

RFP: a matter of patients

Optimizing the Patient Recruitment RFP Process

The complexities of patient enrolment are often underestimated, and procedures employed by pharma to select a suitable provider can be flawed. **Frank Kilpatrick, Michael Hamrell and Jeanne Floyd** outline how improvements can be made to the Request for Proposal process, and reveal how some progressive industry leaders are taking steps to refine both the process and the results

Pharmaceutical sponsors are turning to the Request for Proposal process to identify those vendors best able to deliver successful patient recruitment initiatives. In many industries, outsourcing departments have long since acknowledged this detailed procedure as an effective tool for controlling costs, communicating expectations and building relationships with providers. When applied to the realm of patient enrolment, though, the results often fall short of the desired objectives.

The reasons for unsatisfactory outcomes range from protocols with challenging inclusion/exclusion criteria to vendors with overly optimistic perceptions of their recruitment capabilities. But a faulty Request for Proposal (RFP) result can be symptomatic of deeper problems, most notably weak communication among clinical teams, outsourcing departments and patient recruitment vendors, and a failure to recognise how stakeholders can improve the outcome of the RFP exercise by building relationships in a consultative, information-sharing environment.

A successful RFP process is rooted in information sharing, through which parties

can lay the foundation for what should be the ultimate purpose of the RFP process – the creation of valuable relationships that are akin to partnerships dedicated to achieving key business targets.¹ As Dr Adrian Otte, senior vice-president of worldwide

development operations for Pfizer, explains: “What begins to happen over time is that prospective vendors become more like partners eager to build a long-term mutually beneficial relationship with us. And a level of trust starts to appear.”

At its best, the RFP functions as a communication tool, a jumping-off point for greater discussion, creativity and understanding of clients’ needs.² But quite often, what happens in practice is far from ideal. RFPs received by prospective recruitment providers frequently lack well-articulated objectives. This is especially true if clinical teams and outsourcing departments have limited communication, resulting in RFPs being sent out before the protocol is completed, budgets are finalised, and the success-hinging factor – the types of patients needed – is nailed down. Without this critical information, vendors are responding to a moving target and, as a result, responses may be as vague as the RFP.

Unclear RFPs tend to leave everybody frustrated, and do little to foster the valued relationships needed to make the process work.³ When this happens, the RFP competition may



Clinical trial recruitment services template

- The ideal investigator and site profile
 - Contact and protocol information
 - Scope
 - Principal investigator and site profile
 - Protocol evaluation
 - Medical condition evaluation
 - Subject evaluation
- Strategy and tactics
 - Recruitment and retention strategy
 - Site closure strategy
 - Tactical selection
- Implementation and evaluation
 - Investigator meeting and study communications
 - Implementation and contingency plan
 - Tracking

Source: CTRS (Pfizer)

be reduced to a price war, rendering the process ineffective, perhaps defeating its purpose.⁴

RFP basics

A successful RFP is best achieved when the sponsor's goals are openly discussed between clinical teams and R&D management and then fully communicated to the outsourcing department. To enhance the process, stakeholders need an understanding of the role of the patient recruitment provider in achieving objectives.

According to Peter Carberry, vice-president and head of clinical operations for Genentech: "The patient recruitment vendor should be considered a value-added service that can help sponsors reach their clinical development goals. Sponsors tend to undervalue the contributions that can be made by these providers and it's time to pay more attention and give greater respect to that space."

Consider the following elements in support of a productive patient recruitment RFP process:

1. Alignment with corporate needs.

Clinical teams must ask the right questions if the RFP is to reflect the sponsor's corporate objectives, therapeutic focus, and pipeline strategy. Are the RFP and the clinical trial consistent with the strategic direction of the company? Because senior-level players set the tone for an aligned effort among stakeholders, has their input been solicited to gauge the importance of the trial? Is the budget range presented and is it realistic?

2. An empowered relationship model.

Stakeholders must determine if the

relationship model for the recruitment provider will be tactical or strategic. If tactical, the vendor will function as a service bureau, delivering media services such as print and electronic advertisements, websites and collateral materials. If strategic, the provider will serve as a partner offering insights into protocol feasibility, ROI analysis for various recruitment approaches, and guidance on site performance and other initiatives to enable enrolment success.

3. Alignment with the clinical team's needs. There is often a disparity in goals between the clinical team – whose primary objective is timely trial completion – and outsourcing, whose main focus is generally cost containment. As a result, the RFP may be unclear as to its intent. In addition, key elements of the trial such as the intended subject population may not be well defined, either because the clinical team remains vague on those points or has not communicated this information to outsourcing. To obtain greater clarity, prospective vendors must be allowed access to the clinical team.

