



Sponsors and CROs still do not seem to understand how to work together effectively on a consistent basis. This article examines “influencing”—the process of getting someone over whom you have no direct authority to take the actions you want, in the context of the sponsor/CRO relationship.

Trust-Based Influence and the Sponsor/CRO Relationship

Sponsors are not yet getting full value from the contract research organizations (CROs) with which they work, be they preferred providers or not. Despite all the conferences, workshops, and articles, the two still do not seem to understand how to work together effectively on a consistent basis. More frequently than not, we hear sponsors complain about the quality of the deliverables and CROs complain about how they are treated. The literature, mostly in the area of contracting and trial management, is replete with articles on what works and what does not, as well as prescriptions for what people should do differently. In this article, we hope to add a different voice to the discussion. Our objective is to look at the issue of influencing and its impact on the sponsor/CRO relationship.

Our Approach

Critical to the success of any sponsor/CRO contract is the ability of the parties to work together as a team, to be open to each other’s ideas, and to allow themselves to be influenced by the other party. We define “influencing” as the process of getting someone over whom you have no direct authority to take the actions you want. We draw a distinction between trust-based influencing and contract-based influencing. We see the latter more frequently used in sponsor/CRO transactions. However, we believe the former has the greater potential for long-term success.

We define “trust” as a willingness to be open to, and to take risks with, another individual over whom you have no direct control. As such, trust does not come easy; it takes time and effort. Trust-based influencing, then, requires three critical skills if it is to be effective:

- being willing to listen to the other party and to acknowledge his/her issues as legitimate;
- being clear about your own objectives and what you want from the interaction; and
- being more interested in finding a solution that works for both parties than in “winning.”

The remainder of this article addresses the following issues:

- the distinction between contract- and trust-based influencing;
- factors blocking the active implementation of trust-based influencing; and

- a framework for implementing trust-based influencing.

Although a variety of other issues can and will impact project success, including the protocol, the staff members assigned to the project, and procedures for resolving conflicts, our objective is to look at the narrow issue of how we influence others to take the actions we want.

We draw a distinction between trust-based influencing and contract-based influencing.

In an article in the May 2005 issue of *The Journal of Clinical Research Best Practices*,¹ Norman Goldfarb listed a variety of complaints that sponsors and sites have about CROs. Among the issues he identified are:

- arrogant CROs who want to do the study their way;
- inexperienced and poorly trained staff;
- CROs that claim to have the sites needed for a specialized study, but do not;
- excessive staff turnover; and
- CROs that do not make a good-faith effort to represent the sponsor's position in negotiating a contract with larger sites.

Needless to say, CROs have a corresponding list regarding sponsors, including the following:

- not getting information to the CRO in a timely manner;
- expecting the CRO to meet all of its commitments, when the sponsor does not meet its own commitments;
- inconsistency;
- changing timelines;
- focusing only on the contract; and
- forcing the CRO to use the sponsor's less efficient and less effective processes, rather than the CRO's, which are compliant with good clinical practice.

What is so distressing is that the parties have the same objective—to have a successful, high-quality project completed on time and within budget.

Despite everyone's best efforts and intentions, the parties continue to struggle, unwilling and unable to move beyond the misunderstandings and confusion, to find the common ground necessary to build sound, constructive working relationships. This is in spite of implementing kickoff meetings, escalation agreements, and detailed contracts with clear sets of tasks. Although these all help, they provide an incomplete picture.

What is Missing?

In talking with representatives of both sponsors and CROs, and in the consulting and training we have conducted for both, we find the following factors limiting the implementation of trust-based influencing:

- Excessive emphasis on the contract terms and conditions—There is an assumption that the more detailed the contract, the greater the possibility of success. Contract-driven relationships have a sense of enforcement that gives rise to defensive behavior and less effective problem solving. Contract-based influence rarely works over the long term; although you may achieve the short-term objectives, it rarely serves to enhance the relationship.
- Overreliance on the metrics as the major factor defining project success—It is not that metrics are inappropriate, but that balance is needed between technical data and process, which does not currently exist.
- Failure of sponsors to appreciate a project's complexity—Managing all of the issues involved in an outsourced project requires a great deal of commitment from a large group of people over whom the sponsor has no direct authority.
- Overuse of e-mail as a problem-solving tool—E-mail has severe limitations, the most glaring of

which is that it is a one-dimensional and one-way communications methodology. In e-mail, you see none of the nonverbal behavior that is such a critical part of the communication process; thus, one's ability to correct misunderstandings and confusion is limited. Although it serves to provide a record, it does not enhance the problem-solving process.

