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# A Comparison of Two Commonly Used CRO Resourcing Models for SAS/ Statistical Programmers

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## ABSTRACT:

Why do we have Contract Research Organizations (CROs)? Pharmaceutical, Biotechnology, and Medical Device companies are trying to streamline their costs by outsourcing the processes to conduct and report clinical data. In this paper, I will introduce the benefits of outsourcing to a CRO for companies varied clinical functional activities. The decision to outsource to a CRO is typically driven by business needs that include: either to benefit the expertise of the CRO, or they have limited resources within their company (technology, staff, etc.), and cost reduction. Based on the scope of work and the company's preferences to operate, the sponsor/ client (the company) and the CRO decides on the resourcing model that meets the needs of both parties, which would eventually be included in their contracts. On a broader classification, there are two commonly used models within the CRO industry, the first being "Traditional Deliverable Based Model" and the other is "Full-Time Equivalent (FTE) Time and Material Model (also called as Role-Based model)".

The author has a total of 8 years of industry experience working under both models of the CRO. This paper would present a compilation of the experiences and differences the author has come across and perceived while working with these commonly used resourcing models of the CROs. It will also list the advantages and disadvantages between these two models within the CROs.

## INTRODUCTION:

Below listed are the definitions with general information, which would help the reader to understand the paper.

- *Contract Research Organization (CRO)* – A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [1]

  To elaborate the above, CRO is a service organization that provides support to Pharmaceutical, Biotechnology, and Medical device industries in the form of research services like – reviewing and validating clinical trial data collected (called monitoring), medical writing, regulatory support, investigator selection and qualification, clinical trial management, biostatistics and statistical programming, data management, etc.

- *Sponsor/ Client/ Company (the Client)* – Any Pharmaceutical, Biotechnology, or Medical device company trying to render services from a CRO to streamline their costs for varied clinical functional activities. Throughout this paper, the author is using "the client" as in reference to a company or sponsor.

The decision by Pharmaceutical and Biotech companies to outsource their varied clinical functional activities to a CRO is typically driven by business needs. Some of the reasons to obtain benefits can be identified as:

- *Expertise of the CRO* – When the client is interested in spending for research towards a therapeutic area study, however, identifies and realizes that a particular CRO has the expertise in conducting the clinical activities for this same therapeutic area study, then it makes complete sense to go with this CRO as they have already spent resources and revenue to gain the required experience.

- *Work continuation for a product license bought* – When a large company X (the client) decides to buy a product from a small company Y, which didn't have the resources and hence outsourced to a CRO. In such situations, to make the maximum out of the product bought (for example, the familiarity with data, features, etc.), there is a strong business justification for the company X to continue to render services from the same CRO that company Y was seeking.

- *Lack or limited in-house resources* – If the client is a small sponsor with no or little internal SAS programming staff, then this client will have to rely on the services provided by the CRO. At times, it gets tough to handle the existing projects and/ or new unexpected projects with the limited resources of the client. To use the industry jargon, which clients usually call it "throwing it over the fence" for seeking services from an established CRO.

- *Cost reduction* – If the business model decided by board of directors requires reduction of costs by not expanding the team of specialized staff or not spending the money to improve the technology, then this could be leveraged by collaboratively working with an established CRO.

## HOW IT IS MANAGED BY THE CRO'S?

Once the CRO to work with is identified, the client and the CRO will decide between the two commonly used and widely recognized CRO resourcing models based on multiple factors, which are – scope of work, to consider client's preference to operate, whose systems to work on, fixed budget model or time and material model (i.e. revenue in terms of one time client payment or hours billed monthly), whose SOPs to follow, number of FTEs per study, etc.

Typically, the CRO would prefer a model where a large part of the revenue could be used for future expansion of services to additional compounds/ projects, and if possible to varied clients. The goal is always to have a considerable margin from these revenues, which is truly the result of developed products from the CROs specialized staff. Using these margins, the CRO tries to re-invest by expanding the team that results in an increased continuation of human intellectual services through expertise in processes, project management, programming, biostatistics, therapeutics, technology, and scientific knowledge. In the next two sections, the author illustrates the advantages and disadvantages between the two commonly used CRO resourcing models.

