

Phuse poster

Off shored, 5 years on (PP17)

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o. Introduction

The aim of this poster is to share our experiences of creating and using a statistical programming group located in Mumbai, India. It provides some background on why Roche decided to look for an off shore partner, how this has evolved over the years and the management structure behind this. The focus then turns specifically to the Statistical Programming & Analysis group where it shows how the group has evolved over the past 5 years, the changes in the scope of work and operating practises, the training and sites supported. Based on our experiences, the next few sections highlight some of the challenges we have faced, how this group has benefited us and what key lessons we have learnt since conception of the partnership.

1. Background

Roche has a rich and growing portfolio and it recognised it could not grow its resources at the same rate. There were emerging resource gaps in the 4 functional areas, these were data processing, database programming, drug safety processing & statistical programming. The resource gaps identified were going to be difficult to address given the infrastructure constraints on the existing HQ sites. It was also recognised that the internal headcount would not be able to manage the growing pipeline. At the same time there was a rapid increase in the global sourcing market with a strong emergence of vendors in Asia.

The organisation embarked on a global capacity building initiative to meet it's long term strategic goals. The object of the initiative was to increase capacity, have greater flexibility of resourcing, gaining cost benefits by optimizing their external resource strategy and improve efficiency through process improvement.

After a rigorous geographical and vendor selection process, a BPO (Business Process Outsourcing) organisation in India was selected to help meet Roche's long term strategic goals.

The 4 functional areas where there were emerging resource gaps were set up with this BPO in 2007, which in turn created what is more commonly known within the organisation as Roche Operations Centre India. The focus was on "transactional" type work which could be done easily and relatively quickly without the need to be located on site. The initial 2 years built a good foundation and provided a great platform to increase in scale and also on board new services. The partnership strengthened,

an additional delivery centre was set up outside of India, which led to an increase in the volume of work being handled and greater focus of process improvement initiatives (i.e. reducing turn around time).

The evolution of the partnership required a good governance structure to ensure that the overall company and functional objectives were being met. This required an operational and strategic representative from each department to ensure their functional strategies were carried out. There were also support functions (IT and QA) that helped ensure infrastructure and quality control were in place to support the growing area of outsourcing. The structure was mirrored on the BPO side such that each function had a direct counterpart to ensure the functional needs were being addressed. Internal subject matter experts were created to help with the operational activities within those functions where there were a high number of FTEs supporting their activities at the BPO . The members of the governance committee worked closely which is important to ensure functional continuity and alignment of common activities across the functions.

2. Statistical Programming Group, 5 years on

The statistical programming & analysis group in India was initially created to conduct validation of report objects (TLGs and analysis datasets) using SAS. The group created had limited SAS and pharmaceutical experience hence, a thorough training programme was put in place (& conducted by Roche) to cover all aspects of the system , data standards & programming required. Separate processes and a working environment was created for this group to clearly separate out the tasks being performed by this group without impacting the first line development work being done by the Roche teams. Roche teams in Europe would send work to this group in the form of work packages which simply identified the validation required, the relevant documentation to be used and the completion timelines. As the need for validation work increased, the size of this team increased and also a new team was formed a year later to focus on the use of the in-house safety reporting tool to generate safety reports for inclusion in clinical study reports. This also resulted in more work being sent to this group from other locations including USA & Australia. A separate process was defined to manage the safety work although this group worked more closely with the Roche teams. Having two teams within the programming group performing different tasks had its benefits however it also created differences in the way the interactions occurred. This created constraints on the Roche teams and was resulting in an ineffective use of the resources. From Q2 2011, there was a major change in the way the Roche teams would interact with the off shored group. The validation & safety reporting teams were consolidated into 1 BPO programming team, all processes defined specifically for this group were eliminated which meant everyone followed the same processes as any other Roche person, there were no separate working environments, the scope of work was broadened and all the BPO SPA members became integral members of the different project teams across sites. The assignment of personnel to projects is now longer term in an effort to build knowledge and experience on the project reporting needs. Using this approach has meant that we are better able to identify specific activities which the group could specialise in (for example, data mapping in preferred format). Allocation of the resources is managed by the Roche & BPO operational managers based on demands from the project teams. All the training for new starters or refresher sessions, and competency building activities is conducted and managed by the BPO SPA personnel.

3. Challenges faced

Attrition, Retention and Experience

Like most collaborations or partnerships there are a number of challenges that are faced, some of which are short term and some more frequent & re-occurring. Attrition (or churn) is probably the most difficult challenge faced. Trying to retain the staff for a long period seems to be a common challenge faced by BPOs in Asia. With many opportunities becoming available due to an increase in investment in these geographical locations has meant that retaining experienced staff, at a cost effective rate, proves difficult. This has a direct impact on the investment made into these organisations however the impacts are dependent on the type and complexity of the work that is outsourced. For more transactional work where the training time of new recruits is quite low (i.e., 1-2 days), the quick replacement of personnel can minimise the impact. However, in more complex areas such as statistical programming, this often has bigger impacts so different approaches are required such as replacing with more experienced personnel, having training personnel ready to back fill immediately, and having a much longer handover (knowledge transfer) periods from one person to another. Retention is further made difficult due to many peoples desires to progress to higher organisational grade levels in a shorter time frame. The importance of hierarchy seems to be a influencing factor.

