# Sponsor – Investigator Relationships

## A Crisis of Trust in Life Sciences

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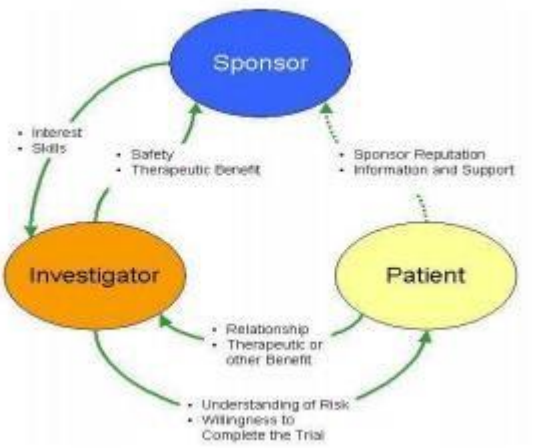
## A Crisis in the Life Science Industry

Recent studies indicate that almost 80 percent of all clinical studies are not completed on time, and 20 percent of those are delayed six months or longer. To Life Sciences companies with a promising new drug, every month of delay could translate into millions of dollars in lost sales. Timely completion of clinical trials is the weak link in the drug development process, and there is no shortage of suggestions for how to improve it. The widely accepted belief is that difficulty in recruiting patients is the central reason for missed deadlines. If this is true, then we are in the midst of a major crisis that will further affect companies' ability to complete trials on time. This crisis is driven by a number of factors:

- The total number of principal investigators has declined 11 percent.
- An increasing proportion of sites do not attain enrollment targets.
- Newer indications are more difficult to recruit.
- Trial sponsors face increasing difficulty recruiting in the United States and Western Europe.
- Trial sponsors also face increased competition for high-quality sites.

Life sciences executives are not blind to these issues and have developed strategic and tactical initiatives, some at great cost, in an attempt to solve them. The danger is that very often these initiatives serve only as tranquilizers—creating the illusion that progress is being made. The thesis of this paper is that these activities overlook the most important contributor to the current crisis: trust. When undertaking new initiatives aimed at improving sponsor-investigator-patient relationships, the primary question should be: "How does this initiative contribute to creating and nurturing of mutual trust?" The term "mutual trust" is intentional; as in all relationships, trust between sponsors and investigators, sponsors and patients, and investigators and patients is a two-way proposition.




Sponsors trust that investigators who commit to a study have the skills to follow the protocol as well as interest in the proposed therapy. While investigators trust the soundness of the science and that the essential safety standards have been met. While we have no empirical evidence to support this assumption, we believe that patients who agree to participate in a study do so based on their relationship with the physician. They trust his or her judgment around the therapeutic benefit that might be gained

from participating, or they participate because of some altruistic motive. For his or her part, the physician trusts that the patient understands the risk and is willing to complete the study. The least-understood relationship is the one between the sponsor and the patient. For obvious reasons, direct contact between sponsor and patient is unlikely; however, we make the assumption that patients are more likely to enroll in a study if the sponsor has a strong reputation based on its ethics and past performance.

## Life Sciences' Answer to the Crisis

Most life sciences companies have initiated one or more projects focused on improving the way they identify and establish relationships with qualified investigators and managing such relationships once they are established. Though worthwhile goals, these initiatives can quickly become a collection of things to do or technology to implement. The true intent— establishing and maintaining mutual trust— is lost. Even the best technology and new processes are wasted if investigators perceive that:

- Study teams are disorganized and unprepared
- Project timelines and enrollment goals are unrealistic
- Grant payments are unfair or consistently late
- Medical, scientific, and monitoring staff are not trained or appear incompetent
- Protocols are poorly designed or often changed
- CRFs are complicated or poorly designed
- Studies are delayed or cancelled after sites are initiated

On the other hand, sponsors are justifiably wary of investigators who:

- Fail to follow protocols
- Fail to enroll patients
- Are slow to respond to queries
- Generate high error rates
- Miss critical deadlines
- Violate confidentiality

We are not advocating that life sciences companies should reduce efforts to improve processes, implement technology to identify qualified investigators, reduce errors, speed up processes, and enable greater productivity. Rather, we are suggesting that understanding the fundamental nature of trust and how it affects these relationships is critical to approaching and designing initiatives. Further, more than a cursory understanding of the nature of trust is required to build and maintain the relationship between sponsors and investigators, investigators and patients, and patients and sponsors.