## DELIVERABLE BASED MODEL:

This model might be optimal when the scope of the work is well defined. So, what constitutes as a well defined scope of work? For example, when the deliverables for various functional areas are well documented and/ or when the timelines are decided in advance and followed strictly, etc.

### ADVANTAGES

- As the scope of work is well defined, which means the specifications/ requirements are in place and concrete, and the timelines are set in stone. So, it's easier for the Project Manager to work on the resource allocation, considering that we know the exact maximum number of hours that could be billed to the client due to which there can't be any discrepancies between proposed and actual cost data (i.e. budget and revenue for the project).

- Within the CRO, if the training, professional development, and mentorship programs are good, then this model gives the advantage of adding resources with either an entry level or less experienced programmers to the team to complete the projects/ deliverables. That certainly helps to save tremendous amounts of direct costs for the CRO organization. However, when compared with the other model, there are clients who request to recruit only Senior and Principal level programmers, which becomes tough for CROs to make margin out of the billing as the direct costs to have these resources is considerably higher.

- In some organizations, only CRO's SOPs are followed; therefore, control over the customized system used for programming, validation, and tracking is decided by the leads at the CRO. This helps, as the associates don't have to spend the time in going through client's SOPs and doesn't have to get trained to work on client's systems. However, if the CRO is expected to use the sponsor's SOPs as well in this model, then the costs might be higher since the budget will be burdened to include SOP training, etc.

- Most of the sponsors still like to maintain the core competency in-house and may QC and confirm the outputs from the CRO. However, when the validation process and the quality control review for deliverables are completely done by the CRO project team, then this model avoids the need for a thorough communication and approval process by the quality team at the client, as CRO project team is accountable for the quality of the deliverable.

- As geographic location is often the key criteria and extremely important factor to help reduce the costs while recruiting programmers to the team. This model gives the flexibility to hire and train the associates anywhere across the globe and get work done with same quality. When compared with the other model, there will be clients who are so specific about having all the programming resources located at a particular CRO office.

### DISADVANTAGES

- As resourcing is decided by the project management or operational team within the CRO, the associates might end up working on multiple projects on the same business day. There is even a possibility of these projects not belonging to the same client. So, there might be lot of bouncing between different projects on the same day for team members in this model.

- In most organizations, the business objectives are to meet the expectations of Utilization, Revenue, and Margin. Additionally, in this model, there is a significant emphasis on the metrics for realization. Due to this

metric, although programmers end up working way too many hours for a project to complete, there is a possibility that some of them might avoid the realistic numbers to be entered in the weekly time sheets.

- In this model, resources work on multiple studies/ projects at the same time for a short period. Due to the limited time spent while working on these studies, this doesn't allow the programmers to develop good grounding of the concepts for the assigned therapeutic area. Probably, they would also miss the opportunity to have an in-depth experience.

## FTE TIME AND MATERIAL MODEL (ROLE BASED):

This model might be favorable for contracts in which the scope of the work is not clearly defined. So, what constitutes as NOT a well defined scope of work? For example, during the study/ project setup, if the scope of the protocol and clinical trial is unclear, then it helps to work within this model as the possibility of requiring additional new work orders is high. Typically, any further requested tasks could be like these: the development of Statistical Analysis Plan (SAP), multiple Ad-hoc requests, Interim analyses, etc. Additionally, due to multiple conflicting priorities for the project team, there is a possibility that the timelines are not decided in advance.

### ADVANTAGES

- As the scope of the work is not clearly defined, there is a possibility of additional work orders through requests like Interim Analysis, Ad-hoc requests, etc., which in turn helps for the CRO to have more work for the associates and to increase organization's revenue.

- In some of the contracts between the client and the CRO, it requests for dedicated resources per therapeutic area within that functional department. This helps the associate to become an expert in one particular therapeutic area and add value to his/ her skill level. Eventually, through the experience of collaboratively working with counterparts at the client, this CRO project team member can become a "Subject Matter Expert (SME)".

