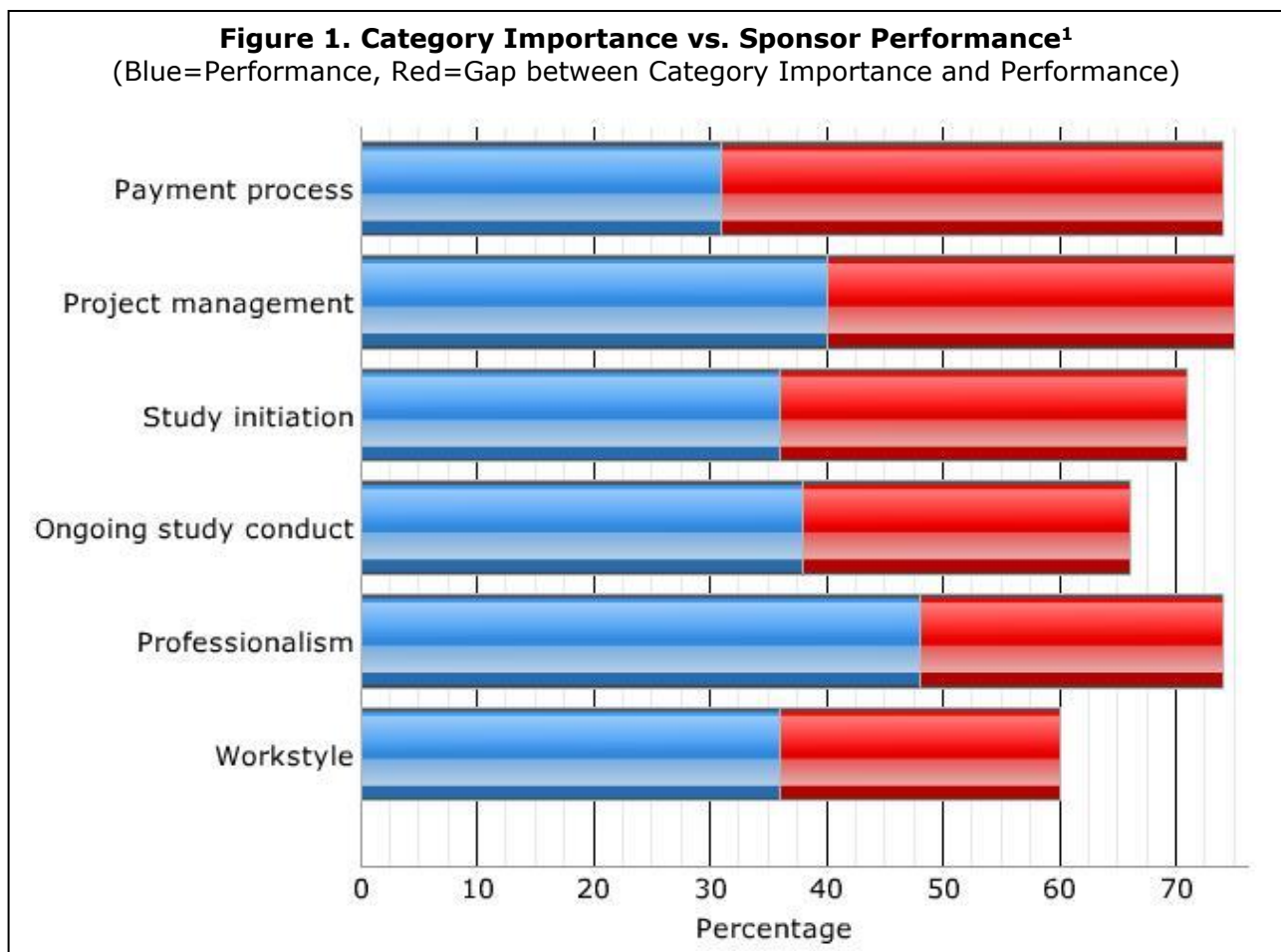


Solving the Revenue Collection Problem for Clinical Research Sites

By Norman M. Goldfarb

Few clinical research sites are willing and able to conduct industry-sponsored research without payment. Budget negotiations typically focus on prices, but a bigger issue for many sites is collecting payment. As shown in Figure 1, there is a huge gap between the importance sites place on prompt payment vs. the timeliness of payment. (In Figure 1, the measure is "Payment process," which is not the same as "Payment promptness." However, CenterWatch's Survey of 111 Investigative Sites in 2003 yielded almost identical results for "Prompt payment of grants": 78% and 30%, with a gap of 48%.)

