



## Alliance Management

### Fix it Before it Breaks: Alliance Diagnostic and Repair

#### Introduction

Alliances in pharmaceuticals and biotechnology are an essential part of the industry’s pipeline. By some estimates there are 10,000 or more alliances among industry participants globally. Big and mid-sized pharmaceutical companies need them to sustain growth, establish positions in new markets and stay on the cutting edge of innovation. Many biotech and small pharmaceutical companies need alliances to access capital without diluting their equity. They benefit from pharma’s development, manufacturing and registration expertise. Most importantly, they can access global markets without having to bear enormous infrastructure costs. Organizationally, the increasing number of pharmaceutical and large biotech companies that have created senior level positions to attend solely to alliance issues is testimony to both their importance and the specific attention they require.

If alliances are launched out of mutual self interest and high hopes, they can founder for a variety of reasons.

#### The Study

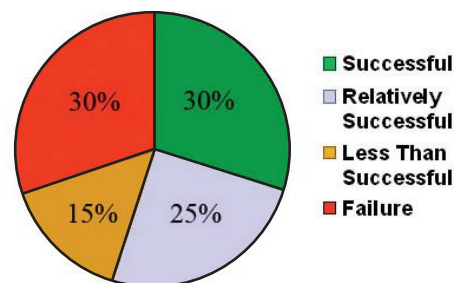
Putnam Associates recently completed a review of some 20 alliances within its practice base to examine proximate sources of satisfaction and disappointment. Data concerning these alliances were derived both from our own practice experience and from in-depth systematic interviews with senior management directly responsible for an alliance. Our specific focus was to understand drivers of success and failure and to detail strategies that succeeded in rescuing troubled alliances.

Among the therapeutic/disease areas covered in these alliances were:

- » Oncology
- » Allergy
- » Liver Disease
- » Diabetes
- » Erectile Dysfunction
- » Cardiovascular Disease
- » Antibiotics
- » Antifungal
- » Urology

Two-thirds of the experiences examined were between a large pharmaceutical company and a smaller biotech organization while one-third of these agreements were promotional partnerships between two relatively mature pharmaceutical companies. It should be pointed out that the cohort examined over-represents the percentage of pharma to pharma deals in the market today. Within the pharma to pharma sub-set, the initial motivation for the majority of these alliances was access to a large general sales force or to a specialty marketing function/sales force with a well-established reputation, e.g. Oncology. 50% of these agreements were between a large U.S. partner and an ex-U.S.-based pharmaceutical company that felt it did not have a sufficiently large U.S. “footprint” to productively take the products in question to market. While these arrangements can be characterized as co-promotion alliances, there is almost always a 51-49% relationship when it comes to key decision points.

#### Characterization of Alliance by Management



Source: Putnam Survey (n=20) All Alliances

## How to Succeed: Pharma to Pharma Co-Promotion

Over 70% of these alliances were categorized by key participants as “relatively successful” or “successful”. The most often cited commonalities of the successful alliances included “a clear set of shared expectations”, “transparency of data” (including forecasts, clinical development status, spend levels, call targets and product/market valuations and analyses) and “open, honest communication between key decision makers”. While all of these agreements had excruciatingly detailed processes for dispute resolution at ascending levels built into their contracts, the willingness to be “flexible” and “adaptive” were most often cited as critical to resolving conflicts. Building trusting relationships at the top level of alliances was universally cited as a key to success. As one study participant thoughtfully said, “You invest hundreds of hours and years of collective experience anticipating contingencies and setting out procedures to deal with them. But you do this hoping you’ll never have to invoke any of the formal processes”.

We attribute the high level of success in the pharma to pharma co-promotion to several additional key factors:

- » Significant confidence in a product’s clinical viability at the time of a deal
- » Shared realistic market expectations for the product
- » Depth of functional competence in both partners
- » Management incentives aligned with alliance’s long term success

## Roots of Failure

Of the less than 30% of the pharma to pharma alliances rated as “less than successful” or “failures”, the most often cited contributing factors were:

- » “Unrealistic expectations”
- » “Lack of honest communications”
- » “Shift in corporate priority”
- » “Change in management/ownership”
- » “Deterioration of trust”
- » “Clinical profile/AEs/labeling”

## Development Stage at Time of Deal

		Pharma to Pharma*	Biotech to Pharma
Post Phase III	→ Approval	29%	0%
Post Phase II	→ III	43%	23%
Phase I	→ II	29%	62%
Preclinical		0%	15%

\* Greater than 100% due to rounding

(n = 7)

(n = 13)

When examined closely, most of the failed pharma to pharma alliances can be traced to a lack of competent due diligence prior to entering into the agreement or to the disruptive effects of ownership and management changes. In the due diligence category, pressure to “do a deal” was cited as a reason thorough analysis of the product’s market potential and value proposition were not performed prior to agreement execution. This in turn supports the common observation in these cases that one party to the deal had unrealistic expectations for the product that were not confronted in a timely manner.

