

How to Build and Manage a Successful and Effective FSP Service for US sponsors out of India

Debiprasad Roy, Medivation, Inc., San Francisco, CA
Ganesh Gopal, Efficacy Consulting Group, Inc., Iselin, NJ

ABSTRACT

Over the last few years the Functional Service Provider (FSP) model has been a successful sought after component, adding a new dimension in the relationship between a sponsor and a service provider. FSP has become a significant byword in the data management, statistical programming and biostatistics value segments. This model is gaining momentum owing to the fact that the client - be it a sponsor or a CRO - gain the advantage of having a flexible work force while keeping central control of an outcome based approach. With increasing cost pressures an FSP model based out of a low cost center such as India, if effectively managed and executed, can be of huge overall benefit across the sponsor-CRO value chain.

Through a case study, which explores the successful collaboration between a sponsor and a service provider we propose to outline the machinery of this model that has worked well for the past 2 and ½ years and experiencing a growth path reinforced by key management methods. In the paper we will describe the challenges and emphasize the methods adopted individually by both parties and as well as the strategies implemented in shaping the protocol of engagement. The perspectives of both the sponsor and the service provider will be juxtaposed for retrospective analysis and prospective planning.

INTRODUCTION

With the revolution in outsourcing maturing among various industries in the last two decades the subsequent emergence of a Functional Service Provider (FSP) model has been undeniably notable alongside – especially in the pharmaceutical industry. The offshoring aspect of outsourcing to low cost centers has been seen to have the proven benefit of cost savings for a global seamless operation. Now, the concept of setting up a FSP model in a low cost offshore center such as India - which is a variation of the Captive Development Center notion - can in addition bring value and efficiency to a client engagement model.

Medivation - the client, and Efficacy - the service provider, have established one such model which is completing 2 and ½ years of success this year with Efficacy's offshore FSP unit in Bangalore, India, providing statistical programming services. From the initial benefit of labor arbitrage this model has steadily moved towards adding efficiency and value to the operation. Efficiency of operation is related to what measurable output is obtained from the offshore FSP engagement as compared to the cost encumbered for the same by the client. It includes factors more specifically as cost of operations, cost per seat /employee, utilization rate and process productivity. Value of operation on the other hand is associated with intangible benefits like robust quality process, seamless integration of global resource pool, increased access to capability and talent, and high scalability in the business. If executed well the value aspect of this model can become significant when highly skilled work force is involved; such as needed in biostatistics and statistical programming which combine the knowledge of SAS, clinical data, data standards and statistics.

But, for reaping the complete benefit of the offshore FSP model there are some key aspects that need to be considered. We shall expound on them including the challenges, benefits and the effective governance options.

MEDIVATION FSP EXPERIENCE – CLIENT PERSPECTIVE

WHY FSP?

There is often a strong need for contractors to bridge the resourcing needs in the area of Statistical and Clinical Programming in Pharma/Biotech industry. The support can be for specific tasks, therapeutic areas or to meet the demands of corporate growth and peaks and troughs of clinical pipelines. The primary reasons for hiring contractors as opposed to hiring fulltime employees are:

- Need for a specialized skillset that is not required long term
- Some highly skilled contractors may not want to work full-time jobs and are only available on a consulting basis
- The company needs someone temporarily without spending too much time as it requires more time to fill the full-time position

- Contractors can cost less in terms of fully loaded costs as companies are not required to pay for benefits like vacations, medical insurance, etc.
- Sometimes the company is limited by its investor/owners/management to limit full-time headcount to maintain flexibility

The recruitment of experienced contractors can also be quite challenging. In tight labor market, especially in the Bay area which has a large concentration of Pharma/Biotech companies, skilled and experienced statistical programming consultants are hard to find with the average rate per experienced contractor exceeding \$100 per hour. Different contracting companies have varying contracting agreements which make it difficult for the companies. Further, companies cannot directly hire contractors who are on employment visas so they have to work with contracting agencies.

