

PharmaSUG 2017 - Paper MS02
The Cross Border Program

Strengthening the Sponsor-Partner Offshore Experience

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ABSTRACT

Pharmaceutical statistical programming outsourcing is a comparatively late entrant to the India offshore market. Merck Statistical Programming initiated the outsourcing of limited statistical programming deliverables in 2007, partnering with small companies in India and China. Lessons learned during this early phase allowed us to development a more effective model as we expanded scope in subsequent years with a new partner. One of the programs we established in 2015 was the Cross Border Program (CBP) where partner staff visit Merck US sites for a period of time. Objectives of this program include keeping intact the strong India team we have invested in, providing team members with a sense of a global team concept, assisting the partner in managing attrition, and providing growth opportunities for partner staff. This is a joint commitment program between Merck and our Partner, including budget sharing and onsite logistics support.

This paper will cover details of the program and present lessons learned from both the Merck and Partner perspective.

INTRODUCTION

A few years into our current statistical programming outsource partnership we at Merck asked the following questions: “Could we strengthen the partnership and possibly take it to another level by having India-based Partner staff spend time in the US shadowing and learning from their Merck colleagues?” and “How would we do this and would it be worthwhile?” This paper will outline the program we put into place to answer these questions and describe our experiences to-date.

PARTNERSHIP – HISTORY AND BACKGROUND

Outsourcing of Pharmaceutical services started in more systematic areas like clinical development and manufacturing, later expanding to support functions like Information Technology. It now extends across a broad range of operations including analytics, business intelligence, forecasting etc. However the fact remains that the Pharmaceutical industry has been slow to adopt outsourcing versus many other sectors. (Source: White paper from QuintilesIMS, 1)

Merck Statistical Programming initiated the outsourcing of limited statistical programming deliverables in 2007, partnering with small companies in India and China. Lessons learned during this early phase allowed us to development a more effective model as we expanded scope in subsequent years with a new partner. The model consisted of all programmers in offshore locations with only two senior leaders onsite in the U.S. The new partnership allowed us to rapidly scale resources up or down as needed and offered immediate access to specialist knowledge without long ramp-up or expensive ramp down, and the ability to flex resources as required. This partnership is not solely about short-term cost and/or efficiency savings and therefore represents both journey and destination. One of the programs we established in 2015 was the Cross Border Program (CBP) where partner staff visit Merck US sites for a period of time.

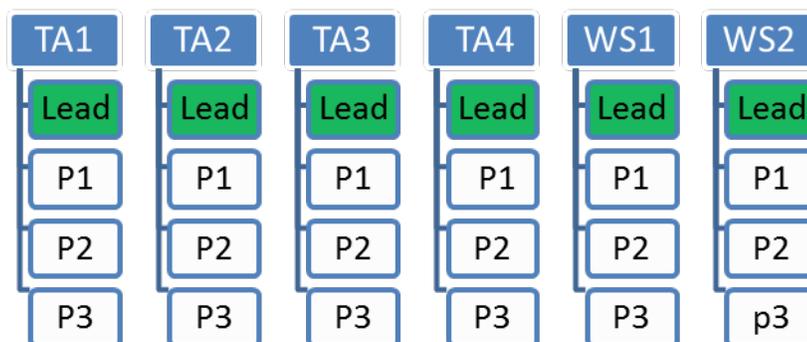
One of the main CBP understandings is an acknowledgment that one partner cannot immediately acquire expertise in the other’s business. This again brings interpersonal skill to the fore. The right chemistry and cultural fit are paramount, especially as outsourcing is often a virtual partnership. The CBP helped in addressing some of these core issues and concerns.

SUPPORT TYPES

The partnership support model encompasses a broad range of accountabilities and deliverables, organized by work-stream (WS) and Therapeutic Area (TA). The support starts from initial collected data mapping activities to in life monitoring effort using object-based reporting software. The TA support covers early development and late stage and can include standard, project specific, and integrated summary TLF support. The submission support is provided by running dataset checks and compiling the various pieces required for the submission package.

SUPPORT MODEL

Each TA and work-stream has an India-based lead as illustrated in the chart below. CBP participants to-date have predominantly come from this group of leads.



PROGRAM DETAILS

The following sub-sections describe the CBP in greater detail.

DESCRIPTION

On a quarterly basis two India-based partner staff travel to the US and stay for a period of six-weeks. They are based out of the Merck R&D sites, spending time at both the New Jersey and Pennsylvania facilities. The number of weeks spent at each site depends on their Merck customer support locations. Their eligibility for the program is based on tenure, leadership position and performance. The program started in 4Q 2015, is currently active, and will run through the life of the Merck/Partner contract.

GOALS

The program is targeted to increase work-stream lead and TA lead engagement and capabilities. The intention is to strengthen relationships with the US programming team as well as US stakeholders including Statisticians, Clinicians, and Medical Writers and provides partner staff with a greater awareness of the global team environment. The program is meant to provide growth opportunities for partner staff and aid in retention. Merck system and process training is extensive and as such retaining trained partner staff decreases team disruption which benefits project continuity.