Research sites, like other businesses, pay most of their operating costs within 30 days. Employees, accounting for the largest share of costs, are typically paid much more quickly. Rent is usually paid in advance at the beginning of each month. When a business' cash goes out significantly faster than its cash comes in, the bank balance can quickly hit zero. Before that happens, performance can degrade as survival drives decisions and morale decreases.



Accounting Principles and Terminology

Research sites ("vendors") sell "services" to research sponsors ("customers"). Vendors earn "revenue" for providing their products and services, while customers incur "costs." ("Expenses" are costs adjusted for accounting principles, such as depreciation. We will use the term "costs" in this article.) Vendors "invoice" customers for services rendered ("billable activities"). Customers pay invoices and vendors collect payment ("receipts"). Customers inform vendors of the services they are paying for by including a "remittance advice" with payment. Customers call costs that have been incurred but not paid "accounts payable." Vendors call revenues earned but not received "accounts receivable."

Vendors calculate "collection period" or "age of the receivables" as accounts receivable divided by average revenue per day. Customers calculate "payment period" or "age of the payables" as accounts payable divided by average cost per day. In most industries, customers pay upon delivery of the service, so the collection period is zero, or vendors invoice customers. However, most clinical research sites do not invoice study sponsors, so the collection period begins upon performance of a billable activity. As a result, the period from billable activity to nonexistent invoice is not included, thus overstating collection periods.

Every business is both a customer and a vendor. Profits are earned when revenues exceed costs. Losses are incurred when costs exceed revenues. When revenues equal costs, a company is at "breakeven." If a company operates at breakeven and its payment period is longer than its collection period, the difference puts cash in its bank account. In other words, its vendors are helping to finance its business. If its collection period is longer than its payment period, it must raise money ("capital") to pay the difference. In other words, it is financing its customers with money they can put in their bank accounts.

"Net cash flow" consists of cash coming in less cash going out. Cash flow is positive when incoming cash exceeds outgoing cash. Cash flow is negative when outgoing cash exceeds incoming cash. Cash flow is different than profitability because profit-related events, such as earning revenue, occur at different times than cash-related events, such as collecting payments. (There are numerous other events, such as purchasing and depreciating equipment, that also cause differences between profitability and cash flow.)

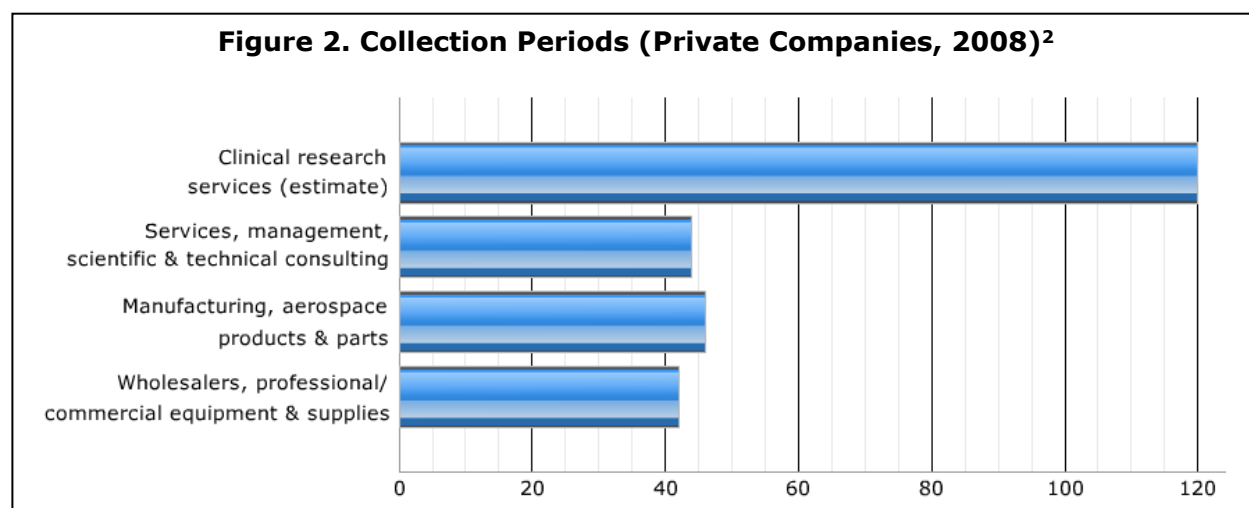
Companies finance negative cash flow with "capital": "equity" (stock) and/or "debt" (loans). Whether equity or debt, the "cost of capital" for operating a business is a real cost. Interest rates on loans are easily calculated. The cost of equity capital is less clear, but most people invest in a business for the purpose of obtaining a financial return that is equal or superior to the return they could earn by investing those funds elsewhere.

