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Partnership Heresy

By Ronald S. Waife

It is almost inescapable today that CROs and biopharma study sponsors refer to each other as "partners." New contracts for long-term or multi-program work assigned to CROs apparently are not exciting enough for what they are — long-term relationships based on significant awards of work — and need to be termed "partnerships." The semantics are obviously important for all sorts of reasons, having almost nothing to do with the achievement of efficient clinical research. The partnership concept is also seriously misleading and sometimes dysfunctional. I suggest the heresy that there is nothing to be gained by characterizing service providers as partners. Indeed, using language accurately and managing accordingly can lead to better performance.

Everyone who provides a service these days wants to position themselves as your partner. Your dentist is your "oral health partner." Your car mechanic is your "automotive mobility partner." Really? The Oxford Dictionaries define a partner as *"a person who takes part in an undertaking with another or others, especially in a business or company with shared risks and profits."* Does your dentist share the risk of toothache if she does not completely clean out your cavity? Does your auto mechanic share the risk of being stranded at night if he does not securely reattach a wire? Or stated positively, does your dentist feel the relief in her mouth when your abscessed tooth is pulled? Does your mechanic get to drive your car after he's fixed it?

These are not silly analogies. Except in the rarest of circumstances, no matter how often the term "partner" is misused, a CRO is, like a dentist or car mechanic, simply providing a service to the sponsor. A sponsor and a CRO both may benefit from a successful study or both be harmed by an unsuccessful study, but they do not share risks and profits in kind nor in degree. Relatively speaking, the CRO's risk is low and its modest profit is predictable and near-term. In contrast, the sponsor's risk is high and so are its potential long-term profits.

When one party provides services to another party, he is called a "service provider." It is the oldest, most widespread relationship in human history. It must work! And it does, in every industry and in every culture. Somewhere along the way, the relationship in which a CRO is a service provider and a study sponsor is a customer has become passé, frowned upon, and almost shameful. There is nothing wrong with this kind of relationship! In a properly defined customer/provider relationship, the roles and responsibilities are clear, the risks are articulated and objectively managed, the tasks, costs and profits are short-term and straightforward, and both sides care just enough to ensure a successful result. If not, the relationship is broken and a new one is formed, quickly and with much less angst than in a divorce of partners.

Let's look at three substantial reasons CROs and sponsors are not partners: profit, risk and care.

Profit

If you and I were partners in a lemonade stand and the price of sugar went up 20%, we would sit down and discuss what to do: Should we raise the price? Switch to a corn syrup sweetener? Make lemonade that is less sweet? We would both care about our product's taste, market success, and cost to produce, because it is "our" business. But if it were my lemonade business and all you do is mix the ingredients, or sit by the road after school and sell the lemonade, what do you care about the price of sugar? How does it affect your ability to stir, or shout to passing cars? It doesn't, and it shouldn't.

Indeed, there is hardly any overlap between the business of a biopharma and the business of a CRO. The CRO performs functions parallel to and derived from what biopharmas do, but the businesses are completely different. The core financial drivers of the two entities are profoundly different; the owners therefore have profoundly different interests and concerns.

A drug in development represents a decade's investment that is unlikely to, but might, lead to a brief but enormous profit. A staged succession of successful development projects can produce some continuity of business over time and has created some of the largest corporations in the world. Investors judge biopharmas based on current revenue and profits, of course, but also on the likelihood that their science and investments could produce a series of low-probability successes.

In contrast, CROs live on numerous, relatively short-term projects from multiple customers, with relatively low but predictable margins. With enough customers and staged projects, CROs can grow steadily with relatively stable profitability. Investors pay more attention to the current financial results of CROs because they are more predictive of future results (squishy backlogs and multi-year "partnerships" with sponsors notwithstanding). There are no blockbuster drugs in the future of any CROs. On the other hand, the failure of a study or the loss of a customer is bad news, though probably not catastrophic.

These fundamental differences in the business models of biopharmas and CROs drive fundamental differences in their attitudes toward a given study. It is impossible to align the goals of two such different organizations in an effective partnership. On the other hand, the customer/service partner relationship is designed to handle such differences. You pay your dentist for competent work. You pay your car mechanic for competent work. It's a bit of an oversimplification, but why not just pay your CRO for competent work without all the "partnership" trappings? Look at any recent press release announcing a new sponsor-CRO partnership. Every single service or advantage listed as part of the partnership can be purchased individually, or in any combination, from that CRO by any sponsor at any time *without* a partnership agreement.

Risk

It should be obvious to even the most ardent proponents of "partnership" labeling that sponsors and service providers do not share the same risks. Do both parties have "risk"? Sure, but the nature of the risks is quite different, and they are certainly greater for the sponsor. To suggest otherwise is misleading.

