



## **Case Study: Selecting a Strategic Contract Research Organization (CRO)**

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## Selecting a Strategic CRO for the Client

### **Business Need**

A global clinical research sponsor was determined to establish long term partnerships with several Clinical Research Organizations (CROs). The sponsor wanted to obtain an unbiased assessment of its identified CRO alternatives and Biovalorem was selected to plan and execute the CRO assessment and provide its recommendations.

### **Innovative Solution**

Biovalorem devised a three prong approach to prepare and execute the assessment. The project used a Characteristic Selection Matrix to determine the weights and outcomes of the assessment.

First, an assessment questionnaire was designed by Biovalorem to assess multiple attributes in key business categories: Capacity, Therapeutic Area, Information Technology, Legal, Project Management, Quality, Human Resources and References. The identified attributes were also weighted to provide a measurement system for the assessment. The attributes and their weights were based on a detailed literature search, experience and historical performance gaps existing with previously hired CROs. The scores were analyzed and three CRO finalists were determined.

Second, a Request for Proposal (RFP) and a Cost Matrix were prepared by Biovalorem and the Sponsor to gather more detailed information regarding the three CRO finalists' capabilities and capacity to perform. A standardized cost matrix framework was used to systematically gather the costs for a study including Project Management, Start-up, Data Management, Statistics, Regulatory, Safety, Medical Writing, Quality Assurance, Drug Supply, Pass-thru and Monitoring. The completed proposals were analyzed in the following categories; Team, Timeline, Approach and Cost. A "Value per Dollar" ratio was calculated using the total scores and costs proposed by the CROs.

Third, an actual physical assessment of the CROs was conducted at a site of high activity. The assessment was focused on the resources present at their site to conduct future studies on behalf of the sponsor. The goal was to determine the alignment of the documented capabilities and capacity against what could be physically perceived by the assessors.

### **Benefits**

Biovalorem's client has selected and identified partners aligned to their culture; therapeutic expertise; operational maturity, and geographic markets as well as an established a process for assessing future CROs. A well-developed analytical process provided an unbiased method of assessment and prevented subjective evaluation to take place.