It is normal for businesses to be unprofitable when they are new or experience a sudden increase in costs or decrease in revenues. However, businesses that are consistently unprofitable go out of business unless their owners wish to subsidize the losses for other reasons. For example, a hospital may operate an unprofitable clinic for indigent patients because of legal requirements. Consistently unprofitable companies go out of business because, eventually, the bank account balance reaches zero, unpaid employees quit, and vendors stop supplying the company. Cash is the lifeblood of a business. No matter how profitable a company, if it cannot collect payment from its customers, it cannot survive.

Clinical Research Site Collection Periods

Accurate industry statistics on collection periods for clinical research sites are not available. However, anecdotal evidence indicates that, even in a good economic environment, they can run 120 days or longer, much higher than in other industries. Research sites with collection periods less than 100 days are rare. Figure 2 shows how these numbers compare with those from other industries.

A business with annual revenues of \$1 million and a collection period of 120 days needs $\$1,000,000 \times 120 / 365 = \$328,000$ in capital just to finance its accounts receivable. If its cost of capital is 10%, this financing costs \$32,800 per year. If its profit margin is 10%, its annual profits of \$100,000 are reduced by 32.8%.



Sponsors pay sites slowly for the following reasons:

- Historically, most clinical research was done by academic institutions, where collections were — and often remain — a low priority. The business model for industry-sponsored research is based on that for government-sponsored research, for which payment promptness is not a subject for negotiation. (Because of this history, the terms “grant” and “budget” are still commonly used instead of “fee” and “price.”)
- While most established pharmaceutical and medical device companies are very profitable, they are less profitable than they used to be, which displeases their investors. Most start-up biotechnology and medical device companies are unprofitable and rely heavily on capricious capital markets. It is easy to conserve cash by slowing payments to vendors, understaffing the process, and not allocating scarce management and technical resources to streamline the processes.
- As mentioned above, most research sites do not send out invoices. Instead, they wait for site monitors to verify their data on-site and authorize payment. Electronic case report forms are reducing these delays.
- Clinical trial budgets are usually complex. Budgets and payment terms are inconsistent from sponsor to sponsor and from study to study. These complexities and inconsistencies make it difficult for research sites to know what revenue has been earned and when payment is due.
- Research sponsors often do not include clear and detailed remittance advices with payments. Reconciling revenue with collections is very difficult in the absence of invoices and remittance advices. Without reconciliation, it is very difficult for a research site to know whether a sponsor has decided not to pay for something, is

holding payment until a problem is resolved, or simply lost the paperwork. Without this knowledge, sites cannot expedite these payments. (They are also handicapped if the Centers for Medicare & Medicaid Services (CMS) or the Office of Inspector General (OIG) want proof that none of the payments were illegal.)

