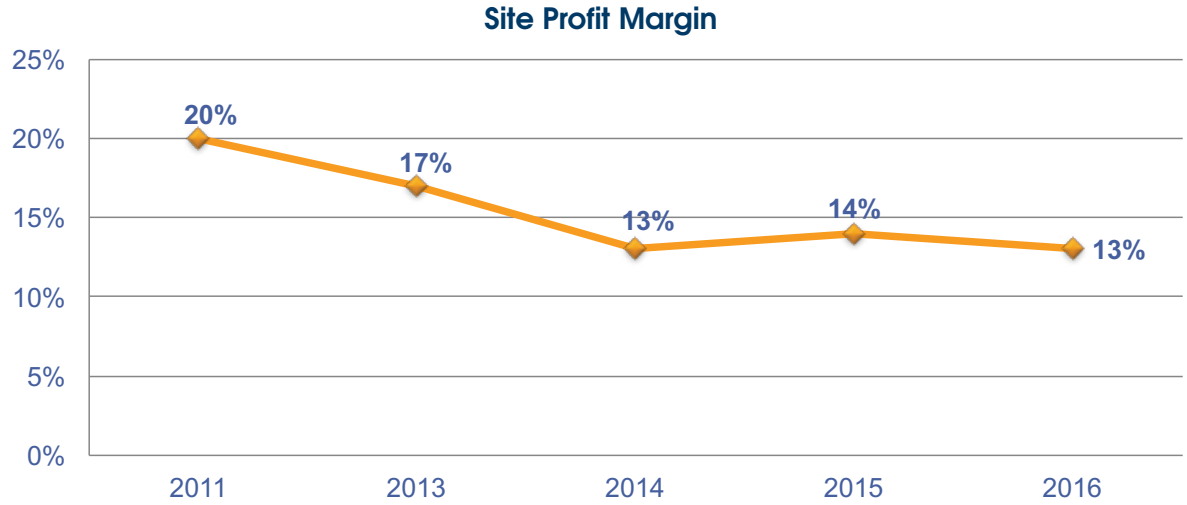

Table 3 Site Profit Margin

Clinical Trial Agreement (CTA) terms that cause payments to be delayed beyond 30 days are a clear threat to site sustainability. It is our position that sites should be paid in full within 30 days of the payment-triggering event. However, a variety of contract terms deviate from this recommendation.

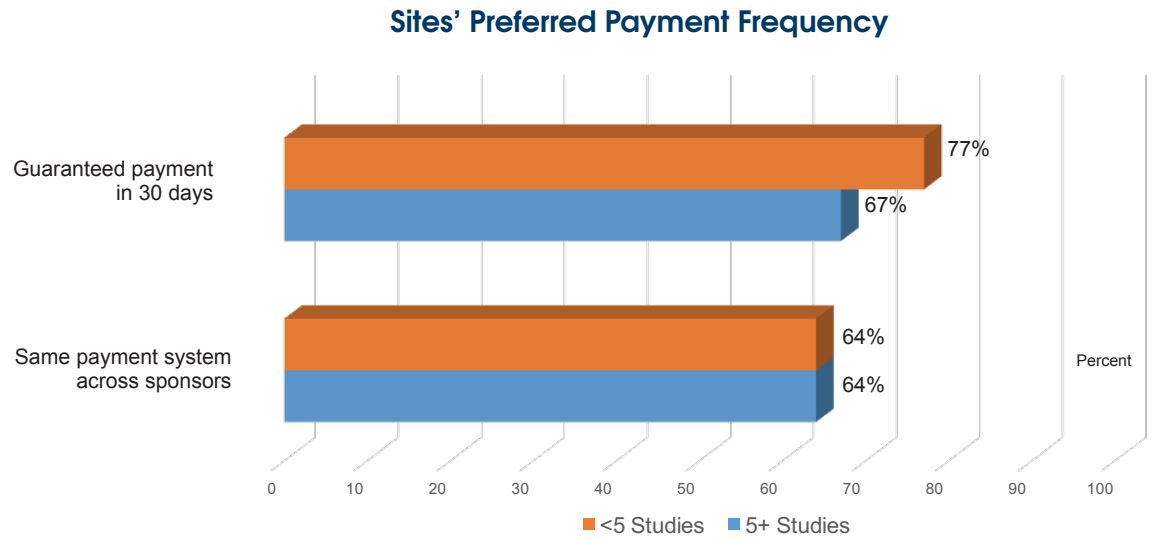

Table 4 Sites' Preferred Payment Frequency[4]

