

## » R&amp;D: OUTSOURCING BEST PRACTICES

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# Outsourcing Best PRACTICES

Trust, collaboration, and communications are three of the key factors to ensuring a successful outsourcing partnership — easy to say, harder to operationalize.

Over the years, PharmaVOICE has covered the necessity for best practices to ensure that CRO/sponsorship partnerships operate at an optimal level, yet most agree there is still a great deal of work to be done to ensure all parties' goals and expectations are met.

Alan Morgan, president of ICON Clinical Research, says the success of an outsourcing relationship depends on a number of factors.

"First, communication is key," he says. "There must be full transparency and an open flow of communication between both companies. Both parties should work in a close, collaborative manner that is based on honesty and trust and openly engage in joint short- and long-term planning so that the needs of the sponsor are fully understood by the CRO. And finally, delivering quality work to agreed milestones is fundamental to a successful relationship."

Joseph Bedford, Ph.D., director of marketing at the Almac Group, agrees that establishing strong communications and governance are two of the most important best practices.

"When both parties in an outsourcing relationship communicate effectively, they are better able to scope and define project goals and objectives, assign joint ownership and accountability of key responsibilities, keep to timeliness, and achieve high levels of quality," he says. "Similarly, when sponsors and suppliers create effective governance structures they often find that study-related goals are met. Ideally, governance structures should involve



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DR. FRANCOIS NADER / NPS Pharmaceuticals



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VINCE AURENTZ / Quintiles

various levels of both sponsor and supplier firms, including the highest levels inside both organizations. When such conditions exist, joint strategic planning and investments are made in the relationship to assure its success."

Darlene Panzitta, president and founder of DSP Clinical Research, believes trust is key to the partnership.

"Pharma companies have to trust their CROs to make the decisions and use their expertise instead of trying to run the study themselves," she says. "Working to develop an atmosphere of mutual trust and respect is the best way to ensure good communications and

a collaboration strategy, to stay within budget, and to have a successful study. Pharma clients should also engage their CRO partner before the protocol is developed.”

Vince Aurentz, executive VP, customer solutions business, at Quintiles, says outsourcing works best when there is a clear understanding of the goals of the relationship; robust planning at the outset; and strong communications at all times.

“Companies are increasingly taking advantage of the vast expertise some CROs have acquired in conducting many trials in similar indications and patient populations,” he says. “A strong alliance relationship allows for an exchange of ideas and recommendations at the beginning of the process and alignment of expectations. This can dramatically reduce change orders and complications that can slow down the trial. But moving successfully from a transactional to an alliance relationship requires a new collaborative skill set that empowers and encourages open communication.”

Andrew Grygiel, chief marketing officer at ClearTrial, says it’s easy to define best practices but much harder to operationalize them.

“There is always a lot of talk about transparency and better communications being keys to better sponsor/CRO relationships,” he says. “But how are companies making these goals a reality? The approach can be summed up in a phrase that was made famous during the Cold War: ‘Trust, but verify.’ The right way to implement this approach is a delicate balance of the two. Most life-sciences companies are leaning heavily toward the verification side, heaping on the oversight and control and maintaining internal operations redundant to those provided by the CRO. While this is somewhat understandable given that sponsors are ultimately held responsible for a clinical study by regulatory bodies, it does little to build a truly sustainable business model.”

Francois Nader, M.D., president and CEO of NPS Pharmaceuticals, says successful partnerships are always based on a win-win equation.

“Both parties need to make sure that the terms of the equation are well-defined before embarking on the journey,” he says. “Both partners have to ensure that a philosophical strategic and cultural alignment are present at

the top of each organization and that this alignment is communicated and practiced as often as needed throughout the course of the relationship. It is of utmost importance to define the roles and accountabilities as clearly as possible and as early as possible during the relationship, as well as putting in place a graded conflict resolution process that identifies the tiebreakers at every stage of the escalation.

## FAST FACT

**WORLD PHARMA CLINICAL TRIAL SERVICES REVENUE WILL REACH \$32.73 BILLION IN 2015. REVENUE FOR THOSE COMPANIES (CROS) TOTALLED \$21.69 BILLION IN 2010.**

Source: Visiongain

Consensus, at times, can lead to the lowest common denominator rather than the best outcome for the project. The interface process should identify clear leadership and decision-making roles.”

Mr. Grygiel says forward-looking organizations are using cloud-based technologies to collaborate closely with their CRO partners, building trust by developing clinical study project plans together from an early stage.

“For example, many companies are using cloud technology to share real-time information regarding project status, trends, and costs tracked against the project plan,” he says. “This approach gives sponsors instant visibility without having to replicate resources. Lastly, the more innovative companies are creating business models that reward outsourcing partners that work collaboratively with the sponsor to increase efficiencies in the work effort that is outsourced. This has resulted in greater adoption of enabling platforms.” **PV**

## EXPERTS



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