Techniques for Managing Projects Outsourced to Offshore CRO

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Abstract
Outsourcing projects to CROs overseas has become common practice in the pharmaceutical industry in recent years. This brings new challenges to project and resource management due to various circumstances uncommon to in-house studies or studies outsourced to domestic CROs. These circumstances include differences in skill sets, work experience, communication style, time zones, cultural norms, etc. In this paper, the authors discuss several techniques being used for functionally outsourced projects where the sponsor process and procedures are required for the success of the project when working with an offshore CRO.

Introduction
A cost-effective business model has always been explored for a successful business operation in the pharmaceutical industry. Outsourcing overseas has been examined and practiced in recent years as part of this model due to the low cost, and optimal resource and market potential in some countries, including India and China. This brings new challenges to our project and resource management due to various circumstances uncommon to in-house studies or studies outsourced to domestic CROs. These circumstances include differences in skill sets, work experience, communication style, time zones, and cultural norms. Management of projects outsourced to offshore CROs directly impacts the success of this innovative module of a cost-effective business model. The authors of this paper have the opportunity to work with an offshore CRO on functional outsourcing that involves a part of the clinical trial data process in Scientific Programming. Functional outsourcing involves outsourcing specific functions or activities rather than all aspects of an entire project. In the following sections, the authors will introduce several techniques being practiced when working with the CRO to overcome barriers in many areas in order to achieve successful project support.

Technique 1. Technical Training and Solution
Due to various drug regulation systems worldwide and the demand for outsourcing resources, the offshore staff usually does not have the direct skill sets or work experience required by our processes. Training is necessary to help build their technical skills to provide immediate project support and meet our long term expectations. The offshore staff that we have been managing focus on several special tasks in our project process, so training is offered to allow them to be specialized in the target area. The following were covered in the training.

1) Initial training was offered by our employees to the CRO through teleconferences.
2) All related documents including guidelines and process flow charts were provided to the CRO for reference through direct access to our systems.
3) An in-house technical mentor was assigned to answer any questions that might be raised during the project support.
4) The CRO staff was also instructed to call the Helpdesk directly at any time for system issues to reduce the turnaround time and utilize the existing support infrastructure.
5) Once the CRO received the necessary trainings, a trainer within the CRO was identified to provide training to any new CRO staff. This arrangement helps to ease the potential impact of any staff turnover.

Technique 2. Resource Estimation
Resource estimation is an essential component of the cost-effective outsourcing model and directly impacts whether our projects can be fully supported. Resources are determined by the number of staff available who have the expertise as well as the complexity of the work. Our resource estimation is conducted in the following stages.
1) After the CROs staff received the initial training and completed a sufficient number of requests, we requested the CRO to estimate the average number of full time equivalents (FTE) needed to perform the support tasks for each project.

2) The average number of FTEs per project and our project plan information were used to forecast the resource needed by month; the forecasted FTEs were then compared with the currently available FTEs to estimate the gap between the demand and availability of the FTEs by month. Flexible FTEs were planned for months with an FTE shortage.

3) Later on, system access to our project plan information was granted to the CRO project manager. This allowed resource estimation to be performed by the CRO.

**Technique 3. Effective Communication Tools**

Effective communication is critical to fully understand project requests, progress, issues, and mitigation planning. When working with offshore CROs, effective communication needs to be achieved through a standardized and defined process. The following communication tools achieved demonstrated success from our experience with outsourced project management.

1) Regular Meetings with CRO Project Manager

   Bi-weekly teleconferences scheduled with the CRO project manager to discuss all project related issues and future plans help to establish and strengthen the working relationship over time. Meeting minutes are sometimes asked to be recorded by the CRO project manager to ensure mutual understanding of the discussion and assignments.

2) Project Request Check List

   Due to the time difference, some messages may take a day or more to communicate with the CRO. A project request check list was implemented to reduce the communication cycle time. It is designed for our project leads to complete before sending the CRO project requests. The list includes the availability and location of the related project documents needed by the CRO to perform their project support, and CRO staff's access to the project folder. Project leads are required to get the items on the check list ready before contacting the CRO for any project support.

3) Project Tracking Sheet

   CRO staff support multiple projects; therefore, it is important to communicate the project progress and achievements to our management and project leads. A project tracking sheet is designed for this special communication purpose, which includes information regarding project details such as, target start and completion dates, actual start and completion dates, and status of work, as follows:

<table>
<thead>
<tr>
<th>Tracking Sheet Year 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Task 1</strong></td>
</tr>
<tr>
<td>Study-001</td>
</tr>
<tr>
<td>Study-128</td>
</tr>
<tr>
<td>Study-005</td>
</tr>
<tr>
<td>Study-089</td>
</tr>
<tr>
<td>Study-019</td>
</tr>
<tr>
<td><strong>Task 2</strong></td>
</tr>
<tr>
<td>Study-024</td>
</tr>
<tr>
<td>Study-059</td>
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</tbody>
</table>
4) Feedback Form
To help evaluate and improve the quality and timeliness of the CRO support, a feedback form is designed for our project leads to fill in during or after working with the CRO on their projects. The authors summarize or review the feedback and communicate to the CRO project manager frequently to encourage best practices and make course corrections for issues.

5) Live Communication
To enhance the implementation of a standard process for the outsourced task and reduce cycle time, the authors also make live communication with both our project leads and CRO staff whenever a need arises in addition to regular meetings. We talk to our project leads directly for questions and instructions on the requests for support. E-mails are sent off to the CRO or our project leads directly when responses, clarifications or follow-up are necessary.

6) Holiday Schedule
Holiday schedules vary among countries and cultures. It is equally important to respect the cultural disparity and meet our project timelines. Based on this principle, holiday schedules from both the CRO and our company are communicated immediately once available for project planning purposes. Both holiday schedules are posted in the eRoom that is accessible to the CRO and our project leads for future reference. This is proven to be an effective means for proactive project planning and obtaining on-time support from the CRO. Moreover, CRO holiday differences can be leveraged to accomplish work when the sponsor company is off.

7) Time Differences
Time zone differences between us and our outsourcing partner provide both benefits and challenges. With approximately a half day difference in time, live meetings, training and other interactive communication requires careful planning. Both parties need to accommodate some flexibility into their schedules for important live discussions. It is helpful to discuss the least disruptive times to meet before scheduling meetings. Additionally, time differences offer benefits. A project request sent to the CRO at 5 PM can be completed by the time the sponsor company starts work the next morning, effectively providing round-the-clock support for project work.

Conclusion
Managing outsourced projects poses both challenges and opportunities. With our success in managing functionally outsourced projects, a commitment has been made to practice outsourcing in different ways with our techniques, and to further explore its impact on the cost-effective business model.

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