BY DENISE MYSHKO

Process Improvement

INVESTIGATOR PAYMENTS

CLINICAL-TRIAL PROTOCOLS ARE BECOMING MORE COMPLICATED, AND INVESTIGATORS AND SITE PERSONNEL ARE RESPONDING TO THE CHALLENGE. YET ISSUES ABOUT HOW SITES ARE COMPENSATED FOR THEIR TIME AND EFFORT REMAIN. AT THE SAME TIME, THE NEED TO CREATE AN EFFICIENT DEVELOPMENT PROGRAM THAT AIMS TO BRING MEDICINES TO THE MARKET FASTER IS PUTTING ADDITIONAL PRESSURES ON CLINICAL SITES.

Clinical investigative sites are a critical linchpin to a drug-development program.

Sites are charged with managing a host of interconnected components — everything from patient recruitment and retention to data capture. Yet, often the business end of the investigative business is an afterthought, which unfortunately, can have a negative impact on how a site performs its assigned functions.

"Sites put a lot of effort into managing protocols but unfortunately many have difficulty knowing what their true costs are for their services," says Chris Cabell, M.D., senior VP, access to patients, at Quintiles Transnational. "Therefore, throughout the industry, it's difficult to assess whether payments are reasonable or unreasonable because most sites don't capture their costs very efficiently."

Experts in the field note that cost transparency is an important consideration because of the increasing complexity of protocols.

"Every year, protocols are becoming 10% more complicated, and every year, investigators are being paid 2% less, comparatively, for that protocol complexity," says Lori Shields, VP of operations for trial planning at Medidata. "Even the inclusion/exclusion criteria have become more complex. In the past, there were about 20 different items in a typical inclusion/exclusion criteria. Today, these criteria can take up as much as three pages of a protocol."

Dr. Cabell says what's happening at the site level is no different from everything else in medicine: more documentation is needed and there are more processes to be followed, which makes the amount of work that goes into specific research projects that much more arduous.

Because of the increasing complexity of protocols, Todd Esporas, senior director of contracts and functional services at INC Research, says it's important that sites know what their actual costs are to conduct research and to be fully versed at conveying the rationale for those costs.

"Investigator sites are becoming more sophisticated about negotiating costs," he says. "Sites should have an ongoing and open dialogue with the CRO so that we can act as a positive intermediary between sites and our sponsors. At a high level, we work with sponsors to develop an initial template for budgets based on fair market value and his-

TODD ESPORAS
INC RESEARCH

HEIGHTENED SCRUTINY THROUGHOUT THE INDUSTRY REQUIRES A HIGHER LEVEL OF TRANSPARENCY SURROUNDING ALL ASPECTS OF SITE CONTRACTS.

torical information. Negotiations become secondary to building a relationship with investigator sites by inquiring about administrative processes and becoming familiar with standard costing structures, including standard of care, at the individual site level. This enables us to come to a consensus more quickly each time that we deal with the site."

Ms. Shields says sponsors are making every effort to ensure that they are covering the costs for the investigators.

"It's not in a sponsor's best interest for a site to fail," she says. "Sponsors are performing a balancing act. They have to live within a budget for a particular trial. They also need to find sites that are performers, have the patients, and are able to enroll those patients. Sponsors use the most current data possible to determine what the appropriate costs are, but the sites need to know what their costs are to be able to negotiate fairly and actively."

One of the newest trends in site payments is the start-up fee, Ms. Shields says. The start-up fee is an additional payment that covers typical administrative start-up costs, such as paperwork or travel costs or the purchase of equipment. Depending on the complexity of the trial, what's covered in the start-up fee differs.

