Covance Delivers 15% Cost Savings with Dedicated Resource Agreement

Executive Summary
Drug development is a demanding, complex, and very expensive process that produces high operating leverage for pharmaceutical companies. Because of this, many pharmaceutical companies choose to outsource drug development services with a contract research organization (CRO). A typical sponsor-CRO relationship is based upon one or more transactional agreements that are each focused on a specific project. While this type of arrangement works very well for some sponsors, particularly those with small, well-defined projects, other sponsors find the transactional agreement model presents challenges. These include a high administrative and paperwork burden and an inability to make changes to the program once it is contracted. Because the sponsor may use the services of several different CROs, these “one-off” transactional relationships are often plagued by inconsistent data quality and poor communication. For this reason, it is not uncommon for a pharmaceutical company to become frustrated and to contract with one CRO after another in an effort to assure high-quality, consistent data, smooth communication, and fast turn-around time.

Covance Bioanalytical created a Dedicated Resource Agreement (DRA) program, in order to provide sponsors with more flexibility and options to fulfill their drug development services needs. The DRA program is an integrated resource allocation and project management option that serves sponsors with large or potentially changing programs. It provides sponsors with a dedicated PI and a dedicated team of FTEs in designated facilities. In effect, the sponsor-dedicated team at Covance becomes an extension of the client’s own laboratory. The benefits of such a program are many, including improved cycle time, a cost reduction of 10-20%, reduction in sponsor's fixed costs, improved data flow, and a strong, strategic partnership between the sponsor and Covance.

In this paper, we will explain why the DRA program was developed, describe its features, and highlight its benefits through a real-world case study of a Covance sponsor.

Why Outsource During Drug Development?
Undertaking drug development in today’s market is a demanding process. The pressure is on pharmaceutical companies to develop drugs faster than ever before in order to maximize patent protection and to secure marketplace advantage. Yet the process of drug development is complex. Pharmaceutical companies need sophisticated therapeutic and regulatory expertise in order to successfully bring a compound through the pipeline to market. This process has become even more challenging in the last 10 years because of the ever-increasing requirements for large multinational clinical trials. Such trials require sophisticated diagnostic and laboratory testing, and they represent a significant financial investment. Indeed, independent audits have shown that it can take over 13 years and approximately U.S. $1.8 billion to bring a new therapy to market.¹

In light of these demands, many pharmaceutical companies choose to outsource parts of the drug development process to contract research organizations (CROs). The benefits of outsourcing, when it is done well, are numerous. First, outsourcing makes good financial sense for pharmaceutical companies in today’s volatile economic and political environment. Drug development, as with any business, carries with it both fixed costs and variable costs. Pharmaceutical companies generally have high levels of fixed costs, and thus, high operating leverage, because of their massive in-house research and development (R&D) programs. The problem is that high operating leverage carries risk—the higher the operating leverage, the more a company’s income is affected by the fluctuations in sales volume that can occur during an economic

downturn. By outsourcing to a reliable CRO, pharmaceutical companies can reduce their operating leverage and reduce risk. Through the CRO, the company can access additional therapeutic and regulatory expertise, extensive nonclinical and clinical drug development experience, and state-of-the-art technology, and additional capacity without adding the associated fixed costs to their R&D overhead.

While these financial benefits are useful at any given point in the drug development process, the second main benefit of outsourcing can only be fully realized when a CRO’s services are provided throughout the entire drug development process. That benefit is speed to market. With expertise from drug discovery to clinical development, a full-service CRO can assist their sponsor by providing discovery services, nonclinical and clinical safety testing, proof-of-concept studies, efficacy testing, and filing for marketing approval. In addition, the CRO can help with launching and marketing a drug, ensuring patient safety and access, and managing risk. It is a rare CRO that can do this effectively, but when done with experience, this type of full-spectrum service brings products to market substantially faster.

**Working with a CRO under Transactional Agreements**

What does the typical relationship between a pharmaceutical company sponsor and a CRO look like? In most situations, the relationship is one that can best be described as transactional. Projects are offered by the sponsor and are generally bid upon by a number of different CROs. Once a project is awarded to a particular CRO, then that organization becomes responsible for the logistics. That is, the CRO sets up the facility, makes technology decisions, assigns staff, organizes the work flow, and ensures compliance with appropriate regulatory guidelines. When the project is completed, the relationship between the sponsor and CRO ends, at least until the cycle of offering, bidding, and awarding has been repeated with a different project.