4. Keep outsourcing in the loop. If, as is typical, the RFP is sent out before the protocol is completed, the protocol synopsis sent with the RFP may no longer represent the current status of the protocol, meaning that the inclusion/exclusion criteria, timelines, and budget may have changed. It is also possible that the outsourcing department is unaware of these changes, and therefore, does not notify the bidders. To address this challenge, it is critical that the clinical team keep outsourcing staff in the loop.

5. Play fair. It is in the best interests of the RFP process for outsourcing departments to treat all vendors equally by sharing information needed to complete the RFP; advocating for realistic timelines for response; selecting the best solution following a fair evaluation of vendor responses, and advising unsuccessful candidates that another proposal was selected.

Proposal fishing, when internal teams have no intention of using an outsourced vendor, or soliciting bids to satisfy a designated number, such as three proposals, when the winning vendor has already been unofficially pre-selected does little to build confidence in the process.⁵

Forward-thinking sponsors are establishing practices to use the RFP exercise for the synergistic purposes of creating strategic relationships and reaching clinical goals. They are investing in standard operating

procedures and making company-wide commitments to process improvement. Genentech's Carberry says the link between good relationships with patient recruitment vendors and a successful RFP process cannot be underestimated. He suggests building relationships by evaluating vendors long before they are needed, to get to know their core capabilities. "It's important to qualify the vendors early on, independent of any protocol, so when we get a statement of work from a team needing to select an appropriate vendor, we can expedite the process," Carberry explains.

Similarly, Peter DiBiaso of Clinical Trial Recruitment Services (CTRS), a Pfizer group dedicated to improving global patient recruitment, retention, and investigative site performance, says his team evaluates potential vendors on a continuous basis. "We make it our priority to stay on top of vendor capabilities, their advances in technology and areas of therapeutic expertise. That way, we're positioned to make informed recommendations and strategic matches when our teams determine they need outside expertise. It's part of our plan to move toward longer term relationships with our vendors and make strategic patient recruitment planning a more standardised business practice," DiBiaso says.

The cornerstone of CTRS is information: its flow among the clinical teams, operations staff, monitoring group, and CTRS; the gathering of it by CTRS to evaluate potential partners; and the sharing of it with appropriate vendors, following the decision to outsource the patient recruitment and/or retention function. CTRS launches the information gathering process by counselling the teams to articulate potential recruitment strategies.

"Specifically, we ask the teams to initiate the development of their recruitment plan prior to site selection. They begin the process by developing a preferred site profile, understanding the medical condition, evaluating the types of subjects needed, and articulating the required strategy and tactics needed to meet the study's enrolment and timeline objectives. We then validate the agreed upon strategy with participating investigator sites to determine its relevance in meeting their needs," DiBiaso explains. This approach reflects a Pfizer policy, effective since January 2004, requiring every new study to have an accompanying protocol recruitment plan.

The five-page template

To assist the study teams in defining their recruitment plans, CTRS encourages them to complete a five-page template that explores the ideal investigator and site profile, strategy and tactics, and implementation and evaluation (see box above). These elements are further refined through a series of questions meant to focus the teams' thinking on the many factors impacting enrolment. Scope, for example, part of the ideal investigator and site profile category, entails identifying factors such as the planned final protocol date, and the planned length of recruitment (see box below).

According to DiBiaso, this practice is meant to provide a realistic evaluation of the company's ability to handle patient recruitment for a specific study in-house or if outside resources are needed. If the answer is to outsource, CTRS uses the template responses as background for determining the right vendors to approach for RFP bidding. CTRS estimates that the template has been used in approximately 100 studies so far.

Solomon Babani, associate director of CRO management for Novartis, says the department devised a multi-tab Excel spreadsheet dubbed the study specifications worksheet (SSW). The SSW is completed by the internal clinical teams with guidance from CRO management to determine the outsourcing needs of each clinical study, including whether outsourced patient recruitment help will be needed. Ideally, Babani likes the SSW process to begin six to nine months before the study launches, allowing time for completion of elements key to successful outsourcing, such as determination of protocol feasibility and completion of the protocol. This timeframe allows Babani sufficient opportunity to research appropriate vendors for the projects and draft the RFP. He ultimately solicits bids from three candidates.

