Program &
Project Management

IPM®

UNTANGLING CRO CONTRACTS LEADS TO SUPPLIER MANAGEMENT BEST PRACTICES

It doesn't matter how brilliant the researchers are or how many lives their potential new drug will save. Scientists can't develop a new pharmaceutical on their own. Many startup companies turn to multiple consultants and other suppliers to help with clinical, toxicology, and other functions until they demonstrate results and gain consistent funding. But small companies are typically not equipped to manage suppliers well. Research and development teams tend to focus on the science, not the business.

When R&D doesn't have a handle on its contractors and their work, they won't have the trust of the leadership team. They risk losing the support needed to get their products to the patients who need it. Good supplier management can accelerate development, ensure quality, and even save money. And ineffective vendor relations can cause misunderstandings, unnecessary work, cost overruns, and other problems.

LOSING CONTROL OVER CONTRACTS

For example, the translational medicine department at a startup biotech company had more than 10 multiyear contracts with a single contract research organization (CRO). The vendor was working on multiple assays for different programs over different time periods. When the department needed a new contract to develop additional assays for its lead candidate, it realized it didn't know how much was left in its $4.5 million annual budget or what exactly would be spent by year-end. The translational medicine department risked a delay in the first clinical data readout for its lead asset, which is a critical milestone for a small biotech company.

At the root of the problem, the company had few processes and limited structure for managing supplier contracts. Scientists who were writing statements of work (SOWs) were focused on gaining the information they needed. For instance, if a certain biomarker might be used by multiple programs, they would put them on the same SOW. As a result, some contracts covered aspects of multiple programs. Some SOWs had multiple purchase orders (POs) because they wrote a new PO for each change order. It was difficult to determine which funds were for which program, and how much money was contracted and yet to be paid.

Too much trust in the CRO was part of the problem. The department viewed the CRO as a partner rather than a vendor. While working together for a common goal as partners can be valuable in product development, this biotech company lost oversight and didn't measure the CRO's performance.

As a result, the leadership team lost trust in the translational medicine department because it didn't know if it had room in the budget for additional research.

FROM CONFUSION TO CLARITY

The company hired Integrated Project Management Company, Inc. (IPM) to help untangle the contracts and budget. With a combination of expertise in biotech product development and program management, IPM's consultant worked with the team, as well as finance and legal, to review the SOWs.

Together, they categorized the SOWs line by line by program and assay. In the process, they uncovered both duplicate and unnecessary work. In fact, the CRO was performing research for a clinical program that the company had cancelled. They also were able to determine accruals and program spend for the rest of the year. They calculated the value of work to cancel across several contracts, including deposits on work that hadn't started yet. The data would enable a fair and objective negotiation with the CRO.

Having sorted out the details, the consultant created a model to track and predict spending across programs and vendors. The team established quarterly reporting and dashboards with real-time data to stay on track and build trust with the leadership team.

The consultant then turned his attention to the quality team, to help set up a new system for SOWs and POs. The new structure ensured that a SOW would apply to only one program and lead to only one PO. If the team needed to do a change order, they would amend the previous PO, rather than issue a new one. IPM's consultant helped communicate and lead training about the new processes.

SHARING LESSONS ACROSS THE COMPANY

Untangling the contracts revealed that the team hadn't spent half its budget. So, it had more than $2 million to put toward the additional research on its lead asset and to avoid missing a critical funding milestone. Negotiating with the CRO on current contracts resulted in cancelling $2.1 million in unnecessary work and a $566,000 credit on future assays.

Importantly, the team regained the trust of company leadership by showing them they are in control of their contractors and their activities.

Management also embraced the new supplier management practices. IPM's consultant joined department meetings across the company to roll out the new policies. The program helped ensure RFPs align with strategic and program goals and include critical criteria. It demanded that contracts include specifics around deliverables, costs, and requirements, and tied each SOW to one PO. And the program outlined how to enhance collaboration with vendors while maintaining clear responsibilities and oversight.

Ultimately, the robust supplier management practices that resulted from untangling the CRO contracts enhanced efficiency and transparency across the organization.