- Many research institutions are not organized to optimize collections: one department negotiates the budget, another conducts the study, and a third receives the payments. These departments often do not communicate well.
- Most research sites do not meet the contractual commitments they make for subject enrollment. It is hard to negotiate for timely payment when you are in breach of contract.
- Clinical research is only a small part of most healthcare businesses that conduct clinical research, so collecting clinical research revenues is a low priority. As a result, research sites may not assign enough management attention, personnel or information technology to the process.
- Dedicated, profit-oriented research sites generally collect payments much faster than academic sites, but study sponsors generally are not set up to pay different types of sites on different schedules.
- Some industries reduce their charges for early payment (e.g. 2% within 20 days) and charge extra for late payments (e.g., 1.5% per month). These practices are seldom used in clinical research.
- When sponsors delegate payment responsibilities to contract research organizations (CROs), the business process may be inefficient. In addition, CROs cannot afford to pay sites until they receive payment from sponsors. Note, however, that some CROs pay sites quickly.

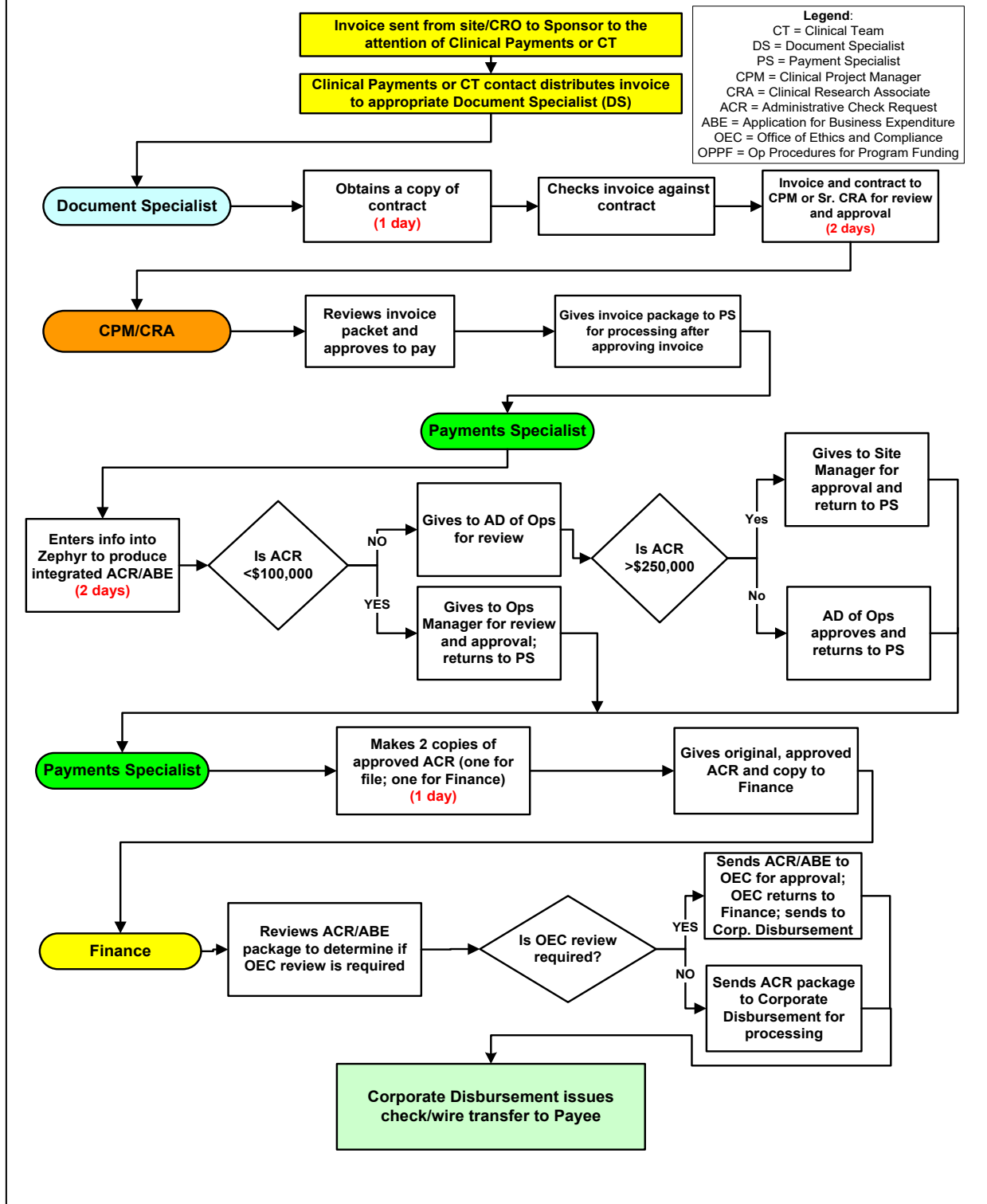
Without widespread pressure from research sites, sponsors have little reason to streamline their business processes and pay in a timely manner. Figure 3 shows the payment process of a large pharmaceutical company as of 2007. Every step in the process has a legitimate purpose, but other industries have found ways to streamline their payment processes. Sponsors with such cumbersome payment processes are likely to prefer quarterly to monthly payments. Note, however, that timely payment does offer one major benefit to sponsors: happier sites with the interest and financial ability to do more and better research for the sponsor. They also would waste less time dealing with payment-related questions and issues.