We do not suggest that you stop using metrics, or that contracts be abandoned. Rather, we suggest that they be viewed for what they are—important tools for structuring and managing a project, which provide a vehicle for measuring the project's success. Nor do we suggest forgoing e-mail, but rather that its limitations be understood and that it be used only when appropriate. It is the overuse or misuse of all of the above that is a concern that we believe is limiting the potential for success.

Trust is the lubricant that allows people to work together smoothly in a collaborative manner.

What is missing is the development of high-trust, collaborative working relationships, and we believe that trust is the lubricant that allows people to work together smoothly in a collaborative manner. People are much more likely to accept another person's point of view and allow themselves to be influenced by people they trust. To quote Linda Hill² in a teaching note prepared for the Harvard Business School, "Trust and credibility increase the willingness of others to be influenced by you.... They will require less proof of the value of what you are offering and assume that you will deliver what you have promised."

Dale Zand,³ in his book, *The Leadership Triad*, also discusses the importance of trust and its impact on influence. He suggests that "trust is the crucial supplement to legitimate power

if leaders want commitment, rather than antagonistic obedience.”

Nirmalya Kumar,⁴ in his 1996 *Harvard Business Review* article on vendor relationships (which are no different from sponsor and CRO relationships), discusses the importance of trust and points out that “it creates a reservoir of good will that helps to preserve the relationship, when, as will inevitably happen, one party engages in an act that its partner considers destructive.”

When people trust each other, problem solving is enhanced, because when people are more open and willing to share information, they are willing to take risks with each other. Absent trust, both parties are very careful as to what they say and share, and the relationship rarely grows. We then become dependent on the contract and the metrics to enforce our point of view.

At its best, the contract provides a framework for defining deliverables and metrics; it does not provide you with a viable relationship. The contract provides only a baseline; you then have to fill in the blanks of the relationship. A collaborative working relationship where both parties are willing to listen and allow themselves to be influenced by others requires work. As Linda Hill² points out, “It takes time and energy to build and maintain a network of relationships, and the best time to begin building these relationships is before you really need them.”

Rosabeth Moss Kanter, in her *Harvard Business Review* article, “Collaborative Advantage: The Art of Alliances,”⁵ captures the essence of the collaborative process when she points out, “Alliances that both parties ultimately deem successful involve collaboration, rather than mere exchange (getting something back for what you put in).” In troubled projects, it is the latter that is most prevalent.

What Should You Be Doing?

We understand the difficulty of managing a multimillion dollar project in which you oversee others who are bringing your project to fruition. This requires a full repertoire of management skills; the most critical outsourcing managerial skill set lies in ongoing

and active communication, which provides the basis for effective influencing and negotiation.

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In a high-trust, high-influence environment, communication is done on a face-to-face basis. E-mail and teleconferences are appropriate only after the relationship has been established and both parties feel comfortable with each other. Although we understand travel restrictions, if you are interested in building a high-trust working relationship, face-to-face meetings are essential.

To be effective and to enhance the influencing process, communication must be open and frequent. Anne Fields⁶ described good communication this way in the May 2008 issue of the *Harvard Management Communication Letter*:

Adapt your communication style—Analyze not only your communication style, but also that of the person you are talking with. Then shape what you say and how you say it to better fit their *modus operandi*. Remember it is up to you to communicate . . . in the most effective way, rather than expecting them to be the ones to adapt.

Read body language and pay attention to vocal dynamics—Much communication is nonverbal. For that reason, how you say something can contradict what you say. Make sure the pace and pitch of your message matches what you want to convey. The slower your delivery and the lower your pitch, the more intimidating you’re likely to be.

Be sensitive to context—Where a message is delivered may affect how it is heard. For a serious conversation, an office is appropriate, not a passing comment during another meeting or telephone call.