FSP BENEFITS

A FSP that can offer offshore resources can alleviate the above challenges. In business, outsourcing involves the contracting out of a business process to another party. It can offer greater budget flexibility and control by providing access to qualified lower cost contractors and services. FSP contractor costs per hour in most organizations in countries like India range from 30% -50% of the US cost based on experience level providing substantial savings. Organizations can pay for only the services they need and when they need them which provide greater flexibility in managing short term resource gaps. It provides access to alternative regions opening up a wider market for the experience level needed. It reduces the need to hire and train specialized staff, brings in fresh expertise and reduces capital and operating expenses. The model can be leveraged as a 24 hour workforce especially considering the time difference between US and Asian countries.

FSP IMPLICATIONS

There are several implications to the offshore FSP model that every company should consider and address before embarking on it.

Greater physical distance between management and contractors often requires a change in management methodologies, as inspection and feedback may not be as direct and frequent as in internal processes. This entails greater management responsibility and will certainly increase the time spent on management of these resources, at least during the initial phase. An organization is responsible for the actions of their entire staff, including offshore contractors, which creates a greater burden on management. Legal and compliance issues need to be addressed through the contract between the client and the FSP vendor.

Language, accents and work culture differences of foreign contractors can be a challenge in communication. Management should understand these factors and create an effective communication plan. Time zone difference can be difficult to work with especially when direct communication is needed. Work hours should be discussed and stipulated so it can be beneficial to both teams.

Security of intellectual property and data should be a priority consideration. Quality and IT infrastructure should be consulted to build an effective infrastructure which addresses the security and regulatory need.

The degree and the level of interaction between the US and the offshore FSP team are characterized by the type of work assigned. It is important to identify the type of work the offshore team will undertake as deliverables that need short term turnaround need consideration before assigning to the offshore team with approximately 12 hour time difference.

It is also important to motivate and train managers to understand the concept of offshore FSP and adapt it as a low cost and effective strategy. Working with remote contractors especially with wide time difference involved can be difficult to manage and interaction thereof challenging. It takes time to build an effective communication strategy and managers should be willing to work through it.

FSP STRATEGIES FOR SUCCESS

CHOOSE THE RIGHT VENDOR

It is very important to choose the right vendor for the outsource FSP project. We looked at several FSP vendors with an eye on the management team, offshore management qualifications, costs and client base to understand how the vendor would be successful in meeting our expectations and needs. We further did client interviews to understand how the vendor has performed with other clients. Legal and contracts team were involved to set up an agreement that took into account the offshore risks from a regulatory, operational and security standpoint. It is also important to set up expectations on performance of the contractors, the hours of operation and mitigating issues if contractors fail to perform as expected. It is advisable to start the model small with 3-4 contractors and then grow the contractor

base as needed, leveraging and modifying the experience from the initial setup.

EFFECTIVE HIRING PLAN

We followed a thorough hiring and recruitment plan which involved setting up requirements and job descriptions for the contractor needs, reviewed several potential resumes to screen for our needs, performed team interviews to understand the qualification, communication style and motivation to succeed. We recruited holding a high standard for the contractors to make sure they were at par with our requirements for US contractors. Expectation for work hours of remote contractors were set up to provide some overlap of hours with the US team so communication can be effective.

INFRASTRUCTURE AND IT PLANS FOR REMOTE CONTRACTORS

It is imperative to build a secure and compliant infrastructure and IT platform for the remote contractors to work on. Our initial model was engaging an IT vendor in India to provide the contractors with Medivation issued laptops. We subsequently changed our strategy to implement a secure Virtual Desktop Interface (VDI) which provided the contractors to work on our environment but also protected the environment so no data can be copied out. This also made the immersion process quicker as issuing laptops took more time for IT builds and deployment. It is important to consider the bandwidth of internet connections in countries like India and proactively engage with the vendor to make sure it does not become an issue in productivity of the contractors.

TRAINING AND IMMERSION

It is critical to develop a strong training schedule and curriculum for the contractors to become productive quickly. We developed training videos of our process and programming infrastructure, manuals for quick reference and identified subject matter experts for quick resolution of issues. Initially the training was provided by US managers but subsequently an offshore contractor manager was hired as part of the FSP team who overlooked the training and immersion process. Specific training related to detailed tasks were also provided to better understand the requirements and deliverables. Our successful training curriculum has resulted in complete immersion of new contractors within 2 weeks of joining the team.