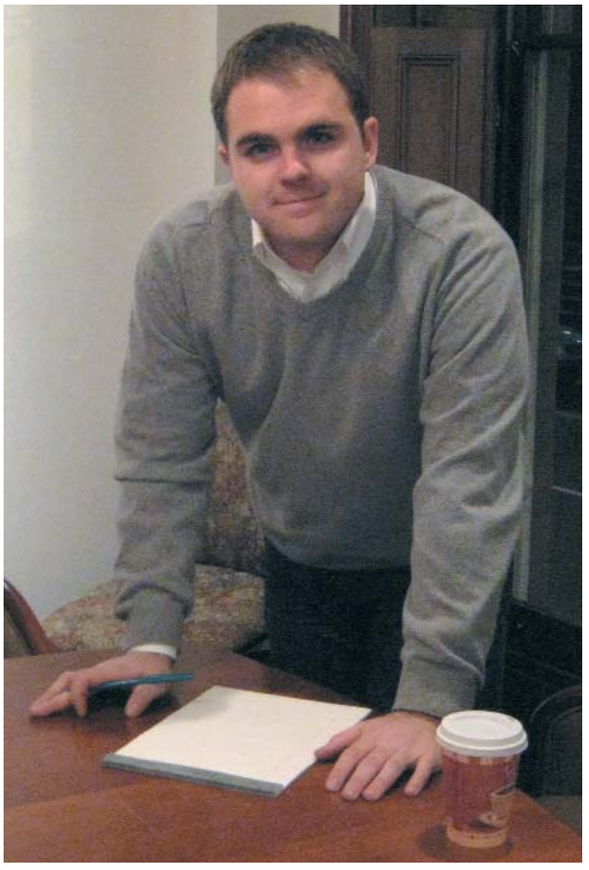
"In the past, it was just oncology sites that were heavily interested in negotiating start-up fees," she says. "But this is becoming a trend for every type of trial, and it's a global trend."

While the addition of a start-up fee has helped sites address some of their costs, Robert Robbins, president of Pinnacle Trials, says it doesn't cover some of the more costly items that sites face.

"For example, some sponsors don't pay for screen failures, or they pay for screen failures

LORI SHIELDS
MEDIDATA

SITES NEED TO KNOW WHAT THEIR COSTS ARE IN ORDER TO NEGOTIATE FAIRLY AND ACTIVELY.



SAMUEL WHITAKER
GREENPHIRE

THE PROCESS OF PAYING INVESTIGATORS IS PAINFULLY SLOW. THERE ARE PROBABLY SEVERAL CONTRIBUTING FACTORS TO THAT. ONE IS A LACK OF TECHNOLOGY SPECIFICALLY DESIGNED TO FOCUS ON THE SITE AND THE INVESTIGATOR.

based on a ratio," he says. "But just as many resources and time go into addressing patients who screen fail as for patients who are randomized for the trial. Sites still have to pay the coordinators, physicians, and study patients."

Another payment issue, Mr. Robbins says, involves extension studies.

"Sometimes when patients finish a double-blind study, there is an option for them to sign another consent form and continue the study on the active drug," he explains. "The only difference is that the drug is open label, which means the site knows the patient is taking the active drug. The site still has to perform the same procedures, but I've seen budgets where sponsors will provide one rate for the double-blind trial and pay half of that for the extension study."

GARY TYSON
CAMPBELL ALLIANCE

SITES AND SPONSORS ARE TRYING TO STREAMLINE THE CONTRACTING PROCESS BY USING A MASTER CONTRACT WHERE MOST OF THE TERMS AND RATES ARE ESTABLISHED.

PAYMENT SCHEDULES

Our experts say even if a site is up to speed in terms of its business processes, it is still dependent upon receiving payments in a timely manner. According to Gary Tyson, senior VP and head of clinical development practice at Campbell Alliance, slow payment is investigators' No. 1 issue.

Mr. Robbins agrees, adding that payment is usually quarterly or monthly based on the work performed.

"But monthly can end up being every other month and quarterly can end being every six months," he says. "Additionally, sponsors typically withhold a final payment until after the database is fully locked. For example, we just got a check for a study even though the database was locked more than a year ago. When sponsors withhold 10% to 20% of the budget for the final payment, that is significant."