Impact of Slow Payments on Site Cash Flow

Figure 4 shows the costs of a simple study. "One-time" costs of \$1,600 are incurred in the four weeks prior to the first study visit. "Period" costs of \$200 are incurred each week, no matter how many subjects there are. Four subjects enroll, one each fourth week, for four weekly visits. "Variable" costs are incurred for each visit: \$400 for the first visit and \$200 for the next three visits. Not included in this example are "contingency" costs incurred for unexpected events, such as serious adverse events and rescheduled visits, or "overhead" costs, allocated as a percentage of all other costs. The total cost of the study is \$8,800 (\$1,600 start-up costs, \$3,200 period costs, and \$4,000 variable (visit) costs).

This study proceeds exactly as planned, with no delays or contingency costs. The site has agreed to a budget that causes it to break even on the study; in other words, when the study is over, revenues will equal costs. The sponsor pays all fees eight weeks after they are earned, except for start-up fees, which are paid when the site signs the CTA and starts the study in week 5.

Figure 3. Payment Process of a Large Pharmaceutical Company³

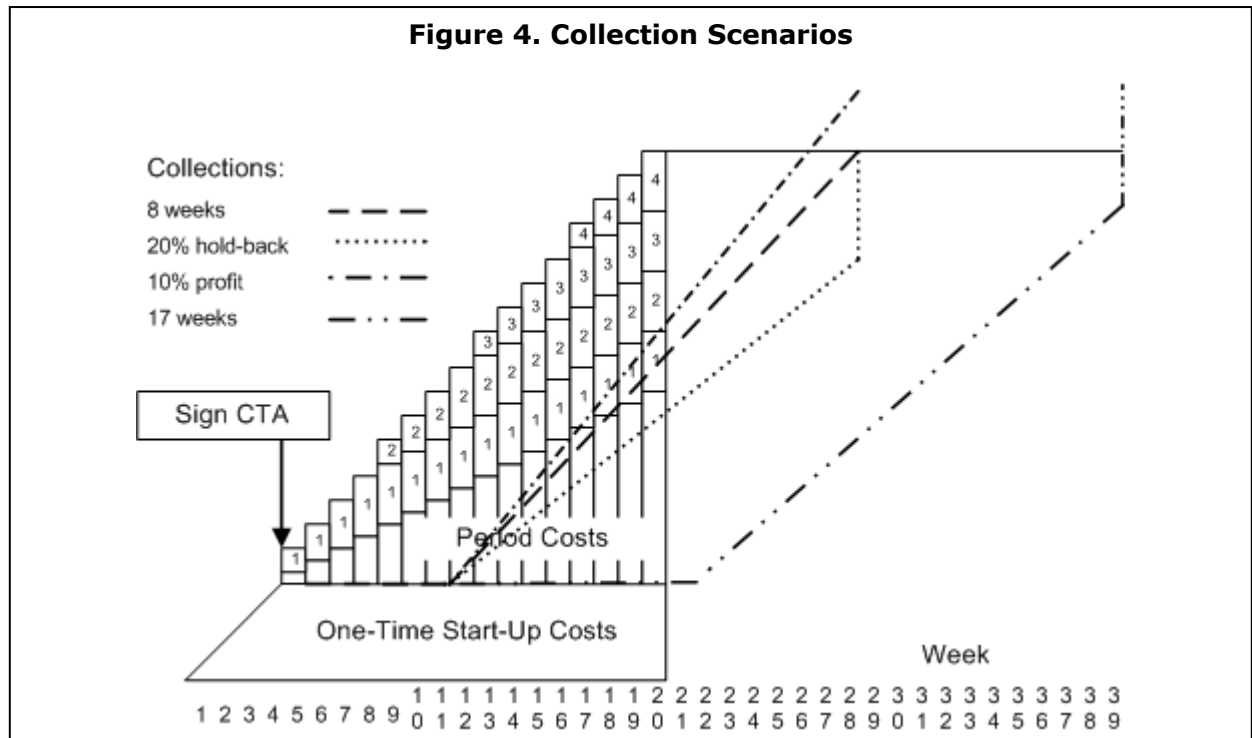


Four diagonal lines show results with the base case, plus three other assumptions:

- The dashed line shows collections ending eight weeks after the study.
- The dotted line shows collections with a 20% (\$1,760) hold-back.
- The dashed and dotted line shows collections with a 10% profit margin.
- The dashed and double-dotted line shows collections with more realistic assumptions of a collection period of 17 weeks (119 days), 10% profit margin, and 10% hold-back.

The site's accounts receivable are the difference between the diagonal line and the topmost solid line. For graphical purposes, all four scenarios assume the sponsor pays weekly. With more realistic monthly and quarterly payment schedules, the diagonal lines would become stair steps below the diagonal lines.

It is apparent from Figure 4 that the site is financing a large part — or all — of the sponsor's costs for this study, even with a 10% profit margin. In the base case, even with the assumption of 10% profit, the site's cash flow on the study does not go positive until 7 weeks after the end of the study.



How Sites Can Accelerate Collections

Sites can accelerate collections with the following methods:

- Conduct research for sponsors that appreciate their work, which requires enrolling subjects and meeting other obligations to sponsors. Do not conduct research for sponsors that pay slowly or may go out of business before paying. Credit information about businesses is available through Dunn & Bradstreet (<http://www.dnb.com>).