With Electronic Data Capture (EDC) system adoption at nearly 100% in major pharma sponsored phase III clinical trials[5], there is little argument to be made as to why sites should not be paid when such data is entered – at the payment triggering event. Knowledgeable research sites understand that their deliverable is the submission of quality research data. Therefore, until the data is delivered for visits/procedures, payments should not be made. It is known within the industry that sites can take some time to enter this data, often waiting for laboratory reports to complete an entry. The Best Site Practices, as established by SCRS in collaboration with the Association of Contract Research Organizations and TransCelerate BioPharma, Inc., is to enter data within five days of the visit. Less than 2% of that data is ever modified through the query process.[6] Unless an invoice is required by local law, the Sponsor/CRO can easily determine that the deliverable was received. Therefore, it is no longer reasonable to withhold payments to some arbitrary time point from historical practices.

The recommendation from this working group is sites be paid within 30 days of data entry.

2 - Contract Terms: Pay When Paid

"Pay when paid" clauses in the clinical trial agreements add uncertainty to the site's cash flow management. These clauses limit the right of the site to receive payment from the CRO if the CRO is not paid by the sponsor.

The Site has no knowledge of or control over the agreement between the Sponsor and CRO and the CRO may not be paid, or have payment delayed, for a variety of reasons. These reasons may include performance failures on the part of the CRO, slow follow up by the CRO to request payment from the sponsor, or study failures such as a data loss from an electronic system. In any case, these are failures over which the site has no control.

Another issue is that the site may only be made aware of a "pay when paid" clause being invoked months after they have continued work. There is no trigger for the clause which can be recognized by the site, thus allowing them to stop work and reduce their exposure.

For this reason, "pay when paid" clauses should be limited to the cause of bankruptcy. Bankruptcy has a clear and public date of effect. Sites understand that there is always the risk of insolvency with startup sponsors and they calculate that risk into their study acceptance.

The recommendation from this working group is that in contracts where a "pay when paid" clause is included, the clause is limited to only cases were the sponsor has filed for bankruptcy.

3 - Payment Back-Up Information

When sites do receive payments, they frequently receive just that – a simple and unexplained check or notification of a bank deposit. More often than not, payments lack backup information explaining in detail the specifics of what the check is for. This lack of detail creates a situation for the site where they either have to spend hours trying to track down what the payment is for so they can properly apply it to their accounting system or they just accept it, deposit it and credit it against the study with lack of detail. As many sites are also healthcare providers, their accounting systems are patient-centric; this leaves the site with no way to reconcile the payment within their account structure. This lack of information then prevent the site from tracking payments and posting deposits following generally accepted accounting practices (GAAP).

The recommendation from this working group is that each payment be accompanied by a report to include the protocol name and number, investigator name, and details of each payment line item including subject identifier, visit number, visit date and procedures outlined if the payment is for items outside the visit payment (i.e. storage fee, pharmacy start-up, etc.) or if any items invoiced were denied or delayed for payment.

4 - Holdback Payments

Almost universally, holdback payment evolved as insurance for industry to assure sites completed various study related activities, and specifically query resolution. Today, as almost 100% of studies are conducted using EDC, sponsors and CROs have full transparency into the sites' attention to the resolution of their queries, yet holdback payments remain in 58% of contracts in the US and 37% worldwide.[2] (Table 5) Additionally, the final payment of the holdback is often contingent upon the study being closed, the database being locked, and all sites being closed out. Individual sites are thus "held hostage" to the activities of other sites in the study. A site can and should only be held responsible for the work they are to do. Recognizing the critical importance of query resolution, SCRS' Best Site Practices outlines that all queries should be resolved within five days of notification.

The recommendation of this working group is that holdbacks be eliminated.