While such arrangements can work well, particularly for projects of a smaller scale, they present a number of difficulties both for the CRO and for the sponsor. First, such transactional arrangements are very rigid. In order to make any program priority changes midstream, the contractual process on both sides must be revisited, with its accompanying cumbersome paperwork. A longer cycle time is almost guaranteed when any changes need to be made with this sort of arrangement in place. Second, transactional relationships are often plagued by inconsistent data quality and poor communication. For this reason, it is not uncommon for a pharmaceutical company to become frustrated and to contract with one CRO after another in an effort to assure high-quality, consistent data, smooth communication, and fast turnaround time.

After years of experience working with sponsor pharmaceutical companies under these type of transactional agreements, Covance intimately understands the associated strengths and weaknesses. Although transactional agreements are the right fit for certain kinds of projects, Covance seeks to offer its sponsors flexibility and a wide variety of drug development services options. Because Covance is one of the world’s largest and most comprehensive drug development service companies with global operations in more than 25 countries, more than 10,000 employees worldwide, and annual revenues greater than $1.8 billion, its employees have the depth and breadth of knowledge to trailblaze new ways of working with sponsors. Thus, when it became clear that certain sponsors would be better served with a more flexible, integrated service agreement, Covance Bioanalytical designed the DRA program to fulfill that need.

**The DRA Program**

What we envisioned with the DRA program was the ability to offer sponsors the choice to undertake a strategic partnership, one that would be characterized by trust, open communication, flexibility, and collaboration. More than just a preferred provider program, the DRA program allows Covance to serve as an extension of the sponsor’s own team, instead of functioning as a separate entity. This is possible because all of the resources in a sponsor’s DRA program are not shared but rather are sponsor-dedicated.
Simply put, the DRA program is an integrated resource allocation and project management program. It is designed to support early to late stage development projects that are or have the potential to be large in scope, have frequently changing priorities (such as dose escalation studies), or require dedicated scientists to ensure consistency of results over the long term. The key features of the DRA program are its simplified approach and its ability to provide an integrated menu of services within one program.

As part of the DRA program's simplified approach, a dedicated bioanalytical team at Covance is assigned to the sponsor; the selection of this critical position is made with sponsor input. The sponsor and Covance then work together to determine the number of full-time equivalents (FTE) that will be needed to complete the work of that which the sponsor requires, which may be two, or as many as over 50. From there, the sponsor controls priority of the FTE activities through communications with the Principal Investigator (PI). Urgent clinical or program priority changes can be made without cumbersome paperwork or purchase order changes. In essence, with this model, Covance becomes an extension of the sponsor's own laboratory. “With a DRA program, the sponsor basically has their own team in our facilities,” says Steve Michael, VP and Chief Scientific Officer for Covance Bioanalytical Services. “Administration becomes simple.”

The second key feature of the DRA program is the ability to provide an integrated menu of services, all within one streamlined program. For example, a DRA program sponsor has full access to Covance Central Laboratory Services (CCLS), a world-leader for clinical trial management services. CCLS manages over a third of all clinical trials conducted in the world and has experience in over 100 countries. As a world leader, CCLS was the first laboratory to develop and implement the use of visit-specific collection kits for clinical studies. The customized kits are user-friendly and consistent across study sites, resulting in higher quality laboratory data from clinical trials. As an integrated service provider, Covance provides efficient, no-hassle shipping of samples between CCLS and Covance’s bioanalytical laboratories. In addition, Covance has designed a state-of-the-art electronic data transfer system, so the movement of data between sponsor, CCLS, and the bioanalytical laboratories is quick and seamless.

