Techniques for Managing Projects Outsourced to Offshore CRO

Hong Qi, Merck Sharp & Dohme Corp., Upper Gwynedd, PA
Margaret M. Coughlin, Merck Sharp & Dohme Corp., Rahway, NJ

Abstract
Outsourcing projects to Contract Research Organizations (CRO) 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's 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 either covered in the training or resulted from 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) Once the CRO received the necessary training, a pilot study was conducted to identify knowledge gaps and questions, and ensure the appropriate conduct of the tasks.
4) An in-house technical mentor was assigned to answer any questions that might be raised during the project support.
5) 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.
6) 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
considering the number of CRO 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 receive the initial training and complete a sufficient number of requests, we request that the CRO 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 are then used to forecast the resource needed by month; the forecasted FTEs are then compared with the currently available FTEs to estimate the gap between the demand and availability of the FTEs by month. Flexible FTEs are planned for months with an FTE shortage.

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

4) Resource utilization is followed up retrospectively to evaluate the accuracy of the resource forecast and the actual workload, and help with the future planning.

Technique 3. Effective Communication Tools

Effective communication is critical to fully understand project requests, progress, issues, and perform mitigation planning. When working with offshore CROs, effective communication needs to be planned and implemented through a standardized and defined process. The following communication tools achieved success 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 is used to reduce the communication cycle time. It must be completed by our project leads prior to sending the CRO a project request. The check list includes the availability and location of the related project documents needed by the CRO to perform their project support. The check list also serves as a reminder for project leads to provide CRO staff access to the project folder.

3) Project Tracking Sheet

CRO staff support multiple projects; therefore, it is important to track project progress and achievements in order to provide status updates to our management and project leads. A project tracking sheet (see below) is used to communicate project details such as: target start and completion dates, actual start and completion dates, and status of work.

<table>
<thead>
<tr>
<th>Project</th>
<th>Project Lead</th>
<th>Plan Date</th>
<th>Target Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Start</td>
<td>Finish</td>
<td></td>
</tr>
<tr>
<td>Task 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-037</td>
<td>A. Hitchcock</td>
<td>15-Jun-09</td>
<td>15-Jun-09</td>
<td>15-Jun-09 complete</td>
</tr>
<tr>
<td>Study-001</td>
<td>R. Smith</td>
<td>19-Jun-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-128</td>
<td>T. Jones</td>
<td>19-Jun-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-005</td>
<td>S. Holmes</td>
<td>19-Jun-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-089</td>
<td>B. Polite</td>
<td>16-Jun-09</td>
<td>18-Jun-09</td>
<td>16-Jun-09 complete</td>
</tr>
<tr>
<td>Study-019</td>
<td>J. Goodnig</td>
<td>16-Jun-09</td>
<td>6-Jul-09</td>
<td>16-Jun-09 in progress</td>
</tr>
<tr>
<td>Task 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-024</td>
<td>A. Hitchcock</td>
<td>2-Jun-09</td>
<td>5-Jun-09</td>
<td></td>
</tr>
<tr>
<td>Study-059</td>
<td>B. Polite</td>
<td>3-Jun-09</td>
<td>9-Jun-09</td>
<td>5-Jun-09 complete</td>
</tr>
</tbody>
</table>
4) Feedback Form
To help evaluate and improve the quality and timeliness of the CRO support, project leads complete a feedback form during and/or after working with the CRO on a project. The project leads summarize and review the feedback with the CRO project manager to make course corrections for issues and encourage development of best practices.

5) Live Communication
To enhance the implementation of a standard process for an outsourced task and to reduce cycle time, it is also important to communicate via teleconference or in-person meetings involving both the project leads and CRO staff in addition to regular meetings. This allows the CRO staff to discuss the request and ask the project leads questions. E-mails are used when additional information, 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 as soon as they are available for project planning purposes. Both sponsor and CRO holiday schedules are posted in the eRoom that is accessible to the CRO and our project leads for reference. This provides the opportunity for proactive project planning and obtaining on-time support from the CRO. Moreover, holiday differences can be leveraged to accomplish work when the sponsor company is off.

7) Time Differences
Time zone differences between the sponsor and the outsourcing partner provide both challenges and benefits. With approximately a half day difference in time, live meetings, training and other interactive communication requires careful planning. Both parties need to be flexible to accommodate these important discussions. It is helpful to discuss the least disruptive times to meet before scheduling meetings. Additionally, time differences offer benefits. A 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. Following our success in managing functionally outsourced projects, a commitment has been made to turn these techniques into best practices, and to further explore their impact on the cost-effective business model.

Acknowledgement
The authors would like to thank management for their support and guidance on working with the CRO, and for reviewing the paper and providing valuable feedback. The authors would also like to thank our outsourcing partners for their dedicated project and management support.

Author Contact Information
The authors can be contacted for questions, comments, and suggestions.

Hong Qi
Sr. Scientific Programming Analyst, Scientific Programming
Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Role</th>
<th>Company</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Margaret Coughlin</td>
<td>Manager, Scientific Programming</td>
<td>Merck Sharp &amp; Dohme Corp., a subsidiary of Merck &amp; Co., Inc.</td>
<td>732-594-3781</td>
<td><a href="mailto:margaret_coughlin@merck.com">margaret_coughlin@merck.com</a></td>
</tr>
</tbody>
</table>

North Wales, PA
Phone: 267-305-7589
E-mail: hong_qi@merck.com