- For programming efficiencies, on both production and validation end, in this model the CRO need not spend the time and resources to create macros to enhance the productivity of the team. As, most of the times, the contract is decided to use the systems and standardized macros of the client to generate the outputs like Tables, Listings, and Graphs.

- When CRO project team members collaboratively work with the team at client, they get the sense of being part of the team (like a stakeholder). This certainly helps many CRO project team members with their motivation and drive towards developing a quality clinical trial analysis.

- The key advantage of this model is the flexibility, which it provides to every project team member involved both at the client's and at the CRO's end.

### DISADVANTAGES

- Due to unexpected and inconsistent requests from the client with short turnarounds for some of the deliverables, it could be completely overwhelming for the CRO project team members. Because of the design and purpose of this model, additional requests can crop up any time for the clinical trial analysis.

- Within this model, a considerable amount of mentorship, training, and time is needed to establish a potential lead who can serve the role with responsibilities that are required as the CRO's Point of Contact (PoC) for each study/ project.

- When CRO project lead collaboratively works with client project team members, it is imperative that the lead demonstrates an exemplary performance in the following areas – trust, communication, persistence, resourcefulness, etc. As emphasis on all of these areas is required to manage and bring the projects to a successful completion.

- A potential draw-back is the inefficiency due to the design of this model. For example, the client's project team members may pro-actively think critically about their additional requests to the CRO, as this is a Time and Material contract and the sponsor is willing to pay for the services like: CRO rework, modification of the specifications or table shells, reiteration of the validation process, etc. But, it is overwhelming at times for the CRO project team members to accommodate client's short turnaround requests.

- On a bi-weekly or monthly basis, preparation is needed for an operational or governance meeting with client's management team where the CRO management team has to present the information covering details like - resource projections, portfolio review, metrics for number of deliverables (on time, delayed, before time), attrition and turnover, quality metrics, compliance reports, and project related issues, etc. When compared with the other model, the time and efforts spent to prepare for an operational meeting presentation can be utilized towards other project related tasks.

## CONCLUSION:

Below chart is summarized to identify and differentiate the major parameters and methods followed by each model within the CROs.

| | **Deliverable Based** | **Role Based** |
|---|---|---|
| SOPs Followed | Follow CROs | Follow both CROs and clients |
| Client or CRO Systems Used | Work on CRO systems | Work on both CRO and client systems |
| Bouncing Between Projects | Quite frequently | Not so frequent |
| Training and Resources | Provided by CROs | Provided by both CROs and clients |
| Variety of Work | High | Not so high when compared |
| Expansion of Services | Medium | High |
| Increase Teams Revenue | Fixed budget | Due to additional requests, chances are high. |
| Resource Projections | Need NOT update the client | Need to update the client |
| Deliverable Metrics | Internal Purposes | Internal and External (the client) Purposes |
| Programmers Experience | Entry Level, Level II, Senior, and Principal | Level II, Senior, and Principal |
| Geographical Location | Anywhere in the globe | Can be restricted |
| Standardized Macros | CRO responsible to create | Client's macro could be used |
| To Gain Therapeutic Experience | Medium | High |
| Measures Realization and Utilization | Both | Just utilization |

From all of the above guidelines with detailed pros and cons, when the client (the sponsor) has decided to outsource a variety of clinical functional activities, and does not want to get involved in the operational activities of the clinical trial analysis but only cares for the final deliverable with outputs, then based on my observations "Deliverable Based Model" would be the right fit for both the sponsor and the CRO to come up with a quality product.

On the contrary, if the client (the sponsor) has decided to collaboratively work with the CRO project team members to be part of project activities and to work towards conducting a clinical trial analysis, then "FTE Time and Material (Role Based Model" would be the good fit for both the sponsor and the CRO.

Irrespective of the model decided by the client and the CRO to operate, the CRO's motto is always to provide superior customer service through quality, speed, and value.

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