The intent of these various approaches is to build rapport with potential vendors through the sharing of information regarding a sponsor's objectives, cost structure, timelines and therapeutic areas. "Eventually, you want to factor in the human aspect of parties becoming comfortable with each other," says Carberry of Genentech.

This perspective is a far cry from the non-plans and non-relationships that remain commonplace in the industry. Too often, sponsors or CROs wait until a study is in rescue mode before approaching patient recruitment providers. This is, as Carberry points out, "the most inefficient use of outsourced vendors. It is

the lowest level of relationship."

The goal, as Carberry sees it, is for sponsors to have relationships between internal teams and vendors that progress over time toward the pinnacle – strategic alliances with a small number of highly qualified partners deemed experts in their areas of therapeutic expertise, stable in organisational structure and well proven entities in their ability to deliver successful recruitment strategies. In this scenario, sponsor and vendor use established processes for sharing knowledge, and both parties could commit to a potential volume of work.

Seeking predictability

A major benefit of a solid RFP process is making the patient recruitment and enrolment task more predictable. Of the many complex steps comprising product development, the patient recruitment and enrolment function represents the largest cause of study initiation delays, and those delays are increasing.⁶

Michael Kerwin, outsourcing manager for Merck & Co, stresses the importance of heavy upfront planning to manage the risk and uncertainty that patient recruitment often represents. Early on, this involves a careful protocol feasibility analysis and an estimation of the number of evaluable patients coming through the recruitment funnel. Later, this information is shared with vendors through the RFP to help them determine if they can reasonably expect to achieve study milestones on time. Merck's clinical trial milestones typically include outreach, response, referral, consent, randomisation and the number of subjects needed for statistical significance. Kerwin explains: "We want to know how probable it is that the vendor will succeed. If the vendor falls short of the agreed to enrolment number, we won't reach the randomisation number on time and that could put our filing timeline in jeopardy." He says the milestones are constructed from a database of cost and performance metrics that benchmark reasonable costs and timelines.

In determining predictability of vendor success, Kerwin and internal teams have learned there's more to it than hard numbers. It is essential to have a good, comfortable fit between the vendor and the clinical teams. Kerwin explains: "Besides cost, we consider past performance and corporate culture of the vendor. We do this by inviting the vendors in to present, and this helps to shape the personal relationships which are fundamentally based on trust."

DiBiaso says Pfizer is also attempting to make the patient recruitment process more predictable. In 2006, CTRS will start to measure the gap between planned and actual timelines for achieving milestones for overall study duration as well as investigative site projections. "Anecdotally, we know that our efforts of thinking through all aspects of patient recruitment are resulting in greater accuracy in our predicting real timelines and improving overall resource utilisation. Next year, we're going to start measuring this process," DiBiaso says.

On the right path

The pharma industry is no stranger to the RFP process, a standard business practice for procurement of goods and services. Like other sectors, pharma is in the business of developing, manufacturing and packaging products, and it seeks to optimise all aspects of its supply chain,⁷ including RFPs.

In recent years, pharma sponsors have turned to clinical trial outsourcing in a big way, spending around US\$10 billion annually worldwide, or 20% of R&D expenditures.^{8,9} While only a portion of that figure is pegged to outsourced patient recruitment activities, it is destined to increase.

To maximise the growing dollars spent on patient recruitment vendors, outsourcing departments would be wise to establish an RFP process that is rooted in an

Project scope

- Planned final protocol date
- Planned first subject's first visit
- Planned last subject's last visit
- Planned length of recruitment, treatment, follow-up, and open label period, if applicable
- Subject accrual
 - Screening goal
 - Randomised goal
 - Completed goal
 - Expected screen failure rate (%)
 - Projected drop-out rate (%)
- Investigator site/accrual activation
 - Target number of sites
 - Target number of sites per country
 - Target number of subjects per country
- Country and site selection status
 - Planned protocol feasibility completion date
 - Country allocation decision date
 - Planned site selection completion date
- Countries selected

Source: CTRS (Pfizer)

information-rich, relationship-based environment. This is the basic tool for setting in motion a meaningful dialogue between potential vendors and sponsors to meet the sponsor's enrolment targets and timeline objectives. As Mark Ridge, associate director of clinical recruitment services at Wyeth, explains: "We are looking at patient recruitment providers as resources. The purpose of putting out an RFP is not to figure out what it will cost to run an ad. The purpose is to see how an experienced patient recruitment provider can partner with us to help us run our business better."

Progressive sponsors are already facilitating the gathering of relevant information from internal clinical and operational teams to make the RFP as precise as possible, the key to a good response and forecastable outcome.



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