## The General Understanding of Trust

The general understanding is that trust is a "thing" to be given or received, as in "I give you my trust." We maintain that this perception of trust as a "thing" is at the root of the breakdown of most relationships. If trust is not a "thing" that we give or receive, then what is it?

Before we say what trust is, we should say what trust is not. Trust is not some spontaneous or arbitrary feeling.

***Trust is an assessment.***

***When we trust someone, we assess that the person is sensitive to our concern and will fulfill his or her promises.[1]***

Typically, we trust within some domain of action. One would not trust a mechanic to diagnose chest pain—or trust a cardiologist to diagnose why a car will not start. When we decide to trust, we make three assessments:

a) **Sincerity** – that the person or entity making a commitment or promise is sincere. In the moment of making a promise, the person or entity has every intention of fulfilling the promise. Conversely, we may say that someone is insincere if not committed to fulfilling promises have made. For example, if an investigator commits to enrolling 10 patients in a study but knows that he or she will be taking the summer off, we might assess that the promise of enrolling 10 patients was insincere.

b) **Competence** – that the person has the skills and ability to fulfill the request. More often than not, competence and access to patients are the main factors project teams assess when selecting investigators. Reliability is a crucial aspect of assessing competence. An investigator may be competent to fulfill the protocol of a study but may not be relied on to screen and enroll patients or to manage the activities of his staff to ensure timely and accurate recording of patient data.

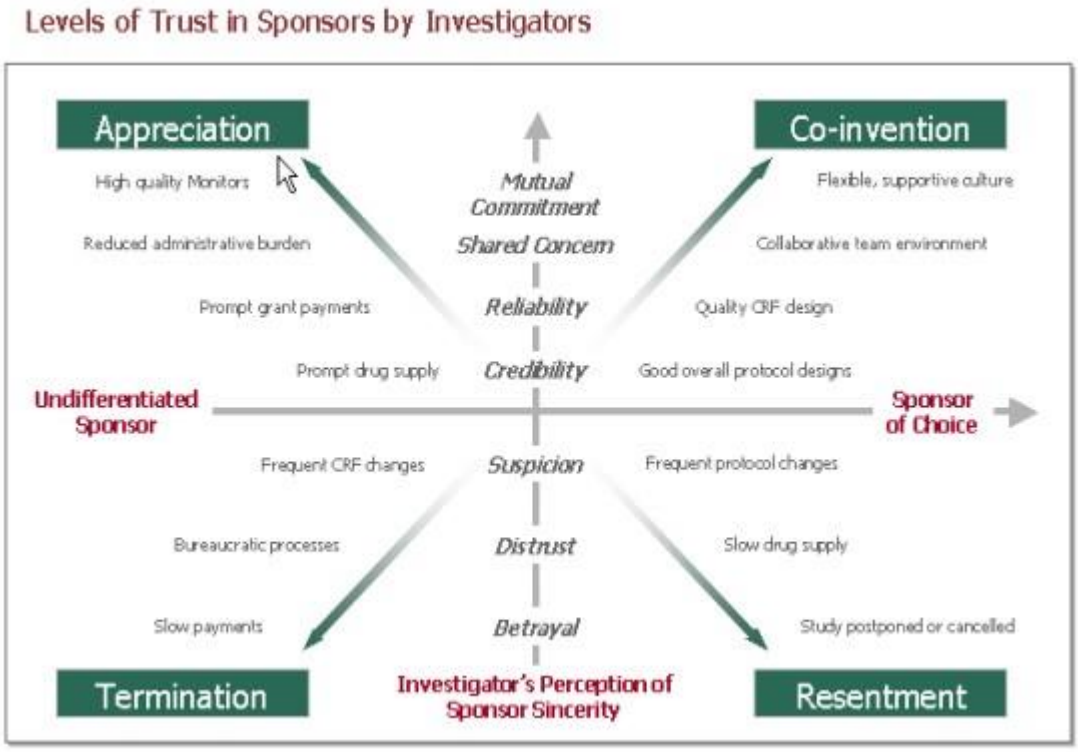
c) **Involvement** – that the relationship has long-term viability. Any time we may a request and receive a promise, we are concerned with sincerity and competence. In "commodity" transactions, sincerity and competence may be our only criteria for trust. But in longer-term relationships—such as those between sponsors and investigators—involvement becomes a crucial issue. We say that there is a high degree of involvement when there is a strong commitment to continue the relationship but low involvement when the commitment is only to the immediate transaction.