MANAGEMENT AND COMMUNICATION

Each team manager was expected to interact with the remote contractor directly. Weekly meetings with entire team including the remote contractors were conducted to provide an overall understanding of the work requirements and also provide the opportunity for the remote contractors to feel as part of the entire team. This created an effective team environment and made the India team feel at par with the contractors in US. A contractor manager in charge of the FSP team was later introduced to manage resourcing across projects more effectively and reduce downtime when a contractor often needed to wait for the US manager for directions. The manager, who had 10+ years of statistical programming experience, was chosen to guide the contractors through complex programming tasks, balance resources across projects and overlook performance and training. Building a high performing global team is a strong priority for success with the FSP model.

CHOOSE THE RIGHT PROJECTS FOR FSP

It is very critical to understand the time difference to plan for projects that are handled by the remote contractors. Projects that require constant directions and interactions with US team are often not well suited as it poses a burden on either side requiring communications at hours that are out of the normal work schedule. Deliverables that have short timelines and require rapid changes are also not easy to manage across a wide time zone difference. Projects which are well defined and have adequate timelines are good candidates for the offshore team. It is important to constantly evaluate the offshore team to understand their capability.

EPHICACY FSP EXPERIENCE – SERVICE PROVIDER PERSPECTIVE

BACKGROUND

Ephicity is a US organization formed in 2005 and the Bangalore, India unit was formed in 2009. Over these years Ephicity has come a long way in understanding the uniqueness of building an offshore Center of Excellence (CoE) in a niche and high value segment such as biostatistics and clinical programming. At first (6 years ago) the challenge was in finding the highly skilled talent in India to serve the mature US and European market. We hence adopted a strategy to put training and mentoring in place to ready up a team that not only can provide service directly to the US and European customers but also double up to spawn new and highly skilled work force. And now, in 2015, after 6 years of our inception, and with concomitant growth among other players, we find that a significant pool of skilled talent is available in India in this space. Ephicity has also now built a credible brand for itself over the years with a

clear understanding of the market needs and challenges. This has consequently helped in attracting the right talent and in retaining them as the employees feel that there is significant growth opportunity within Efficacy.

One of the keys to success in building such an organization is that the Principals of the company be entrenched in this niche domain. At the decision making level there should be a clear understanding of the statistical programming and biostatistics space and the knowledge of the regulated environment under which such analytical work is done. Efficacy has the unique advantage of having such key figures at the helm, both at a functional and an entrepreneurial level with years of clinical industry experience. This has been the primary differentiating value component of our offering.

CHALLENGES AND THE RIGHT MOVES

As a new organization in India back in 2009 we had quite a set of challenges to face. These challenges were primarily with regards to talent recruitment and retention, identifying leaders within the organization who can be functional with client-facing abilities, and obtaining visibility among customers for business development.

We realized that a strong HR practice was required that can tether the organization with appropriate incentive and retention focus – hence we invested heavily in HR and made sure that a philosophy with best practices was established that will create brand value around uniqueness and attractiveness of our work culture. Since Efficacy has the advantage of being both a US and an India player, we were able to appoint expatriate Indian workers returning from the US in leadership positions. They, upon returning back to India, wanted to continue working for Efficacy owing to the cultural comfort and the niche value involved as opposed to seeking employment with large offshore giants. We continue to attract such talent on an ongoing basis to build the leadership layer of our organization. And as for obtaining visibility among clients, we have fuelled our business development engine only to the tune of our organic growth. This way credibility is built over word-of-mouth intimacy as opposed to deliberate marketing. Over the last couple of years, however, we have started to showcase our offshore strength through conferences and industry connections to a measured extent.

Other challenges we faced relate to technical infrastructure, communication methodology and expansion of work space. Efficacy has proactively sought to be on the cutting edge of hardware/software infrastructure and especially information security. We realize the importance of quality and data security in this heavily regulated environment and Efficacy has now two special feathers in its cap - ISO 9001(Quality) and ISO/IEC 27001(Information Security) certifications. As for communication bandwidth is concerned we have provided our employees with the highest bandwidth available in the market and we also observe that the clients have their specific needs such as the use of Virtual Desktop Interface (VDI). Our IT in Bangalore is up to snuff on any client infrastructure requirement. We also recommend the use of cutting edge office tools such as Slack to manage remote workers efficiently and seamlessly.