- Negotiate clear and timely payment terms in clinical trial agreements (CTAs) with sponsors that are willing to negotiate. Include appropriate language pertaining to

invoicing instructions, remittance advices, and accounts payable contacts. If possible, obtain payment by electronic funds transfer (EFT).

- Complete CRF pages and activities so they are billable. An empty data field can delay payment for an entire visit.
- Make it clear to the sponsor that delaying payment because the site monitor is not available for a visit is not acceptable. Only site visits near the end of a payment period delay payment. If the amount is significant and your data is normally high quality, ask for an advance.
- Generate invoices, even if only for internal planning, tracking and reconciliation purposes. Send invoices to sponsors even if they say they will ignore them.
- Track and reconcile revenue, billings and receipts. Identify and resolve problems quickly; do not wait until the end of the study. Do not give sponsors reasons to delay payment, such as inadequate documentation of third-party charges. Monitor compliance with CTA budget and payment terms, e.g., screen failure limits, to minimize problems.
- Do not be afraid to ask why a payment appears to be delayed. Although sponsors may have policies and procedures that cause payments to be slow, they seldom instruct their payment specialists to intentionally slow things down.
- Track and manage collection periods for individual customers and the business as a whole. Identify the major causes of slow collections and apply resources accordingly. Most sponsors do not want your metrics to prove they are your slowest paying customer.
- Streamline business processes and employ technology where appropriate. Paper- and spreadsheet-based systems are time-consuming and error-prone.
- Establish communications and relationships with relevant sponsor personnel before problems occur. Accounts payable clerks are people too.
- If internal resources or expertise are inadequate, work with service providers that specialize in helping sites collect revenue.

How Sponsors Can Accelerate Payments

Imagine some typical payment parameters:

- Sponsor pays quarterly.
- Sponsor mails checks 30 days after a payment period ends, arriving at the site 3 days later.
- A 1-day monitoring visit occurs every 6 weeks.
- Payment is for approved completed case report form (CRF) pages. It takes the site monitor 7 days after a visit to submit his or her approval for a CRF page.