*What we need to understand is that the sponsor and physician are both making these assessments. In today's market, investigators are being equally selective about which sponsors they work with. Sponsors assessed as trustworthy become "sponsors of choice" among top investigators.*

[1] The distinctions of Trust cited in this paper are based on the work of Dr. Robert C. Solomon and Dr. Fernando Flores in various publications from 1988 through 2001 including Building Trust: In Business, Politics, Relationships, and Life

## Trust and the Sponsor-Investigator Relationship

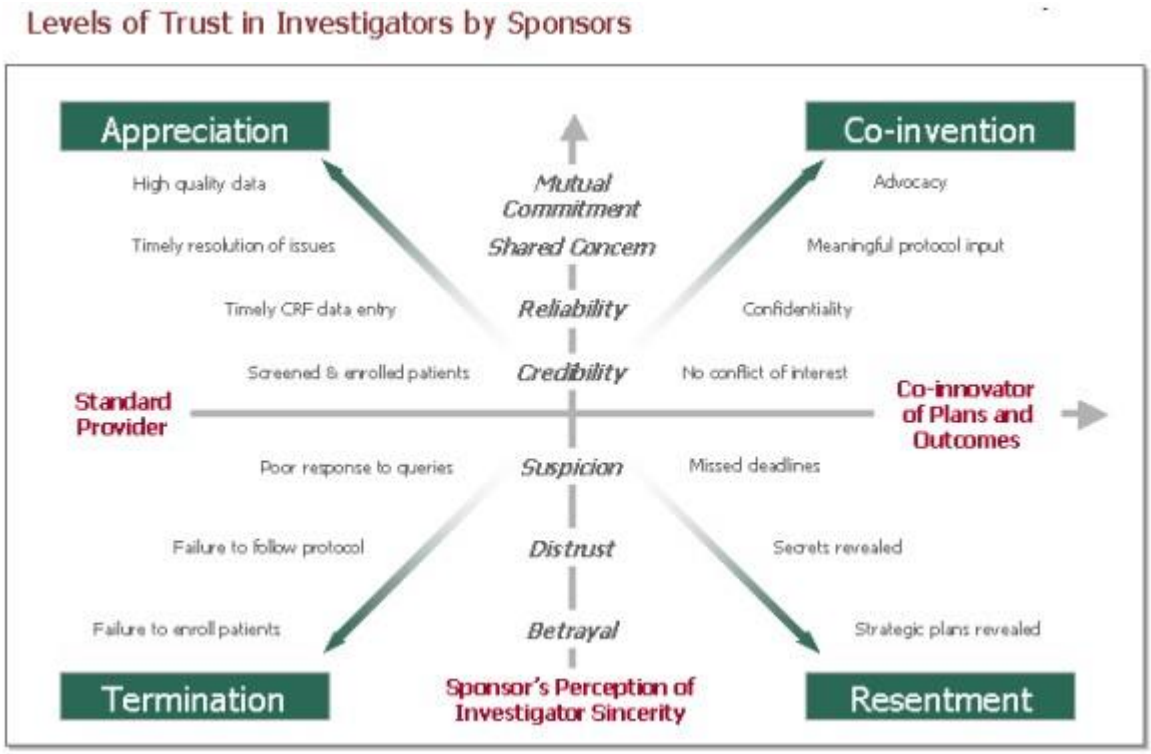
Looking at sponsor-investigator relationships from the perspective of trust, we can classify relationships into four categories: Termination, Resentment, Appreciation, and Co-invention. Termination and Resentment result from low levels of trust, while Appreciation and Co-Invention are the products of high levels of trust.




1. **Termination** – Sponsor may observe behaviors, such as consistently miss deadlines or betrayal of confidentiality, and will terminate the relationship with the investigator.
2. **Resentment** – Sponsor may observe a lack of patient enrollments, failure to follow the protocol, or poor response to queries. These observations may also lead to termination.
3. **Appreciation** – Sponsor observes that the investigator is screening and enrolling patients, issues are resolved quickly, and data quality is good. As a result, the sponsor appreciates the investigator and site personnel, and trust is developed or strengthened.
4. **Co-invention** – In addition to the characteristics observed under Appreciation, the investigator may provide meaningful input to the protocol and is perceived by the sponsor as a committed advocate for the study. Co-invention represents the highest state of trust.