## Valuing the Deal

Placing a future value on a product under development is both an analytic and emotional challenge. All parties look to analogs and experience to guide their individual valuations, but may interpret the data through different lenses. For the developer of a new product the “number” is both economic and personal validation. Data clearly show that a small publicly traded company will often get a substantial increase in market valuation after the announcement of an alliance. Our analyses of the failed deals showed that widely differing views of the ultimate value drivers of a product in the marketplace contributed to the alliance failure. Often these dramatically differing views of a product’s market worth were subrogated at the time of a deal but reemerge during the development process to the detriment of all concerned.

Our experience is that rigorous, objective analysis that incorporates product-specific performance attributes, direct competitive and substitute product threats within the appropriate future national reimbursement contexts can greatly help both parties come to agreement on value issues.

Mergers that result in a shift in corporate priorities and a consequent downgrading of the importance of an alliance, as well as recent trends in acquisitions toward wholesale replacement of management help to explain two other causes of failure. Additionally, it should be noted that even in mature, fairly well run companies, poor personal relationships can significantly harm business prospects.

## Biotech to Pharma Alliances

The bulk of the cases in our study are more classic alliances between pharmaceutical companies and smaller biotech firms. Less than half (46%) of these alliances were deemed to be “relatively successful” or “successful”. Since the majority of these agreements were made at an earlier stage of development than the pharma to pharma sub-set, it is not surprising that many of them failed at some level of clinical development. Others failed due to a combination of significantly elongated development timeframes, a shift in partner priorities, a less than desired clinical profile or labeling and/or some of the communication/human interrelationship issues discussed earlier.

Successful biotech to pharma alliances share all of the attributes of pharma to pharma successes with the additional need for a greater degree of “flexibility” in their roles and division of responsibility. The larger pharma partner often has significant range of capabilities and depth of experience that, while not always specifically called for in an agreement, may prove to be important to its success. Senior alliance management on both sides having aligned incentives to make the relationship succeed was also seen to be key.

The need to address the incentives issue explicitly is growing in importance as more biotech firms hold on to country or segment specific marketing and sales rights in the course of an alliance. In these cases the smaller partner is often creating a commercial organization that “shadows” that of the larger partner. As the potential for overlap of responsibility increases, keeping management focused on the success of the total alliance becomes more important.

Most interesting was our finding that close to 20% of the failures could have been rescued had there been earlier corrective action to repair some of the problems with the alliance.

While decision making structures in these alliances have evolved over time, there are issues at each stage of the relationship that hold the potential for conflict and dysfunctional behavior. Common points of contention seen in the study are illustrated below.

The nature of these relationships is one of inequality seeking change. Biotech companies utilize the capabilities

and resources of the pharmaceutical partner while often attempting to build capabilities of their own. They trade a portion of their intellectual property for capital, expertise and market access. The pharmaceutical company is a necessary and desirable partner because they possess the commercialization capability needed to create value. But increasingly biotech is seeking to hold on to more of that value. Most biotech companies are science dominated organizations that want to participate more fully in activities and key decisions leading up to commercialization without having the full infrastructure to support such involvement. This can lead to errors and misplaced expectations on both sides of an alliance. Uncorrected, these positions lead to value destruction.

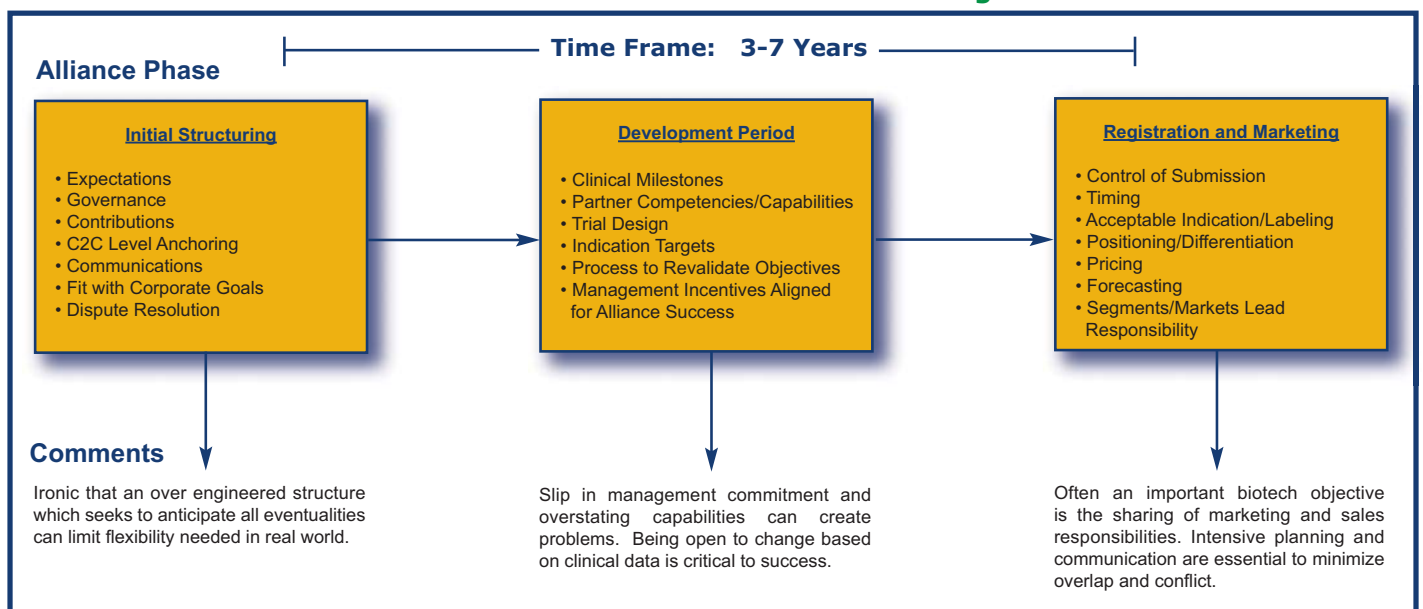
## Diagnosing and Correcting: A Case Study