The objective is to cultivate a collaborative atmosphere in which people allow themselves to be influenced and are willing to work together to negotiate outcomes that work for both. We would add one additional item to Anne Fields’ list: Listen to and acknowledge the validity of the other party’s concerns and why that person believes he/she is “right.” This does not mean that you agree with everything said or done, but that you understand what is motivating or of concern to that person. It requires listening and paying attention—not just to the words, but to the feelings behind the words.

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Influencing is a two-way process; it is not only the CRO being influenced by the sponsor, but the sponsor being open to the ideas and influence of the CRO. Moreover, it is not an abstract process; although trust provides the framework, a methodology is needed to ensure that one’s objectives are achieved. The goal of this methodology is to have a collaborative conversation that reaches a conclusion that works for both parties and serves to enhance the relationship. Our version of that methodology follows.

Step 1: Planning and Preparation

Prior to any meeting, preparation is essential. At a minimum, ask yourself the following questions:

- Why are the issues important to me?
- What data do I have to support my point of view?
- How do I think the other party will react?
- What does the other party want from the meeting?

- What is my ideal outcome for this meeting?
- What am I willing to accept?

If several people will attend the meeting, clarify the role each person will play. Share your agenda with the other party, so that the other party can prepare and bring the right people to the meeting.

Step 2: Climate Setting

Once the meeting begins, focus on setting a collaborative climate. The goal is to reduce anxiety, so that the other party can hear what you are saying and react appropriately.

Many people like to “get down to business” and see initial small talk or climate setting as having limited value, but research suggests that this is a mistake. Janice Nadler, in a recent article in the *Program on Negotiation Newsletter*,⁷ writes this about a study that she conducted:

Small talk created rapport before bargaining even began. Those who had engaged in small talk felt more cooperative towards their counterparts, shared and reciprocated more information, made fewer threats and developed more respect and trust than did those who skipped the small talk. This rapport had an economic payoff: “small talk” negotiators were more than four times more likely to reach agreement than their “no ‘small talk’ counterparts,” who, more often than not, walked away from offers that would have left them better off.

Step 3: Clarifying the Issues

This stage answers the questions: Why are we meeting? What are the issues that we need to resolve? At this stage your preparation becomes critical. Can you describe the problem in terms that the other party can hear and accept? This is the core of the influencing process; if you are ineffective in describing the problem, the remainder of the discussion is going to be difficult, at best. It is not only *what* you say but *how* you say it. If you open the discussion in a way that says you are trying to solve a problem and not punish the other party, you increase the potential of success.

Step 4: Solving the Problem (Part #1)

As a first step, describe why you see this topic as an issue, and then allow the other party to respond. Next, confirm your understanding of the other party’s perspective. If there are any underlying issues, make sure they are explored. Many times the problem, as described, is only a symptom of much deeper and more complex issues. If you can bring the underlying issue to the surface, you may solve not only the current problem, but others that may be lurking.

Step 5: Solving the Problem (Part #2)

The second part of the problem-solving process involves the soliciting and sharing of possible solutions that work for both parties. However, this step involves taking a certain amount of risk, so be very clear as to how you would like to see the problem solved. It is important to be open to the ideas and suggestions that the other party may bring to the table. Sponsors should keep in mind that the CRO has probably faced this problem with other clients and may have solutions that the sponsor had not thought about or considered. Sponsors should remember that they hired the CRO, in part, because of its experience conducting this type of trial; so they should use that experience. Similarly, the CRO needs to understand that the sponsor brings an expertise to the table that needs to be appreciated and utilized.

Step 6: Settlement

In this step, the goal is to summarize the agreement, and the summary should be presented in the meeting setting. Make sure that the other party is comfortable with the settlement, and that a follow-up e-mail provides the written record of the agreement.

Summary

Both sponsors and CROs have a choice: They can continue with the contract-driven, metric-specific approach that has brought, at best, mixed results, or they can look to the future and work in ways that build high-trust, collaborative relationships. Trust-based influencing has the potential for reducing defensiveness and bringing out the best

in people. Although trust-based influencing is not easy or intuitive, it is our belief that it will provide much better results as well as the desired metrics.

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