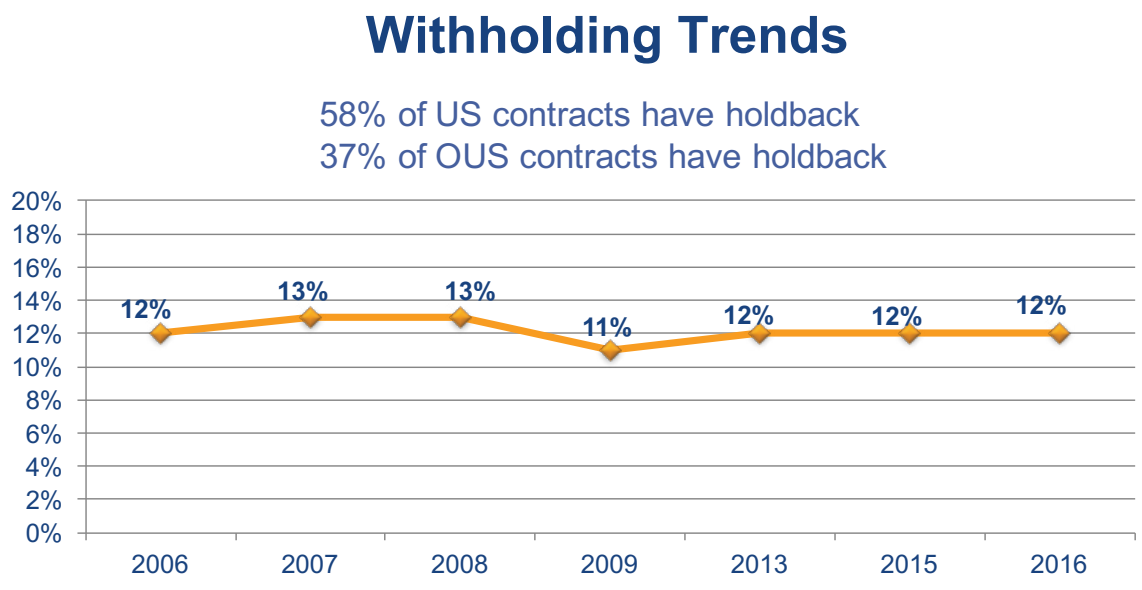

Table 5 Withholding Trends

5 - Dispute Resolutions

When there is a dispute or a need for clarification around payment issues, understanding who a site is to contact regarding payment can be quite complex: some trials are fully outsourced, some are outsourced to multiple parties (site recruitment, monitoring, and payments to different providers) and some are handled directly by the sponsor. Consequently, a common escalation path is via the clinical research associate (CRA), who tends to not have direct access to the financial contacts and simply has to escalate the problem to the project manager. The project manager, not being a member of the finance team, then has to forward the request onto yet another person, thus further delaying a response or a payment.

Likewise, the process at the site for resolving disputes may be unclear to the sponsor or CRO, especially at a very large site. This process can be especially complex when various departments are responsible for different parts of the study. Sites should also create a clear process for resolving payment disputes, make this document available to the sponsor or CRO, and keep it current.

The recommendation of this working group is that all parties to the contract should include within their standard study documents an escalation process and contact information specifically for financial information. These documents should be completed and shared with the other party prior to study initiation and filed in the study binder.

Conclusion

The working group will continue to work into 2017 to develop further recommendations and build industry consensus for solutions on worldwide site payment burdens. Organizations are invited to join this critical project.

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[1] SCRS. Site Landscape Survey. 2011.

[2] SCRS. Site Landscape Survey. 2016.

[3] Greenphire. Site Payment Study. 2016.

[4] DrugDev Investigator Survey. 2015.

[5] Borfitz, D. Forecast: EDC Money-Making Shifts to Phase II Trials. Bio-IT World. 07 Oct 2016. Accessed from: http://www.bio-itworld.com/bioit_article.aspx?id=35322

[6] Newbigging, A. An Eye for Change. International Clinical Trials. Nov 2014. Accessed from: https://www.mdsol.com/sites/default/files/RBM_Eye-for-Change_20141101_ICT-Article.pdf

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