Also, there are procurement challenges that stem from considering India as a low cost IT work force from previous benchmarks - this does not translate favorably to high skilled labor scenarios. Here the functional group of the customer should be amenable to bringing this discrepancy in pricing to light and offer to facilitate a smoother negotiating process between the procurement and the service provider. We at Efficacy have resorted to the concept of an open-minded approach with our customers to help resolve this challenge.

HIRING PLAN

To gear up for recruiting it is of utmost importance to understand the specific requirements of the customer with respect to the following. These are the questions that we typically require our customers to assist us in answering:

- Technical requirements – For example: knowledge of therapeutic areas, type of programming experience and depth needed such as in Tables/Listings/Graphs, ADaM or SDTM programming, validation experience of the same; SDTM and/or ADaM mapping specification writing, standard macros development etc.
- Skill level and leadership requirements – pertains to whether the resource will be required to perform specific tasks or is leadership aspect a focus; also whether this resource would be considered down the line to grow into a leadership role, etc.
- Communication requirements – although a certain level of communication comfort is essential for the customer with the resource, how far do we want to stress on this aspect? Can the communication aspect be discounted to some extent if the resource is technically a good fit?
- Cultural suitability – With all qualifications mentioned above being a good fit we further examine if the candidate can fit well within the warp and the woof of the culture of the FSP team. Or does he or she show signs of being a lone player? As we now have several FSP engagements at play we do observe that each one of them create their own dynamics, owing to the hybrid nature formed from the uniqueness of the customer management style and the consequent reactive psychology of the team.

COMMUNICATION WITH CUSTOMER

- Understanding hiring needs and transforming the specific requirement to drive the recruitment in India is essential
- Gaining visibility into future work can provide operational visibility and as well as ensure proper resource planning - as in India the notice period for an employee to join another organization is 2 to 3 months
- Appointing a point person as a line manager in India and evolving that role into a fully engaged project manager can facilitate a well-managed ramp up
- Having clear escalation mechanism shared with the customer is crucial for any problem resolution
- Ephicity being a US organization the customer relationship was primarily handled locally - which is a plus

BENEFITS TO CUSTOMER

A well-managed FSP engagement can prove to be of long term benefit to the customer from multiple perspectives and some of the key points to be observed are:

- Solves the supply side of the problem when demand globally is high for such talent – be it low cost or not
- Achieves significant cost saving with no loss of efficiency - for example a team of 10 members can save the US customer 1 to 1.5 million USD per year
- Provides flexible work force with ramp-up and ramp-down capability
- Allows central control while there is transfer of defined responsibilities
- Access to highly skilled work force with overall value addition much higher than a simple labor arbitrage scenario
- Creates a seamless global work force that can lighten the load of heavy submission work
- Establishes a dedicated team that can offer process and resource continuity owing to minimal bench costs – the impact of billing during downtime on the budget is insignificant
- The team can over a period of time move into the zone of efficiency and value of operations
- Relationship strengthens once the model leans more towards a KPO which in turn improves retention and provides incentive by default. Hence this transforms into a pure synergistic play from both ends
- Establishes a go-to reliable FSP partner with like-mindedness with respect to understanding the highly regulated nature of this space

CONCLUSION

The FSP model implemented at Medivation's Biometrics department with Ephicity has been very successful. The FSP model has been in operation for the last 2 and ½ years and has grown to an extent that the India component has increased from 10% to 35% of the overall global team composition. The India team is involved in all aspects of statistical and clinical programming and has proven to be an effective augmentation of the programming team contractor base.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Name: Ganesh Gopal
Enterprise: Ephicity Consulting Group
Address: 33 Wood Avenue South, Suite 600
City, State ZIP: Iselin, NJ 08830
Work Phone: 201-633-4680
E-mail: ganesh@ephicity.com
Web: www.ephicity.com

Name: Debiprasad Roy
Enterprise: Medivation, Inc.
Address: 525 Market Place, 36th Floor
City, State ZIP: San Francisco, CA 94105
Work Phone: 415-829-4185
E-mail: debi.roy@medivation.com

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