The benefits of the DRA program are numerous. First, DRA sponsors experience improved cycle time and a higher degree of flexibility. Because of the simplified approach to project management, contracts between Covance and the sponsor are limited to the one overall agreement, so there is a significantly reduced administrative burden. There is no need to provide separate quotes for internal authorization and PO issuance for new method transfers, validations, or changes in sample volume, saving an enormous amount of time for both operational and business representatives. This translates into improved cycle time for the sponsor's products and reduced outsourcing costs for the sponsor. The simplified approach also means that the sponsor has a high degree of flexibility. The DRA program does not require the issuance of work scope changes when priorities change, allowing the study team to continue on with their work versus waiting for approval. Again, workflow improves and cycle time is reduced. Yet, even with a simplified approach to project management, the DRA program is designed to help the sponsor easily partition the DRA program costs into its own various program budgets. Each Covance staff member working under the DRA records the time, to the quarter hour, spent each week linked to each particular sponsor program or project. This makes budgeting straightforward on the sponsor side.

A second major benefit of the DRA program is that it makes the most efficient use of the sponsor's financial resources. The integrated service package that Covance offers can save the typical DRA sponsor over 10% in external CRO costs compared with a similar set of projects awarded through standard transactional agreements. These savings accrue through full-service sample management and reduced shipping fees, and improved data quality and efficiencies in sample analysis production. Additional in-house savings are also realized under the DRA program through a large-scale reduction in paperwork and administrative duties as well as from improved cycle time. These internal savings can add up to an additional 10%. Not only does the DRA program provide reductions in external and internal costs, it also reduces the sponsor's operating leverage. As discussed before, in today's economic environment, the flow of work is not always predictable, but the in-house fixed costs of preclinical and clinical programs are difficult to reduce. Because the DRA sponsor is free to add or delete program personnel at Covance as needed, they can
The DRA in Action: A Sponsor Case Study

Perhaps the benefits of the DRA program are best illustrated through a real-world case study. Starting in 2005, Covance began working with a pharmaceutical company sponsor looking for outsourcing support in the areas of large molecule bioanalysis, with the work to be completed under the standard transactional agreement model. Over time, the volume of work increased, and because the work was assigned under the transactional agreement model, the work was parceled out to various CROs. Seeing the inherent inefficiencies in such a divided system, Covance proposed that a DRA program would improve cycle time and save money for the sponsor.

At first, the idea met some resistance on the sponsor side, so as a first step, Covance offered to assign a dedicated PI to manage all the sponsor’s programs. That action, and the PI’s dedication to providing signature client service, began a very loyal CRO-sponsor relationship. As the scientific exchange grew between the sponsor’s team and the sponsor’s dedicated team at Covance, a close working relationship developed. Soon, collaboration in the lab and contributions to program methods and processes gave way to joint presentations at scientific conferences and symposia. A Senior Account Executive at Covance says, “Whenever I go to professional meetings, our PI is invited to sit with the sponsor’s people as one of their team. This is very rewarding to see.” This cohesiveness vividly demonstrates how the DRA program fosters a cultural and a personal bond between the sponsor team and the sponsor’s dedicated Covance team.

As the relationship between the sponsor and the dedicated team at Covance continued to grow, it became clear that the sponsor desired a very high level of flexibility. The PI and bioanalytical team were willing to deliver this. For example, the sponsor

Sponsor Benefits

- Total cost savings of 15%
- Increased cultural bond between sponsor and Covance
- Leveraged flexibility with control over FTEs priority and allocated

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— Sponsor Representative

Both the monetary and operational benefits have been enormous. Operationally, the process of changing clinical programs and implementing new projects has been streamlined into a single page of paperwork that can be approved in hours, not weeks. This has improved communication between the sponsor and Covance and has eliminated costly delays in sponsor programs. The sponsor has also been thrilled with the smooth integration of services offered by Covance, particularly the tight relationship that has evolved between the sponsor’s study sites, CCLS, and the Covance bioanalytical laboratory. They have realized cost benefits with efficient sample shipping and reduced outsourcing documentation, and they have enjoyed near real-time access to study data through the electronic data transfer system.

The sponsor has also leveraged the program’s flexibility in the number of FTEs. Although the relationship began with 4 FTEs, it quickly became clear that there would be enough work for 12 more, which is something that is easily accomplished under the new agreement. Economically, the sponsor has enjoyed a 15% savings in both external and in-house costs by using the DRA program as compared with bidding out the equivalent in transactional projects. The result has been that the sponsor has recognized Covance for its excellence, saying, “Covance is the most transparent of all the CROs. I can’t think of a better team of people who could complete this project in such a short time given all the obstacles we faced.”