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WHITE PAPER

Escrow-Free Grant Management:

On-Demand Payment Technology Offers Accuracy, Speed, and Transparency

Managing accounts payables to investigator sites during clinical trials is undeniably complex. But that complexity no longer needs to be the reason for putting tens of millions of dollars in escrow. The practice, which was once established as a matter of expediency, can now be abolished as obsolete and even a hindrance to achieving the very goals for which it was first begun.

New technology solves the accrual and forecasting —and visibility—challenges that have plagued the investigator payment process for decades. An on-demand, escrow-free payment system allows trial sponsors to retain their working capital, Contract Research Organizations (CROs) to focus on trial execution, and investigators to be paid accurately and on time.

The following brief reviews current grant payment practices and explains how new software tools can transform the process, efficiently solving the problem that first gave rise to sponsor-funded escrow accounts.

The Rationale Behind Escrow-Based Grant Funding

Accurately budgeting and then forecasting for investigator site payments in a clinical trial involves a bit of guesswork due to the number of variables involved—the number of countries and sites, how the Clinical Trial Agreement (CTA) is executed, patient enrollment rates, and site performance, to name a few. Typically, sponsors/CROs establish payment terms with sites (which are laid out in the CTA) based on the performance of specific transactions, such as patient screening, enrolling patients, and treating patients during site visits. However, enrollment rarely proceeds as planned, and unpredictable numbers of patients fail the screening process or drop out of the study. So, at the outset of a study, any estimate of the total grant spend is imprecise at best.

When CROs are engaged by sponsors to conduct clinical trials on their behalf, which can include managing payments to investigators—the sheer mechanics of which are Herculean. For a large global trial, a CRO may have to track, calculate, and disburse payments based on 1000+ investigator transactions each month. To simplify the process—especially as there is uncertainty around how much money will ultimately be required, and when—the industry developed a solution: escrow accounts are established for sponsors with monies earmarked for grant funding, and which the CRO can draw down over the course of the trial.[1]

Prior to the world financial crisis of 2008, most pharmaceutical companies were able to accommodate this arrangement, as they had fewer constraints on their working capital.[2] Meanwhile, it served CROs well, as they had access to cash when they needed it to pay sites, which, theoretically, both simplified and sped the process. And, of course, the interest profits that CROs made from the holdings in escrow were compensation for the additional tracking and reconciliation burden of maintaining the accounts. It is not unusual for CROs to have tens of millions of dollars in escrow from each of several sponsors. Prior to 2008, such accounts were generating 7-10 percent interest whereas the interest rates are currently well under 2 percent.

A Good Idea in Theory Falls Apart in Practice

What started out as a reasonable approach to ensuring the expediency of payments to sites has become complex to manage and has led to some undesirable industry conventions, including:

- **Co-mingling of funds.** The escrow accounts are not always, as is common practice in other sectors, specific to individual sponsors or to individual trials.
- **Inefficient study balance tracking.** Although sites' billable activities are captured in Electronic Data Capture Systems, (EDCs), without the right software integrations, these records are not automatically converted to any meaningful, current tally of what is owed to sites vs. what has already been paid. Issues with this approach snowball as site payments are delayed, monthly accruals are based on estimates, and forecasts are ill-informed. This lack of real-time reporting and transparency often results in difficulty forecasting payments to ensure enough cash is left in escrow when it comes time to make site payments.
- **Lack of accountability.** Sponsors are not able to obtain real-time updates on the account balance and payment status. When the escrow account gets low (which, remember, is often shared with other sponsors), sponsors are asked to top it up, often with little-to-no warning.
- **Delayed reconciliation.** Without technology, it is difficult to perform a full reconciliation of payments against the trial budget until after the data lock at the end of the trial. Often according to contract terms, this must take place within 90 days. Thus, sponsors must wait for months before learning what has been paid on their behalf and what they still owe.

In the absence of automated systems that can help track and manage payments, escrow accounts have become the accounting equivalent of black holes into which sponsors' money disappears for years at a time. Figure 1 illustrates the flow of funds in the traditional system.

Figure 1: The Flow of Funds Into and Out of Escrow Accounts

Problems Up- and Downstream

The escrow-funded payment system has been perpetuated in part because there has been little demand to change it. So, it is only natural that many site payment providers have been content with the *status quo* and have not, until recently, been compelled to invest in the tools and processes to improve their forecasting, tracking, and reporting.

Meanwhile, the existing processes have negative ramifications for all parties involved.

A Hardship for Sites

On average, it takes 120 days for sites to receive their grant payments, despite the fact that most contract terms specify a payment cycle of "net 30 days." Sites' cash flow suffers as a consequence. Based on data reported by the Society for Clinical Research Sites (SCRS), we know that:

- 15 percent of site revenue is more than 90 days old
- 33 percent of sites are writing off aged receivables
- Sites carry an average debt load of $400k
- 65 percent of sites lack the funds to operate for a full quarter

It is no wonder then, that 40 percent of US clinical trial investigators have identified payments as their top concern.[3] This, in turn, strains the relationship that sites have with sponsors, and an alarming number (40 percent) of first-time sites decide not to participate in future trials.

