RH Bouchard & Associates, Inc.
18 Brightman Avenue
Tiverton, RI 02878
401-624-7288

STRATEGIC RELATIONSHIP INITIATIVES
A WHITE PAPER

I. Introduction

Over the last ten years, the Pharmaceutical/Biotech/Contract Research Industry has searched for methodologies, processes, and relationship structures which would better define their working relationships, reduce stress and result in greater success in their long-term partnerships. For the most part, these “partnerships” or affiliations have not worked to the advantage of either party.

Flaws in the design of the relationship(s) become evident well after the affiliation has begun and many die from neglect, overwork, or poor selection of the partner. The success of any long-term relationship is dependent upon the ability to meld the cultures of the two Companies, establish accountability and measurements (metrics) which define how the relationship is benefiting BOTH parties, not just the Sponsor.

This White Paper will discuss strategies and options to build strong long-term business relationships.

II. Review of Relationship Models

Many different relationship models have been put in place in the Industry over the last decade. Several Companies have tried multiple models at the same time; based on their Phase, Therapeutic or Functional needs. The following is a review of the most prevalent models. Although many are overlapping the success factors are remarkably similar.

- **One Project, One Contract**
  This is the original model for all CRO outsourcing and remains prevalent today**.** As project teams require capacity outside of their internal staff, CROs are asked to bid on a specific project or a specific set of tasks within a project. A one-time-only agreement is issued for this work.

PROS	CONS
Opportunity to use a variety of Providers based on the project needs	Time consuming process
Sponsor is not committed to use of the Provider on other projects	Contract negotiations are often protracted and can hold up project start
Since a long-term relationship is not the goal, less effort goes into the care and maintenance of the relationship	Provider is not as committed as the Sponsor
Focus is maintained on the specific project	Minimal effort is put into the relationship on either side
	Lessons learned are not captured or used for improvement
	Sponsor and Provider staff may not become a harmonized team
	Provider does not learn Sponsors preferences
	Metrics and communications planning are often ignored

Lessons Learned: Both Sponsors and Providers feel this model has produced a commodities approach to outsourcing. The Sponsor is contracting for a labor force in the same way temporary help is hired. The Provider does not feel part of the Project Team and because they are not integrated, the Provider is often micromanaged. This creates conflict and finger pointing on both sides. There is little incentive for the Provider to exceed expectations as they feel they are treated as the "hands and feet, no brains" of the project.

Stress is created on the Sponsor side because they lack trust in the Provider and no long term relationships are established. Every project is a new learning experience and continuity is lacking. The Sponsor Team has the ultimate responsibility for the final product and, taking that responsibility seriously, they will often over manage the process and the Provider. This can result in scope creep, rising costs, and delays to timelines.

A well established working relationship with the "right" providers can reduce errors, create a contributing, integrated team and provide a consistent level of service.

- **Master Services Agreements (MSA)**

  The MSA is the most popular method of establishing a more meaningful and long lasting relationship with a Provider. MSAs are negotiated when the first project is awarded, if the Sponsor believes the Provider may be asked to work on additional projects or to provide a specific service for multiple projects (i.e.: Data Management) in the future.

PROS	CONS
Opportunity to use a variety of Providers based on the project needs	Provider rarely has an opportunity to define their expectations from the Sponsor in meeting the goals of the relationship
Sponsor is not committed to use of the Provider on other projects but they have a mechanism in place to make the use of the Provider easier	There is no "guarantee" that the Provider will ever be used again
Legal language is negotiated only once and in place for a minimum of 3 years	Relationship management, outside the current set of projects, is often ignored
Startup is faster	
Both the Sponsor and the Provider feel more committed to the relationship and most MSAs have sections that define expectations of the Sponsor regarding accountability, metrics and maintenance of the relationship	Lessons learned are rarely captured or used for improvement across projects
After multiple projects, the Sponsor and the Provider have a better understanding of how to work together	Metrics and communications planning are often given minimal attention since project start-up is also ongoing

Lessons Learned: The MSA can be viewed as the opening steps for a more meaningful relationship. As one Sponsor puts it "Before I get married I want to have a few dates". The purpose of the MSA is to set the ground rules for the relationship. It assumes that the Sponsor will award additional work to this Provider if they do a good job on the current project. It allows for all the legal issues to be addressed once and assumes this will speed the execution and start-up of subsequent work. It is a motivator to the Provider as it creates the opportunity for repeat business and a deeper relationship. Since it is no more difficult to negotiate than a single study agreement, there is really no reason not to do an MSA, even if a Sponsor is not fully committed to the continued use of the Provider.

Most Sponsors have adopted this approach for the vast majority of their clinical and non-clinical outsourcing. Only the most specialized one-time services are relegated to the single-source contract. Some Sponsors have developed MSAs for use with Consultants, Investigators and other third party Providers.