EXPECTATIONS

Program participants are immersed in a training and learning environment. They are expected to learn through exposure by shadowing programming leads, attending team meetings and directly interacting with stakeholders. They are expected to observe how the US-based leads interact with their client counterparts as they collaborate, determine requirements, complete work assignments and negotiate timelines. Partner staff meets with Merck Subject Matter Experts (SMEs) to engage in a comprehensive review of Merck processes, systems and best practices. Partner TA leads have the opportunity to learn from the cross-functional TA knowledge holders. The program also provides the ability for participants to meet Merck partner management contacts and Statistical Programming and Biostatistics senior leadership.

Upon return to India, partner staff shares their learning experiences with India colleagues through mentoring and knowledge sharing sessions. They are expected to stay with the Partner for a minimum of one year. This helps in retaining top talent and recouping the money and effort spent on the program by both Merck and Partner.

ADMINISTRATION

Funding for the program is shared jointly between Merck and the Partner with both parties equally committed to and invested in the success of the program. The Partner handles all VISA and transit in/out of the US logistics while Merck provides laptops, working areas at each site, and site badging specifics. Daily transportation and transportation between sites is the responsibility of the Partner and Partner staff.

BENEFITS

First year program feedback is very positive from both Merck and Partner staff and management. CBP staff feedback includes feeling a part of a global team, seeing the benefits of working face-to-face with study team members including statisticians and clinical members, witnessing first-hand the US working atmosphere, programmer work ethic and work life balance, commute time and time-zone challenges. The program aided Merck managers in establishing partner staff as full members of their programming teams and helped to break down cultural barriers and forge new relationships for a better support system going forward.

By meeting with Statistics, Clinical and other programmers face to face, Partner programmers were better able to understand stakeholder needs and the interactions helped to build Merck comfort and trust in the off-shore teams. This increased trust in their capabilities can result in an assignment of future work of greater complexity. Face to face engagement helps to dispel the often common perception that CRO/Partners serve only as a faceless vendor.

Some key benefits:

- Participants see firsthand the challenges faced by the US programmer and can relate more directly
- Provided an opportunity for the off-shore team to know Merck's working culture by observing our daily work in the US
- Improved mutual understanding and resolved misconception in some cases that work assigned to off-shore teams is less important than work assigned to US programmers
- On the job learning in the areas of: project management; understanding the enhanced QC process used to ensure quality SAS® programs; good documentation practices; effective communication.
- Hospitality extended to visitors was very much appreciated and resulted in the desire to reciprocate with US visitors to India
- Timely discussion of key process improvement initiatives between India Lead/SME and US SME
- Coupled with our yearly sponsor visits to India the program allows for a continuous cycle of face to face meetings
- All team members (US and India) can now put faces with names/voices
- Increase partner decision making capability
- Partner participants provided with opportunities to meet with senior management to discuss challenges and perceptions

CHALLENGES

When implementing this program we encountered a number of challenging areas, many of which were logistical in nature. Some of the early issues were due to the lack of public transportation from the hotel to the Merck site and between Merck sites in Pennsylvania and New Jersey. While initially Merck helped in shuttling CBP resources, these rides were not sustainable and led to a vulnerability of legal and insurance

issues. For later trips the partner modified their travel planning approach to include proactively setting up taxis and hired cars.

Another challenge was finding office space for the relatively short six week visits given Merck facilities were already very crowded. Enabling phone services at the sites required the coordination of Jabber Voice account setup with laptop setup, required for teleconference participation. Not being accustomed to connecting to the Merck network remotely in a US domestic setting, it was necessary to familiarize the participants with the software and processes required to do so. This was required in order to accommodate for inclement weather which was an issue on multiple occasions.

The logistical and setup issues seen in the early days of the program have for the most part been addressed as the program progressed.

Sponsor attrition and retention issues continued to be a challenge, including replacing experienced senior staff. However for CBP participants this has been minimal to-date due to the early phase of the program. Conversely, it is a challenge to retain Partner senior staff that are not selected for the CBP program.

CONCLUSION

To be successful the Sponsor-Partner business model must meet the specific needs of the Sponsor. There are many options to choose from however it is clear that developing the optimal model takes time and must evolve, and thus requires a long-term relationship and a collaborative mentality. The Cross Border Program is one component of this successful evolution.

The Cross Border Program has decidedly strengthened our partnership and has come a long way in assuring our Sponsor needs are being met. We see the program as a worthwhile investment of both sponsor funds and sponsor employee training and mentoring time. The program has resulted in stronger, more cohesive and capable teams, and provided us with some indirect control of partner attrition rates. However the ever-present challenges of offshore partnering are still underlying adverse factors, specifically the difficulty in finding and retaining experienced programming staff.

Partner staff with pharmaceutical industry experience are of value to the Sponsor. Of even greater value are Partner staff with Sponsor-specific experience that are retained on projects for an extended period of time. Further still, it is ideal to have Partner staff that have moved from a transactional, hand-off mentality to one of practical leadership that includes critical thinking and problem solving skills. This results in the ability of Partner staff to anticipate issues proactively for the Sponsor. The CBP is one component of this targeted experience-gaining plan, providing learning opportunities in all three of these areas. Through this program we have created an immersive experience which has resulted in long-term value to Merck, the Partner and all team members.

REFERENCES

Khanna, Vishal. QuintilesIMS.2017 “Seizing the potential of commercial outsourcing in the pharmaceutical sector”. - A white paper from Quintiles IMS, in partnership with pharmaphorum: Quintiles IMS 15.0076-1-02.17_QI

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The Cross Border Program
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