The service provider's risk in non-performance is mostly one of tarnished reputation. While news of non-performance spreads quickly in our intimate industry, such news is far from rare and the responsibility for failure is usually obscure. Theoretically, a service provider could be investigated by regulatory authorities, but the number of such incidents is very small. A greater risk for service providers is not being paid, although sponsors are notoriously loathe to pursue any sort of penalties for their service provider's non-performance. If there is a sanction, it would most likely be loss of additional work. But anyone familiar with CRO contracting knows that sponsors routinely continue to give work to service providers who have failed them in the past.

Compare this level of risk to that of the sponsors. A poorly conducted trial risks regulatory rejection, late market entry (which could significantly reduce lifetime revenues), patient safety, and the return on millions of dollars of investment. It threatens international reputation, rapport with the medical community, and employee morale. At best, it means delay, re-work, higher costs, or even repeating the trial. Clearly, the sponsor has much more to lose.

Care

Considering the above differences, it simply cannot be said that the service provider cares as much about the performance of a clinical trial as the sponsor. This is not to say that service provider personnel are not professional and do not take pride in their work — surely most of them do. Neither are all sponsor personnel undyingly committed. But, no matter how professional your dentist, it's not her tooth; it's yours. Your mechanic is not repairing his car; it's yours.

The practical result of this gulf in caring is potential (not universal) problems, such as CROs assigning junior people to a project that is mission-critical for the sponsor, or a slow response to a data quality issue or protocol revision, or tolerance of process inefficiencies that the sponsor would deem unacceptable (if it knew about it).

At the most fundamental level, it is impossible for organizations with such different interests to be "partners." But can they play a critical role in each others' success for high mutual benefit? Of course.

Improving the Service Provider/Customer Dynamic

The practical way to ensure that the relationship of service provider and customer will work effectively is for the customer to actively manage three basic dimensions: cost, risk and care.

Cost Management

Effective cost management begins with clarity on both sides of the relationship. Many sponsors, even those with years of outsourcing experience, put out RFPs to CROs that are too vague, too open-ended, and with insufficient detail, especially for contingencies. CROs are equally guilty of responding in kind, including vague assurances for specific contingencies. CROs so love the partnership concept because they can use it as a license to issue change orders without restraint, and change orders are where the profit is. If a sponsor complains about excessive change orders, the CRO that has a major multi-year "partnership" agreement with that sponsor is very likely to assert that this is what partnership means — in return for dedicated staffing, guaranteed capacity, and such, the service provider needs to be able to make up for the unexpected (a given in clinical research) with a steady flow of change orders. Since it is a "partnership," both parties are "in it together." The CRO can submit change orders with confidence because both parties "share" in the successes and failures of the partnership. Eventually, however, the sponsor may realize that the partnership is not working as expected and be brave enough to upset the partnership status quo, a rare event in today's outsourcing environment.

Clarity of expected costs and responsibilities, honest expectations of a trial's changeability, analysis and prevention of change orders, and a steady eye on integrated cost reporting will help both parties plan their timelines and resources better in a healthy service provider/customer relationship.

Risk Management

The first step in proper service provider/sponsor risk management is to recognize the imbalance of risks and start to manage the project accordingly. Accept that the two parties are not partners sharing equivalent risk. Risk management is best addressed through clear project accountability, which means placing project control in the hands of the party with the most risk (the sponsor), and detailing what the service provider will be accountable for, within the limits of their responsibilities. This means dropping the fashion of both parties having equal voices in a Joint Operating Committee (JOC), which suffer from the failings of all committees and also the ambiguity of who's in charge.

The parties should agree upfront on a clear procedure for replacing CRO personnel who are not performing adequately. This procedure must spell out how such replacements will be made quickly, rather than allowing the CRO to stall for time, which the trial cannot afford. The parties should also agree on what trial performance metrics are important and how often they should be reported, with what explanations. For instance, EDC tools can tell the sponsor if, when and how often CRO personnel are "in" the sponsor's data, which is one indicator of whether the CRO is actively performing the necessary work. Good CROs embrace such reporting as an opportunity to prove the quality of their service and other competitive advantages.

Caring

Eliminating the partnership myth will help the sponsor understand the inherent limits on how much a service provider will care about what is really important to the customer. It will also help the service provider understand why the sponsor needs to be in charge, no offense intended. The parties can then act and communicate honestly according to their natural, differing priorities. The things each party cares about will not be the same, nor do they need to be. The motivation for performance, not a shared reason for it, is important part.

Conclusion

Both sponsors and service providers have different, but powerful reasons to see the sponsor's development succeed. No sponsor today is likely to return to a time when it did all clinical development work itself. While shared objectives are essential to successful clinical study execution, pushing the "partnership" myth has been useful for CRO marketing but has done no favors to clinical trial execution and customer management.

The criticism of a pay-for-service relationship in favor of something somehow more lofty is misplaced and misleading. The oldest form of relationships may be the better way to develop new medical therapies.

Author

Ronald S. Waife, MPH, is President of Waife & Associates, Inc., a change management consulting firm dedicated to improving the efficiency of clinical research. Since 1993, the company has served over 230 clients worldwide, providing analysis and improvement of clinical research processes and tools. Contact him at 1.781.449.7032 or ronwaife@waife.com.