For the most part, these Agreements are positive for both parties. Problems occur when Sponsors use the MSA in place of a Preferred Relationship process. They include in the MSA all of the requirements for building a preferred relationship (at significant cost to the Provider) without providing an up-side; such as a limitation on the number of bidders or a predetermined set of work. These Agreements can become very one-sided and onerous to the Provider. A balance must be struck for both parties to feel they are benefiting from the relationship. Handled correctly, these provider relationship may become the preferred providers of the future or even a more meaningful strategic provider.

- **Preferred Relationships**

  The Preferred Relationship process is most often initiated through a Request for Information (RFI) and Providers are requested to complete lengthy questionnaires regarding their services, capacity, experience and financial health. A large number of Providers are asked to complete the RFI process resulting in the elimination of those who do not meet the criteria to become "preferred providers". The two most common types of preferred relationships are:

  a) A pool of CROs that competitively bid for specific projects or programs. The pool is normally segregated into global providers, niche providers, or national/local provider (particularly in Europe). The CROs chances of winning a project are increased when they have fewer bidders with which to compete and they are being compared with "like" Providers.
  b) Multiple Providers are chosen, one for each particular program or function. There is no competitive bidding within this group as long as pricing is competitive in the marketplace and has been negotiated in advance.

These relationships usually last from 3-5 years before they are revisited, although most require and annual update and face-to-face review at higher levels than the Project Teams. These relationships are facilitated through an MSA and a contract manager is normally assigned on both sides to "manage the relationship"

PROS	CONS
Sponsor has a pre-qualified set of Providers from which to choose. Shortens the process of selection and start-up	The RFI process is usually time consuming and difficult for the Provider to complete in the time given. There is no "guarantee" that completion of this process will result in a "preferred status"
Sponsor is not committed to use of the Provider on other projects but they have a mechanism in place to make the use of the Provider easier	There is no "guarantee" that the Provider will receive a specific level of work.
Provider can feel comfortable that they will receive some level of work from this Sponsor over a 3-5 year period	If a Provider does not make the cut, it is unlikely they will have an opportunity to work with the Sponsor for 3-5 years
Legal language is negotiated only once and in place for a minimum of 3 years	Sponsors can be unreasonable in their requirements for discounts or preferred rates. This may cause the Provider CRO to turn down projects because they cannot make acceptable margins
Communications plans are worked out in advance and key individuals are named on both sides. Multiple levels of the organizations are involved in nurturing the relationships	Because the Provider is brought in earlier, before the project specifications are complete, additional changes in scope may occur
Both the Sponsor and the Provider feel a strong commitment to the relationship. Senior Management representatives are normally involved on both sides, regular meetings (usually quarterly) are held to discuss the relationship, lessons learned, accountability,	For non-competitive bidding models, the Sponsor must make a concerted effort to manage costs and to stay abreast of the marketplace

and metrics. These are shared within the organization and quality initiatives as well as joint SOPs are often developed through this mechanism	
Pricing if often determined in advance and annual increases are built in. Sponsor and Provider can develop mutually agreeable methods for determining hours and costs and most budgets are transparent	.
Because Providers are brought into projects earlier in the process, they can provide advice based on their prior experience with similar studies	

Lessons Learned: The number one mistake made by Sponsors in launching Preferred Relationship Initiatives is making the process too complicated. While it is critically important to select the right Providers, it is equally important to control the amount of time and effort required to plan and launch the initiative, prepare and complete the RFI and to determine the final Providers.

Several large Pharma companies launched 2-3 year selection processes during the 1990's that pulled staff from around the world in to participate on the selection teams. Because the scope was too broad: pre-clinical, toxicology, laboratories, Phases I-IV, and all ancillary services; and the team was spread across multiple countries and time zones, nothing could be accomplished quickly or easily agreed. In one case over 250 possible providers were sent the RFI. The response to the RFI required sever thousand pages of documentation including 3-5 mock bidding exercises to be qualified to move to the selection process. The cost to complete this exercise was excessive in time and money for the Providers and many had to drop out simply because they could not provide the information in the time requested and still conduct their business. The penalty for not participating was a 5 year ban from receiving any work from that Sponsor. If you were chosen to continue in the process, there was another round of mock bidding, several presentations (both in the US and Europe), an audit and the negotiation of discount pricing before you were selected as one of the 3-5 in each category. All of this was expected to be funded by the Provider.

Another Pharma Company developed a discounting schedule that was so impossible that two of the three selected Providers stopped accepting projects after the first year as they were losing money on every project. The negotiation process in this case required the Provider to "take it or leave it". They were presented with the expected cost of the project without discussion as a fixed price, no change orders allowed.