Managing Perceptions and Mind-set shifts

Managing the perceptions of internal project teams who are required to use the off-shore personnel is also a big challenge. Gaining their buy in and confidence in using these groups can be difficult but can be managed by gaining support from upper management, identifying early adopters to help promote the group, providing guidance to the projects teams regarding interactions and also providing more detail on the experience levels and skillset of the individuals in the off shored group. Changes in mind-set of the off-shored personnel is often difficult to address especially as the off shored group is more of a service provider and will tend to do what the clients ask. In an integrated model the expectation is that all individuals critically challenge the work to done and challenge requirements & specifications. This type of behaviour is easier to develop within the customers environment, however, it is something the off shored personnel find difficult to do given they are service providers. This is where the internal teams need to educate the off shored personnel that it is ok to say 'No', 'I disagree' or 'I have another suggestion'.

Systems

For the SPA group, a continual challenge has been around the management of accounts for accessing our systems. Obtaining access to applications and sometimes having the appropriate access rights has proved to be time consuming and often resulted in our internal teams having to find work around solution, which in turn creates an overhead & frustration amongst the internal project teams. The speed (and connectivity) of using applications from the off shored location is something that should be monitored in order to determine if some activities can be completed in the appropriate time.

4. Benefits gained

We have seen a number of benefits as the partnership has grown. There was the initial support on the validation work that was being done by the off shored. The use of these resources to perform validation meet our internal teams could focus on development and other activities. All training is completely handed over to that group to train new starters or conduct refresher training session where necessary. This has saved internal resources having to do this. A train the trainer approach had been taken so that the training can be managed by off shored group. Building experience of using our in-house safety reporting tool is now resulting in most of the development and QC of the safety reports (using this tool) is now being done by this group. The main benefits here is that the internal Roche teams are more able to focus their time on some of the more complex activities that require close interactions with our statisticians and scientists. By consolidating into 1 BPO SPA team we are better able to use the resources across the projects. Conducting some cross training so that everyone is able to use the safety reporting tool and do SAS work, has meant there is greater flexibility in using the resources assigned to a project to help support a variety of tasks. It helps us to explore other areas of SPA work where we feel the BPO SPA teams can add value. Building up the experience and expertise is a continuous process, and as this is evolving, this off shored group remains a viable resourcing option for SPA.

5. Learning's from the partnership

Communication and Expectations

A number of lessons have been learnt over the years which will help when entering another partnership like this in the future. Open & honest communication is vital to ensure everyone involved has a clear understanding of what needs to be done and whether there is the relevant competency to do it. It helps build trust, mutual respect and confidence in all teams as part of their interactions. Setting clear expectations is important as it ensures that everyone has a common understanding of what the quality & completion timelines are expected, and also helps identify activities that should remain within the internal Roche teams. There is also a requirement to provide guidance to both the internal teams and the off shored group in order to help build good interactions and set realistic expectations. This is particular important when you have personnel with varying levels of experience.

Operating Model and Governance

Maintaining visibility and awareness of how the interactions and work progresses is important to ensure you make the optimum use of the off shored group. Depending on the internal strategies & workloads, there may need to be modifications (or major overhauls) in the overall interaction methods between the internal teams and the off shored group. Having a good management team to oversee the functional interactions and strategies is important. The governance structure plays a big role in ensuring the company & functional strategies are being implemented and executed. When working with the wider governance structure (i.e., all functions involved) it helps brings a certain level of alignment and finding common ways to address pain points, road blocks and increase capacity. Having internal team members who can help promote & champion the interactions proves to be a great benefit to the operations leads in helping to bring buy-in & a willingness from the internal

teams to be more engaged.

Local Challenges and Cultural Awareness

Understanding some of the local constraints helps identify the capabilities and challenges the off shore group face in completing tasks, ability to take on new or more work, recruiting the right talent and retaining the experience. There may also be systems related constraints, for example, no access to the systems from home, poor system speed and system connectivity issues. Knowing and maintaining awareness of these helps identify the types of activities that should and shouldn't be outsourced.

Having the awareness of the culture is important to help understand what certain gestures, behaviours and their customs mean as part of interactions. In some areas there are high aspiration to progress up the promotional ladder which brings a certain level of respect to individuals. Being recognised and rewarded (especially from the clients) plays a bit role in maintaining moral and provides them with a sense of achievement and a desire to do better.

Conclusion

In conclusion, we have learned a lot from our experiences with working with an off shored group. We encounter challenges but managed to address many of them by working more closely with the off shored organisation. This has helped build a level of trust and has also helped understand the demands, constraints and challenges both organisations face. This experience has just as importantly identified areas where both organisations need to improve in order for this type of relationship to be optimised. Having a much better understanding, we are now more able to make effective use of the off shored resource and explore new avenues to further utilise these resources. The partnership is in a mature state and these resources remain part of our SPA resourcing strategy.

Disclaimer : All views expressed are based on my experience and thoughts and not necessarily those of Roche Products Ltd