White Paper

FIVE EASY INVESTIGATOR PAYMENT FIXES TO IMPROVE SITE RELATIONS

Resolve issues and improve efficiencies to increase site satisfaction

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INTRODUCTION

Investigator payments have long been a challenge for both sponsors and sites because the process is complex, fragmented, lacking in transparency and without standardization. Site satisfaction is closely linked to the frequency, accuracy and timeliness of payments. With 66 percent of sites having less than three months of operating cash on hand[1] it is imperative that sponsors and CROs do a better job paying sites to ensure their financial viability. This white paper reviews five common issues that delay site payments and offers recommendations to resolve these issues, improve payment efficiencies, and ultimately site satisfaction.

ISSUE 1: SCREEN FAILURES

CHALLENGE

Screen failures above the contracted limit are one of the most common reasons for payment delays. Screen failures occur when a patient is screened for a trial but not enrolled due to the inclusion/exclusion criteria or for other reasons. This adds significant costs, so sponsors set limits on the failure rate to incentivize targeted recruitment. Limiting the screen failure rate can backfire on sponsors because failure rates for some therapeutic areas such as oncology or CNS can be as high as 75 percent, and this policy penalizes high-performing sites that recruit the greatest number of patients. From a process perspective calculating screen failure payments as a percentage introduces a myriad of complexities for data entry, capture, and review in both the design and implementation of EDC and payment systems. There is no standard reimbursement model or fee for screen fails, so each study could have its own payment policy for screen fails.

RECOMMENDATION

The screen failure topic should be discussed during the

Limiting the screen failure rate can backfire on sponsors because failure rates for some therapeutic areas such as oncology or CNS can be as high as 75 percent.

startup stage, including Clinical Trial Agreement (CTA) payment term development, and prior to any study set-up. The anticipated number of screen fails should be researched thoroughly in advance as the historical percentage of screen fails will differ based on the therapeutic area and other variables. The calculation to reimburse screen fails should be simplified so reimbursement can be automated. IQVIA recommends all sponsors and payers offer a flat fee for screen fails. This can be done by splitting the screening visit into tiers with one tier for the basic screening procedures and one tier that includes additional services such as imaging. Most patients fail prior to the more complex or expensive testing so these flat fees would reduce expenses and streamline site payments. Screen fails should be paid as the work is completed to improve site cash flow. In the meantime, sites should not be afraid to appeal the limit of screen failures if they are prepared to provide data/history that supports a request.

ISSUE 2: WITHHOLDING

CHALLENGE

Most sponsors withhold 10-15 percent of the visit payments with the intention of incentivizing sites to respond to queries and complete final documentation and case report forms at the end of the study. This practice originated in pre-technology days when study teams took months to collect data manually and submit case reports. From a technology perspective, calculating a withholding amount as a percentage also adds complexity to the payment process and makes it difficult to automate because the visit payments are a rolling total. This practice also penalizes high patient enrollers because they recruit the greatest number of patients and so more funds are withheld. Sites invest a lot in the beginning of a trial that isn't covered by the startup fees, but their reimbursement is held back, resulting in poor cash flow and reduced working capital that could be invested in advertising or training.

RECOMMENDATION

Now that EDC information is submitted in real-time, the need for withholding no longer applies and the practice should be eliminated for experienced sites. IQVIA also suggests that a standard flat withholding fee be established for new sites ($2,500) to remove the challenge of paying on a rolling percentage and simplify the payment process. Let's move away from a practice that no longer applies and move toward a policy that rewards high-performing sites, supports new sites, simplifies the payment process and promotes a true partner relationship with our sites.