The most interesting process during this period was one that attempted to standardize the methodology and practices of the bidding process. The Sponsor using a standard RFI procedure, selected three Providers and then asked them all to work together to develop a standard bidding method for use with the Sponsor. They were not required to use the same rates or the same number of hours for a task, but to create a unit based budgeting model that allowed "apples-to-apples" comparison across the Providers (i.e.: all units were defined the same way by all Providers). This was a very positive process and resulted in the Providers getting to know each other, as well as, defining the Sponsor's expectations. The Sponsor created a methodology that produced more consistent projects, budgets, and established a standard of quality; all driven through this definitional exercise at medium to high levels in both Companies. A cautionary note, this process eventually broke down because it worked so well, that the Sponsor asked for lower and lower levels of detail. At some point, it becomes too cumbersome to try to replicate a single methodology across diverse Companies. Additionally, this requires dedicated Teams that understand the model and can work to expand it throughout their own Company culture.

- **Strategic Alliances**

These relationships take on a variety of forms that include such models as:

a) A Provider opens a strategically placed office and staffs to meet Sponsor's work requirements.

b) Provider provides all of a certain service (i.e.: safety database) for a Product or group of products, working to Sponsors requirements. This is ideal for smaller or virtual companies.
c) Provider and Sponsor agree to work together exclusively on a program, Provider is guaranteed all the work for that program, and in return, Sponsor gets a guaranteed Team and a premium discount based on volume.
d) Sponsor and Provider form a joint venture for the development of a compound with the Provider performing all (or a designated piece of) the clinical trial work (Risk Sharing).
e) Provider purchases facilities or services provided by the Sponsor (i.e.: a phase I unit) and Sponsor guarantees all their work will be done at that unit for a specified period of time.
f) Provider licenses or purchases a compound from the Sponsor that they do not intend to develop.

PROS	CONS
Sponsor and Provider have a strong commitment to the success of the relationship. These represent true "partnerships" that are negotiated and maintained at the highest levels of the Companies.	These are difficult relationships to find and forge. Selection of the right partner on both sides is critical to success.
These are long term commitments with well defined expectations and legal ramifications for non-performance.	If something goes wrong with the relationship, it is often difficult to modify the term of the agreement, and penalties may ensue.
These relationships have risen to the level of strategic rather than functional "partnerships". Both sides have much to gain and much to lose.	These relationships are considered high risk for both parties.
Communications plans are in place at multiple levels in the organizations. These partnerships often occupy a full-time person at each Company. Full transparency is required on both sides.	

Lessons Learned: These are very specialized partnerships that require participation at the highest levels in both Companies. The risk is great. Both partners must be willing to accept that failure is a possibility and care must be taken to build in recovery plans. There can be high cost associated with these models, it is critical to get enough return on investment to make these partnerships worthwhile.

Several Sponsors have identified services or subsidiaries they would like to divest. By selling these subsidiaries to Providers and providing guaranteed work for a period of time, the Sponsor still maintains the quality of work from the same individuals (for the most part) they have worked with in the past and while demonstrating a positive change to their balance sheet. These relationships have worked very well, for the most part. However, it is critical that the Provider focus on building a base of Sponsors who will maintain the business after the Original Sponsor is no longer required to place work at the facility. These relationships have been put in place primarily for clinical laboratories, Phase I units, analytical labs, and packaging facilities.

Another popular model creates a dedicated office for the use of a Sponsor at a location of their choosing. The Provider staffs the office for the functions the Sponsors feels they will need over a certain time frame. These often include data management, programming, project management and biostatistics. Problems arise when the staff cannot be kept fully occupied by the Sponsor and other Sponsors may not be available or desirous of using the location. This can often result in transfers or layoffs of the Providers staff, inconsistent staffing and the need for "just in time hiring" which can result in a less experienced staff.

Risk sharing or licensing of compounds has become a popular model with some of the larger Providers over the last 3-5 years. Issues here revolve around conflict of interest, the perception that the Provider is trying to become a Pharma Company (hence a competitor) or that the ties to a particular Sponsor are so strong that the Provider can no longer be trusted with another Sponsors

data/project. In this situation, it is critical to create firewalls and arms length corporate structures that segregate the joint venture from the Providers every day business. Employees must not cross-over and provide services in both areas. For the Sponsor, this is a very positive model as it reduces the cost of development, allowing compounds that might be shelved due to limited potential, to be developed and result in an income stream that would otherwise be lost.

III. Success Factors

No matter what relationship type two Companies choose to enter into, the following key success factors must be put in place and honored by both sides:

- Communications plan for each project and across projects
- Accountability on both sides
- Development and management of metrics, regular measurement and constant improvement
- Quality improvement initiatives which are undertaken together to improve process and reduce costs
- Commitment at the highest possible levels and throughout the organization(s)
- Team building, the Provider and the Sponsor Team(s) need to work as one
- Full understanding of expectations before the relationship is launched
- Regular relationship management meetings
- Annual reviews of the successes and failures on both sides
- Dissemination of lessons learned throughout the organizations and implementation of “Best Practice”
- Designated Relationship Manager on both sides
- An opportunity for both sides to benefit from the relationship
- Respect for each other as individuals and as corporate partners