With these parameters, what is the collection period?

A quarter has 13 weeks, or 91 days. A monitoring visit occurs every 6 weeks, or 46% of a quarter. The last monitoring visit occurs, on average, $46\% \div 2 \times 91 = 21$ days before the end of the quarter. Given that CRF approval takes 7 days, work completed in the last $21 + 7 = 28$ days of the quarter will not be included in the quarterly payment. However, work completed in the last 28 days of the previous quarter will be included. When payment is received $30 + 3 = 33$ days after the end of the quarter, the average age of the receivables is $(91 \div 2) + 28 + 30 + 3 = 106.5$ days. This result assumes everything goes according to schedule. (However, many companies that say they pay in 30 days really mean they pay in the month that begins in 30 days. It is common for a site monitoring visit to slip, problems with CRF

pages to delay their acceptance to the next site monitoring visit, the approval process to take longer than expected, etc.)

What happens to the collection period if monitoring visits occur at a different frequency?

For example, monitoring visits might occur every 4 weeks, or 31% of a quarter. The last monitoring visit occurs, on average, $31\% \div 2 \times 91 = 14$ days before the end of the quarter. Work completed in the last 21 days of the previous quarter will be included. When payment is received 33 days after the end of the quarter, the average age of the receivables is $(91 \div 2) + 21 + 30 + 3 = 99.5$ days, 7 days faster. From this example, we can conclude that any change in the frequency of monitoring visits will cause a change in the period change equal to 50% of that amount.

What happens to the collection period if the monitoring frequency is 4 weeks and the payment cycle changes from quarterly to monthly?

An average month is 30.4 days. With one monitoring visit per month, the average monitoring visit will occur 15 days before the end of the month. Given that CRF approval takes 7 days, work completed in the last $15 + 7 = 22$ days of the month will not be included in the monthly payment. However, work completed in the last 22 days of the previous month will be included. The average age of the receivables is thus $(30 \div 2) + 22 + 30 + 3 = 69$ days.

What happens to the collection period if, on the last day of each month, the site invoices the sponsor for all work performed during that month and the sponsor mails payment 30 days later?

If, as in other industries, the collection period is calculated starting from the invoice date, it is 33 days. If, however, the collection period is calculated starting from the date a billable activity is performed, the collection period is $33 + 30.4/2 = 45$ days.

What happens to the collection period if there is a 20% holdback?

Assume a study lasts 12 months, with equal billable activity for all months. Assume a collection period of 108 days for 80% of billings. Assume the holdback is paid in full 33 days after the study ends. The average collection period on the holdback is thus 180 days (6 months) + 33 days = 213 days. The average collection period on all billable activities is thus $(106 \times 80\%) + (213 \times 20\%) = 127$ days. In other words, a 20% holdback increases the average collection period by 21 days. Reducing the holdback to 10% reduces the average collection period to $(106 \times 90\%) + (213 \times 10\%) = 117$ days, a reduction of 10 days. Reducing the length of the study to 6 months (with 20% holdback), reduces the collection period to $(106 \times 80\%) + (123 \times 20\%) = 109$ days, not a significant impact. If the majority of billable activities occur during the first half of the study period, the impact of the holdback is larger.

In summary, reducing the monitoring period by two weeks reduces the collection period by only 7 days (106 to 99 days). If, in addition, we change the payment cycle from quarterly to monthly, we reduce the collection period by a further 30 days (99 to 69 days). Eliminating the delay from monitoring visit to submission of approved activities can save 7 days more. Remote monitoring and approval of data can reduce monitoring delays to almost zero. Making payments by electronic funds transfer can reduce "the check is in the mail" delays to almost zero. Minimizing hold-backs substantially decreases collection periods for long studies. Streamlining the approval process, e.g., by pre-approving routine billable activities for reliable sites, can save up to 30 days. In other words, collection periods for reliable sites could shrink to almost zero. That would be quite an incentive for sites to perform their best work.

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