ISSUE 3: FUNDING

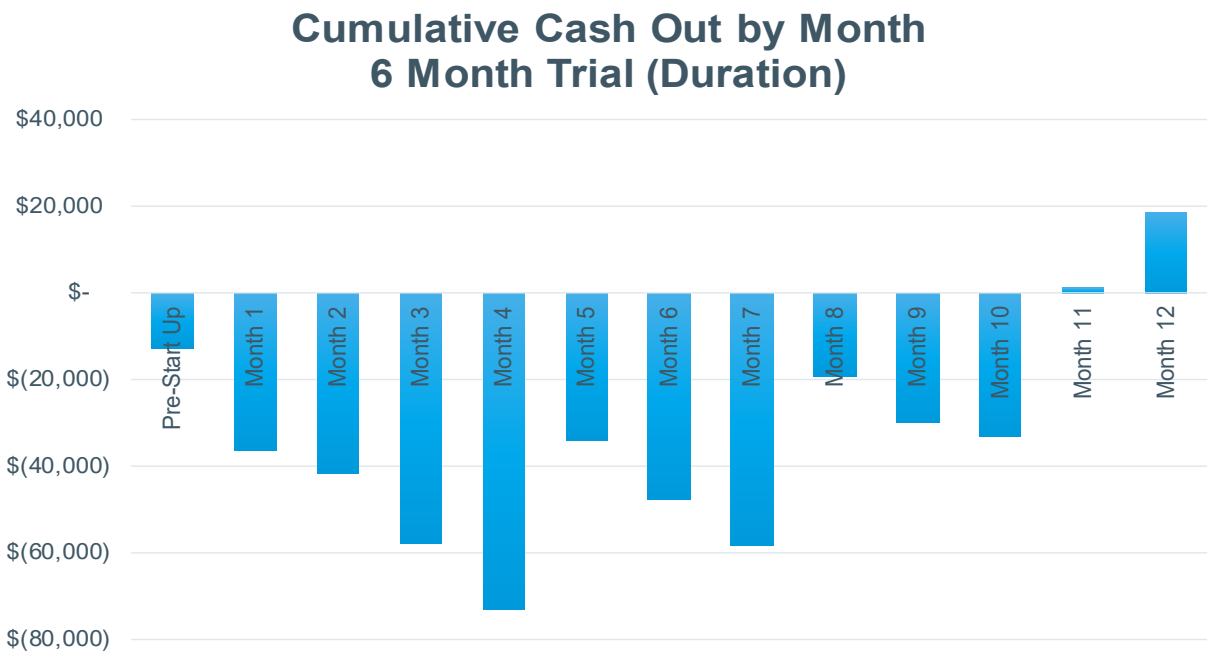
CHALLENGE

There are often payment delays as the payer waits to get funding from the sponsor. Delays typically happen because the sponsor's approval process to release funds includes multiple stakeholders and their respective processes and the importance of the funding payment terms has not been streamlined and communicated to the sponsor's finance, accounting or procurement groups. Often, standard funding practice is instituted rather than establishing a process up front that takes into consideration the unique requirements of clinical trial payments and ensures the swift payment of sites.

RECOMMENDATION

There are multiple ways to handle funding and this important part of the payment process should be discussed in advance and arranged based on the business and reporting needs of the sponsor. Just in Time (JIT) funding, where funds are transferred in real-time based on a monthly report, is the most efficient model and prevents needless tie up of sponsor cash. The more traditional model of advanced funding is commonly used by full-service CROs, where a lump sum is transferred to the payer in advance and the reporting is done after disbursement, but this model is not as

Figure 1: Cash Flow Projections with Quarterly Payment Terms[2]



efficient as JIT. Hybrid models can also be developed based on sponsor internal needs and timing capabilities of funding release.

ISSUE 4: UNMONITORED DATA

CHALLENGE

Remote or risk-based monitoring causes a shift in EDC submissions and impacts the payment process leading to overpayments or incorrect payments. Historically, monitors would frequently visit sites for source data verification and to review any site personnel questions. With remote monitoring becoming more prevalent, data quality check activities have moved from the sponsor/CRO to the site. This shift of responsibility to the sites can lead to timeline shifts in the delivery of the EDC data from the site to the sponsor/payer, resulting in delays. Quite often funding models are based on EDC data so any change to the EDC submissions also impacts funding and can cause further payment delays.

RECOMMENDATION

System checks should be set up by the payer to identify changes in data points or EDC submissions. This will red flag any changes and prevent payment errors. An experienced payment partner will be aware of this challenge and set up automated system checks to identify any changes and adjust payment disbursements to eliminate these types of errors. These system checks will mitigate errors and reduce the time sites need to spend troubleshooting accounts receivable. It is imperative that sponsors communicate any delays or shifts in EDC submissions to both sites and payment partner to allow them to adjust.

ISSUE 5: COMMUNICATION

CHALLENGE

Poor or slow communication often causes payments to be delayed because either the site doesn't respond in a timely fashion or doesn't provide adequate documentation required to process payments. In a

recent internal year-end review of a Top 25 pharma client with 90 studies, 60 percent of the payment delays stemmed from the sites' slow response in remitting information or responding to questions from the payer. Staff turnover and incorrect contact information contribute to this issue. Complex payment terms or vague budget language can also leave the sites unclear as to what back up documentation is needed and when items should be invoiced. Only 52% of sites report having dedicated accounting staff[3] which also leads to confusion.

RECOMMENDATION

A communication plan that outlines how questions and information changes should be exchanged (phone or email) and an escalation process to resolve issues should be put in place. Changes in site personnel should be communicated to the sponsor and payer so contact information is updated and new personnel can be trained on how to access the details of their payments (e.g., a payments portal). A generic payments email address that can be accessed by multiple site employees can also ensure timely communication. Payment term confusion can be avoided if the clinical trial agreement (CTA) is developed with easy to execute payment terms and all payer personnel are trained on the CTA and payment terms. Coordinating budgeting, contracting, and payments in advance will help to streamline payment execution.

CONCLUSION

The sponsor/site relationship should be approached as a partnership and processes streamlined to automate payments. Sites have a vested interest in recruiting patients and for performing well yet often they are not paid for the work they do until 90-120 days after the work is completed. If not paid promptly sites often must cover expenses and do not usually get reimbursed for finance charges. To become true partners sponsors should set up financially sound contract and payment terms that don't place undue hardship on the sites and allow them to be paid correctly, transparently and on-time. Understanding the site perspective and making these five changes will go a long way to developing a trusting, transparent partnership.

REFERENCES

1. SCRS Site Survey 2017.
2. Webinar - Site Perspective: Why Payment Terms and A/R Processes Matter, Ana Marquez, Founder & CEO, Clinical Site Partners, Cesia Abea, Accounts Receivable Manager, formerly Clinical Site Partners.
3. Site Payments & Patient Reimbursements: A Global Perspective, SCRS, 2017.

ABOUT THE AUTHORS

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With over 9 years of experience in clinical trial financial operations, Ryan advanced from a payment specialist to Manager of Study Operations to his current leadership role as Associate Director. Recognized for his natural aptitude for clinical trial financing and payments Ryan has been heavily involved with the evolution of clinical trial payments software and services available to our financial lifecycle clients. Overseeing many top 25 pharma accounts he is dedicated to reducing the administrative burden for sites and study teams by aligning processes, services and software to mitigate financial risk and improve site satisfaction.

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Danielle has focused on clinical trial finance and payments for the past 5 years starting in clinical trial data management and advancing to study operations with responsibility for a portfolio of TOP 25 Pharma clients. With her incredible client focus and dedication to improving processes Danielle has helped to expand business with the clients she manages Her expertise lies in building strong operational teams to support our clients as well as continuously improving internal processes and standards to improve efficiency.

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