Given the many opportunities for an alliance to encounter development pains, the value of engaging in an objective third-party evaluation of an alliance’s functioning can be high. Following is a case study of a strategic diagnostic and corrective action project performed by Putnam on a high profile biotech to pharma alliance.

## Background

In a recent assignment Putnam Associates was asked by a Top 10 pharmaceutical client to help diagnose and “fix” a troublesome alliance with a biotech partner. The alliance involved a rather complex co-development of a first in class product that was expected to achieve blockbuster status once it reached the market. The product was several years late and management on both sides were deadlocked on

### When and Where Problems Can Emerge



key developmental issues. Our client's senior management had set a clear internal deadline to either fix or discontinue the alliance.

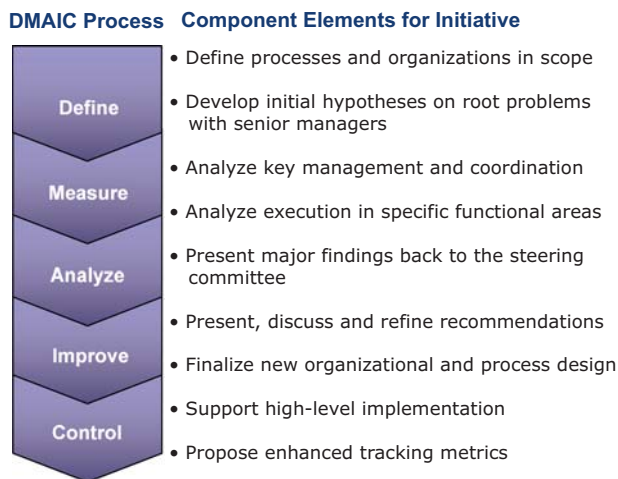
## Assignment

Putnam was tasked to:

- » Diagnose critical path operational problems
- » Bring to bear "Best Practices" lessons and insights
- » Make recommendations on:
  - » Key management processes
  - » Alliance decision making processes
  - » Organizational structures
- » Achieve partner's consensus on change objectives and plan
- » Support implementation

## Process

### Applied Six Sigma Frameworks to Diagnose and Improve Alliance Management



Utilizing the Six Sigma framework illustrated above, we identified significant problems in five areas:

- » Structural complexity
- » Failure of decision making forums
- » Cross-organizational accountability
- » Top-level project management (roles and tools)
- » Two lynchpin processes

Over time, alliance management on both sides had changed repeatedly. The dispute resolution process framework so carefully constructed at the alliance's inception had deteriorated into buck passing forums that caused organizational arteriosclerosis. Tough, important development decisions were continually being deferred. Top decision makers on both sides did not have enough "skin in the game" to drive the process to success.

## Corrective Actions

Our report was made jointly to top management on both sides. We facilitated a series of alliance sessions to resolve diagnosed strategic disagreements. Putnam helped to conduct a fundamental rebuilding of the product development plan. We collaboratively redesigned a streamlined alliance structure and helped to relaunch it with both partners. Key to the new structure was simplified team foundations with shared accountability and aligned incentives among team co-leads.

## Results

A distressed alliance in danger of failure was saved. The product's NDA was filed within 10 months of the project's completion and the drug was recently approved. It is on track to achieve \$1 billion+ in sales within the first 18 months. A second alliance product is now under development.

Putnam followed up six months after the redesign implementation and resurveyed key personnel on both sides of the alliance. 63% of respondents thought progress on the compound was better or much better since the redesign vs. 13% who thought things were slightly worse, with the rest neutral. Team leaders and members were especially appreciative of the substantial drop in the estimated percentage of time spent in "crisis mode" -- from an initial average response of 67% of the time down to 32% of the time as the teams tackled the challenge of nailing down the NDA. As one participant put it, "We went from constant fire drills and backpedaling to actually getting the work done -- to checking items off the list."

## Conclusion

Given the critical importance of successful alliances to the future of companies large and small, recognizing troubled alliances and taking corrective actions can create substantial value for all parties.

## About Putnam

Putnam Associates is a strategy consulting firm focused exclusively on the health care field. We have an 18-year track record of helping pharmaceutical, biotechnology and life science companies create strategies that maximize the revenue and profitability of their products throughout their lifecycles.

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