Some in the field say the adoption of EDC by the sites could help speed payment.

"In today's world, much of the data are collected electronically," Mr. Tyson says. "Because a sponsor doesn't have to wait for a CRA to go to the site to make sure the data are collected, payments should be made in a more timely manner. A number of sponsors are working toward more rapid payment since this is such a concern for investigators."

Dr. Cabell agrees that the investigator payment is one area where electronic data capture can be used to address a pain point.

"In general, to create some leverage, sponsors don't pay a site until all of the activities are completed and the data are clean," he says. "Under the old paper-based system this could take a long time to reconcile. In the electronic world, this becomes much easier and there is the hope that payments can be expedited."

He says Quintiles has implemented several initiatives around expedited site payments and completion of specific tasks related to electronic data capture.

"We are trying to leverage technology with our partner sites to create efficiencies related to all aspects of the clinical research process."

There are other technology solutions to further streamline payments to investigators. For instance, GreenPhire is developing a Web-based system, which is expected to be available by April 2009.

"By validating the back-end payment schedule based on a site's or sponsor's internal systems, investigators are notified when a payment is received and they can log onto a Website and manage their money and either transfer it to another bank account or access it with their debit card," says Samuel Whitaker, CEO of GreenPhire.

Mr. Whitaker says sponsors and CROs are beginning to embrace technology as a way to simplify the investigator payment process.

"Over time, the process will become completely automated, which should make everything easier for all involved — investigators, sponsors, and CROs."

William Gannon Jr., M.D., chief scientific officer and medical director at Capital City Technical Consulting, says what is needed is a more streamlined process for sponsor approval of site payments.

"EDC technology doesn't necessarily help the reimbursement process," he says. "Electronic transmission makes the process go faster, but if payments are being delayed, the delay is due to the human aspect not the electronic aspect. To improve turnaround times, a standard operating procedure would be if investigators submitted a bill electronically to the CRO, which turns it around in three or four hours to the

SITE PERSPECTIVES ON CONDUCTING RESEARCH

ACCORDING TO A 2007 SURVEY CONDUCTED BY EPHARMASOLUTIONS, A MAJOR ISSUE FOR SITES IS SLOW GRANT PAYMENTS. OTHER RESULTS INCLUDE:

REASON FOR CONDUCTING CLINICAL RESEARCH

88% Altruistic reasons (not for the money)

REASON FOR ACCEPTING A PROTOCOL

65% Patients who could benefit from treatment

28% It's an interesting protocol

MAJOR FACTORS THAT WOULD STOP THEM FROM CONDUCTING RESEARCH ALTOGETHER

52% Protocols too challenging

31% Workload not commensurate with compensation

COMPENSATION

86% Believe they are fairly compensated by pharma

52% Believe that protocols are becoming increasingly difficult and the work won't equal the pay

MAJOR CAUSE OF STUDY DELAYS

46% Regulatory document and contracting completion process

29% Finding/recruiting patients

22% Unrealistic protocols

3% Technology implementation

2% Staffing issues

2% CRF completion

WORKFLOW EFFICIENCY

65% One URL/UserID/Passcode (workspace) for each study

19% Patient recruitment support

9% Staffing support

7% Better training

Source: ePharmaSolutions.
For more information, visit epharmasolutions.com.

DR. CHRIS CABELL
QUINTILES

IT IS CHALLENGING FOR INVESTIGATORS TO CREATE ECONOMIES OF SCALE THAT FIT INTO THEIR DAILY ROUTINE. THE SITES THAT ARE MOST EFFICIENT AT CLINICAL RESEARCH ARE SITES THAT PARTICIPATE IN MANY PROTOCOLS.

sponsor, which turns the payment around in 48 hours back to the CRO to release funds."

There is a move toward transparency in the area of site payments, just as there is throughout the rest of the industry, Mr. Tyson says.

"In the past, it was hard for a site to know where it stood regarding payments," he says. "Some sponsors are making an effort to create Websites that allow investigators to check on payment progress." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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