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Variable Billing Vs. Fixed-Price Models – What Does Your Clinical Trial Stand To Gain?

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Written by: Chris Porter

According to a recent article in the Wall Street Journal, the legal profession is undergoing a significant change. Many corporate clients are asking their counsel to restructure their billing practices from an hourly to a fixed-price model.

Law firms that would have found this notion unthinkable years ago are now complying. Why is this relevant to CROs? Because the same economic pressures that have been forcing law firms to alter their billing practices are bearing down on CROs as well.

The dynamics of billing by the hour are now proving to be counterproductive to the achievement of mutual goals by CROs and research sponsors. In this article, we'll examine some of the drivers that are pushing traditional ways of billing aside, including:

- the recognition that hourly billing is excessive in difficult economic times
- a gnawing feeling that clients are poorly served by hourly billing and the bidding practices that it engenders
- a shift toward building strategic relationships between CROs and sponsors
- the desire to mitigate risk and contain budgets.

THE STATUS QUO: SCOPE CHANGES AND CHANGE FEES

Fortune 1000 firms have responded to the economic crisis by putting their legal counsels on notice that hourly billing is no longer acceptable. Particularly for more repetitive, routine work, a fixed-fee structure makes sense.

Let's face it, we all understand the way the hourly billing system works in a variety of professional service industries — legal, accounting, consultancy, and yes, CROs. When services are sold by the hour, there is a direct incentive to bill more hours to make more money. There is also an incentive to bill for the time of higher-priced, senior-level partners or principals while minimizing the amount of work those resources perform, and perhaps even padding some of those hours with the time of lower-paid, junior staff. In the hourly model, there is very little incentive to limit hours or put a cap on costs.

In the white paper CRO Differentiation by Industry Standard Research (ISR), it is suggested that because many large CROs lack differentiation from each other, the primary selection driver is price. When the best price is all that is required to win a deal, there is an added incentive to bid low to win the job. And when a low

How Technology Is Driving Down The Cost Of Clinical Trials

One reason CROs are able to offer fixed-price contracts is that they have adopted an integrated technology platform as a key component to fundamentally restructuring clinical trials. The use of technology to drive process reengineering is critical to gaining maximum cost reductions and efficiency benefits across the spectrum of phased trials.

According to some experts, it is outmoded to think that different technologies are needed for different trial phases. Processes in any trial still include patients, physicians, data, logistics, monitoring, and various levels of reporting. These are the basics. Although subtleties exist between phases and across trials, a single software package can, and should, meet multiple requirements.

Similarly, it is also a mistake to think that technology can simply be layered on top of existing manual processes. Adding technology to a flawed process doesn't reduce costs — it simply creates a more expensive and complicated process that is just as flawed as the original.

Now that technology has evolved beyond simple electronic data collection, CROs can use a comprehensive technology platform to reduce costs through improvements in efficiency over the full range of processes. It's the purposeful integration of technology and business process improvements that enables the next step in the evolution of the CRO business model — fixed-price contracts.

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bid is truly unrealistic, it opens the door to future scope changes and change fees. Most contracts anticipate scope change and put a limit on it. But what does it say about a system that often allows a range of 50% to 100% difference between the original bid and the end cost? It says that it is acceptable to underbid the job by up to half in order to win it, and it is also acceptable to make up the shortfall with change orders.

We all understand how complex and risky clinical trials can be. It is not always clear at the outset how much time it will take to meet key study milestones. There are so many variables that even the most experienced estimators can be way off the mark with their best efforts. There are plenty of legitimate scope changes that are needed, but an additional 50% to 100% of the original bid may indicate a complete lack of trial design or a gross underbidding to win your business.

EMERGING COMPANIES DEMAND TIGHTER COST CONTROL

The evidence is mounting that more and more research sponsors will no longer tolerate this model from CROs. This is especially true as more early stage research is being undertaken by emerging companies with tight budgets and very limited ability to absorb cost changes over the course of the study.

Emerging companies are looking for innovative ways to stretch their budgets, gain some stability in uncertain economic times, and mitigate risk. Many are turning to CROs that are actively embracing new ways of doing business, such as incorporating electronic data capture, just-in-time monitoring, and strategic partnering. These innovative approaches are making it possible to swing the billing pendulum in the other direction — to a fixed-price model.

From a customer's perspective, fixed price has a lot of appeal. Customers know from the outset what the study will cost and can budget appropriately for it. They appreciate the predictability of a fixed-cost spread over the life of the study. Customers particularly appreciate not getting hit with costs associated with scope changes that should have been anticipated from the beginning. This predictability is especially valuable in a turbulent economy, when cost containment is crucial.

Fixed-fee contracts inevitably reduce the need for constant negotiation over change orders and uncomfortable requests for more money. As many sponsors seek a more strategic relationship with their CRO, fixed-cost billing helps build that relationship by allowing more focus on the study instead of on negotiating pricing.

From the CRO's perspective, fixed-price billing has benefits as well. Chief among them is reduced overhead on internal accounting and tracking systems over the course of the project. A fixed-price agreement can foster a friendlier and productive relationship with the customer by virtue of eliminating time wasted on discussions over money. This furthers the CRO's goal of working as a trusted partner and not just as a "body shop."

MORE RISK, NEW INCENTIVES FOR THE CRO

Of course, this engagement type places maximum risk and full responsibility for all costs and resulting profit or loss on the CRO. It also provides maximum incentive for the CRO to control costs and perform effectively. At the outset, there is significant pressure on the CRO to estimate the project correctly, assess potential problem areas, calculate resources, and account for a reasonable profit when crafting a fixed-price bid. There is also more incentive to work as a strategic partner with the sponsor to communicate, collaboratively resolve issues, and address small problems before they derail the study.

Estimating a fixed-price bid takes more effort on the front end, along with a healthy application of experience from prior projects. When crafting a fixed-price bid, it definitely pays to do extra work up front to make sure the estimate is as accurate as possible. Any CRO considering fixed-price bidding should heed the following advice:

- Don't just take information the sponsor provides at face value. Many requests for proposal are recycled from previous efforts and may not show the complete picture. Be ready to do some legwork at the target sites. For example, speak to the doctors and nurses to get a sense from them about the recruitment of patients.
- Use your own experience along with industry benchmarks for the type of study being performed (drug, surgical, etc.). This includes a careful assessment of potential risks and how they may affect the course and outcome of the study.
- Build in some cushion. You may want to consider establishing a contingency fund (with the sponsor's consent) and determining the amount by an assessment of high, medium, or low risk.

Pricing and billing ultimately affect the relationship between the sponsor and the CRO. In our experience, clients have responded favorably to fixed-price contracts because they know the CRO has extra incentive to perform efficiently. Often, that

results in a collaborative effort to seek those efficiencies through technology, improved business processes, and enhanced communication. A collaborative and strategic relationship between sponsor and CRO makes everyone feel invested in the process and the outcome.

Research sponsors shouldn't be reluctant to request a fixed-price bid from their CRO. A CRO with the right combination of experience, technology platform, and commitment to partnership won't hesitate to consider alternatives to traditional pricing.

About the Author

Chris Porter is cofounder and COO of Clinipace. Previously, he served as VP of corporate development and legal affairs for Drug Safety Alliance, Inc., (DSA). Additionally, he served as group manager of the Siebel Venture Group, Siebel Systems, Inc., where he was responsible for all of Siebel's venture transactions and management of a $30 million portfolio.

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