Given the time lag, the opportunity for human error, and the lack of transparency, tracking payment status and reconciling invoices with payments is a significant administrative burden for investigator sites. One investigator expressed frustration over the inefficiency of the current system, saying, "It has never been so difficult in 23 years of participating in clinical trials to get your money in the door for work done. I have spent hours on the phone, teleconferences, and have been unable to retrieve over five figures."

A Disadvantage for Sponsors

Obviously through the escrow process, sponsors lose access to millions of dollars in working capital and the opportunity to utilize that money elsewhere. But, that is, arguably, the least of sponsors' issues, even if it is the easiest one to which a cost can be assigned.

The lack of visibility to how the escrow account is being drawn down handicaps sponsors' fiscal planning. Over the course of a trial, they are often hit with the unpleasant surprise that more funds are needed, and they're expected to meet the request with no accounting of the spending to date. And, at the end of the trial, they could just as easily learn that they have overpaid as that they still owe millions. Any such post-trial reconciliation of funds poses a challenge for accountants, for to which year of a trial should the adjustment be assigned?

Without real-time visibility into what is going on, sponsors are hindered in any attempt to learn and improve their ability to estimate grant costs for future trials.

And, finally, perhaps most devastating in the long run is the fact that sponsors' reputations with investigators are tarnished when sites are not paid properly and promptly.

An Administrative Headache for CROs

CROs that have not invested in payment software solutions, also, of course, bear the burden of operating with inefficient systems. They must go through a cumbersome process of loading site data, cleaning it and passing it through a logic check, and calculating what is owed to sites. Often, data captured in the EDC are entered manually into a spreadsheet, which leads to errors in payment calculations and protracted payment cycles. Both situations inevitably make it difficult for CROs to reconcile their books and to address questions from sites. If individual sites are spending hours chasing funds they are owed, imagine how many hours CROs are spent fielding calls from hundreds of sites.

On-Demand Payment: An Escrow-Free Solution

Today, there are clinical trial payment systems that enable users (sponsors and CROs alike) to project, trigger, calculate, and disburse payments in any currency. When these systems are integrated with the trial's EDC, payment amounts are determined as soon as the month's books are closed, automatically. Figure 2 illustrates how it works. Essentially, the EDC registers the reimbursable milestones, as reported by sites, and a payment engine calculates the amount due. The system then generates a Request for Funding by trial, site, and country. Upon approval, the amount owed is then transferred electronically from the sponsor or CRO's bank to the banking network, from which it is disbursed to each site within days in the correct currency.

With this on-demand payment model, *there is no need to put money in escrow.* The system is similar to that which has been used by payroll processors for years. It is automated, fast, free of human error, and transparent.

Figure 2: On-Demand Payment Model Requires No Escrow Account

A Win-Win for All

The benefits of such a model extend from sponsors and CROs to sites. Sponsors are able to retain their working capital until the last possible moment. No middleman handles their money, has to reconcile it, or profits from it. **The savings that sponsors can realize from this are substantial. For example, one large manufacturer previously had a total of $22 M held in escrow with various CROs. By moving to an escrow-free system, the company saved more than $1.2M a year in working capital costs.**

And, sponsors have visibility into current study expenditures such that they can better manage the trial budget and plan for upcoming trial expenses. Over time, they can work to improve their forecasting abilities.

CROs are freed from the hassle of managing accounts payable for hundreds of investigators without the tools to do so efficiently. An automated payment system relieves them of a great clerical and accounting burden. The typical CRO currently devotes countless hours to this effort each month. And, perhaps even more importantly, CROs that have such a solution can use this as a competitive advantage to win business. The ability to operate without the need for an escrow account, to provide visibility to their sponsor clients into the status of payments, and to maintain positive relationships with sites are all selling points.

Sites benefit directly in that the correct amount for their grant payments is transferred into their account on time, according to the terms of the CTA. What's more, they're also granted visibility into the process; they can enter a portal in the system at any point to see the status of their invoices.

Conclusion

When the practice of creating escrow accounts for grant payments was first begun, it did make it easier to expedite payments due to the difficulties in forecasting. The practice, however, also enabled site payment providers to operate without the aid of sophisticated tracking and reporting tools, even as these became widely available.

Parties on either side of the payor "middleman" have been demanding more transparency, speed, and traceability in how escrow funds are handled. Now, with the availability of automated systems to track payable transactions, calculate payment amounts, and disburse funds electronically, the need for holding monies in escrow no longer exists. The payment workflow is streamlined and automated, bringing much needed efficiency and visibility to the process for all involved.

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Endnotes

1. An escrow account is one controlled by someone not a party to the transaction and into which funds are held until the completion of the transaction.

2. Working capital reflects a company's ability to fund day-to-day operations from its most liquid assets. It is calculated as the difference between a company's current assets and its current liabilities.

3. Getz, Kenneth, "Chasing Veteran US Sites Out of the Enterprise," *Applied Clinical Trials,* Nov. 1, 2010.