## Trust and the Investigator-Sponsor Relationship

We can apply the same four categories to investigator-sponsor relationships as well.




1. **Termination** – An investigator may terminate the relationship with a sponsor if he or she observes that protocols are changed frequently, drug supply is slow, or the sponsor postpones or cancels studies regularly.
2. **Resentment** – Slow grant payments, frequent CRF changes, and an unsupportive bureaucratic culture within a sponsor organization can fuel resentment by the investigator and site personnel. Low patient enrollment by the site is a telltale sign of Resentment.
3. **Appreciation** – The investigator observes timely grant payments, prompt drug supply, professional and high-quality monitors, and sponsor tools and processes that reduce the site's administrative burden.
4. **Co-invention** – In addition to the factors present under Appreciation, the investigator observes good protocol and CRF design, as well as a flexible and supportive culture within the sponsor organization. In this state, the investigator will perceive the sponsor as a "sponsor of choice" when selecting studies in which to participate.

## How to Build Trust

Trust is earned, not given. Sponsors earn investigator's trust through actions that are consistent and that demonstrate their credibility, reliability, and a shared concern for both patient and investigator. Over time, these actions translate into an assessment of trust. Without trust, ineffective listening, poor

coordination, cost, and confusion all grow. Strategic and even tactical change is difficult, if not impossible, to manage. Therefore, distrust in an organization has a direct impact on the bottom line. Every interaction in which one cannot trust the other person to produce on what he or she promises will require me to build a redundant request to someone else to stand by—in case of the failure of the first. One, two, all three, or none of these might actually satisfy the promise. In any case, the process is repetitive and wasteful and demonstrates the very real impact of distrust.

## Bringing It All Together: Competitive Imperatives and Critical Competencies

So far, this paper has covered the fundamentals of how trust affects sponsor-investigator relationships. To identify and work with competent investigators—while building alliances and maintaining flexibility—sponsors must become competent at:

1. Listening and innovation
2. Coordination and commitment
3. Mobilizing new practices
4. Employing the tools for coordination and redesign of business processes

### The Role of Listening

**Authentic mutual trust** is built by listening to other people's concerns and taking action to address their needs. Sponsors must develop a culture in which "listening" and "interpretation" are key skills. Such a culture requires training people to relinquish the notion that listening is just "gathering data." People who work with investigative sites must be encouraged to observe the difference between experience and bias and trained to listen in such a way that they can make grounded assessments in the domains that constitute trust. Too often, pre-study site qualification visits focus on completing the questionnaire rather than listening to investigators' concerns and commitments and to other site personnel in the context of their lives, work habits, and histories. The traditional the role of field monitor has been to audit the quality of site data and ensure compliance. While the auditing role should not be minimized, with the increased deployment of EDC and other technologies, the role of the site monitor should be transformed into relationship manager, coach, and ombudsperson. Monitors and other people who work with investigative sites must be trained to listen for breakdown in trust whether related to sincerity, competence, or involvement in either direction. Monitors should be empowered to take the appropriate action with the site or study team members to resolve breakdown or needs that lessen trust.

### Coordination and Commitment

Impeccable coordination should be the standard for all activity in an organization. This is even more critical in the execution of a clinical trial. Having this standard will not guarantee that everyone will keep his or her promises all the time, but it does ensure that any lack of fulfillment will be properly managed so that incomplete commitments never become an accepted standard. If a promise is not going to be kept, it should be renegotiated or revoked. This standard of operations centered on promises needs to be built through the cultivation of a "culture of commitment." Such a culture is characterized by:

- On-time grant payments
- Timely drug supply
- Well-designed protocols, with changes kept to a minimum

## Mobilizing New Practices for Change

In today's market environment, many enterprises regularly seek to make a range of organizational changes—from supporting simple changes in customer satisfaction (new products and services) to strategic shifts that change the nature of the industry. However, many improvement initiatives end up producing plenty of new written procedures, lots of pretty process maps, and great strategies that go nowhere.

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