Paper LI06

Starting a new Functional Service Provider relationship may be daunting and presents many challenges: Where do we start?!

Nicky Lawrence, Fortrea, Maidenhead, UK

ABSTRACT

Many pharmaceutical companies are now working with CROs in a Functional Service Provider (FSP) relationship – this may be across several services, e.g. Clinical, Biometrics, Safety, Medical Writing, or perhaps only Statistical Programming. We will concentrate on FSPs where study work is assigned to and managed by the CRO. Once the agreement is in place and first study(s) assigned – how do we operationalise the plans? We will look at the importance of strong communication and clarity of responsibility and roles. Both teams will have their own standard processes – how do we find one process going forward? What are the expectations in terms of study delivery requirements, overall performance and metrics? How do we keep learning and improving as we go? These are just some of the considerations in a process that needs to be set-up for short term delivery and long-term partnership to ensure maximum performance for the sponsor.

INTRODUCTION

A large amount of work goes into the preparation and execution of a bid for work for a new FSP partnership. FSPs generally fall into two different categories:

a. The CRO provides resources in a staff augmentation model, providing the sponsor with a more flexible workforce.
b. The sponsor outsources studies and/or tasks to the CRO, who is responsible then for staffing and timelines to ensure on-time, quality delivery.

Either or a combination of the two may form the award. This paper will concentrate on scenario b) where studies and/or tasks are outsourced for statistical programming. After the award, there will be a period of excitement about the new relationship! However, the award is only the beginning – the hard work is about to begin! A great amount of preparation is still required to move from award to working reality. There is a need to align the cultural values of the two organisations, set up a governance framework, decide on processes to be used, work out contractual and financial aspects and set-up the teams on both sides to go ahead with the work.

CULTURAL ALIGNMENT AND PARTNERSHIP OBJECTIVES

To form a successful partnership when teams from two companies are being brought together, it is important to understand each other's culture and build a common mission. The CRO's first task is to understand the Sponsor's perspective and outlook. Does the Sponsor have a history of outsourcing these activities, or is this new for them? If work has historically been processed in-house, how is this change being communicated to their team internally? The impact to the sponsor internal team can impact how the partnership is received and the associated messaging. There may be a need for the CRO to collaborate with the Sponsor in 'selling' the outsourcing model to their broader team. What are their development plans and their attitude to new innovations in the industry? It is important to understand all of these, then look at the same things within the CRO. What areas do we have in common? How do we need to bridge any differences? Most importantly, how can we best provide what they are looking for in a CRO? It is important to kick-off the partnership efficiently and effectively to set the relationship along the right path towards success. An important step in this is the Kick-Off Meeting (KOM).

KICK-OFF MEETING (KOM)

An initial KOM allows all the significant people from both the Sponsor and the CRO (who may or may not all have been involved in the initial bid process) to meet. It is important to get to know each other – an FSP relationship will last longer than just one study! Building the relationship and gaining trust are important for the future partnership success. Consideration should also be given to whether meetings should be face-to-face or virtual. Meeting face-to-face can have great advantages for relationship-building but may not always be practical. Realistically the kick-off period will be longer than just one meeting and will spread into a stream of other meetings before and after the central KOM in order to get the partnership up and running effectively, however, it allows the culture and goals to be set along with a plan to meeting partnership kick off objectives.

It is critical that the KOM is productive, so there needs to be a clear agenda created ahead of time with input from both the Sponsor and CRO. The attendees should be selected appropriately to ensure that the decisions that are needed can be made. Logistics include ensuring a meeting venue, travel and accommodation. Time needs to be allowed for that organisation when making plans.

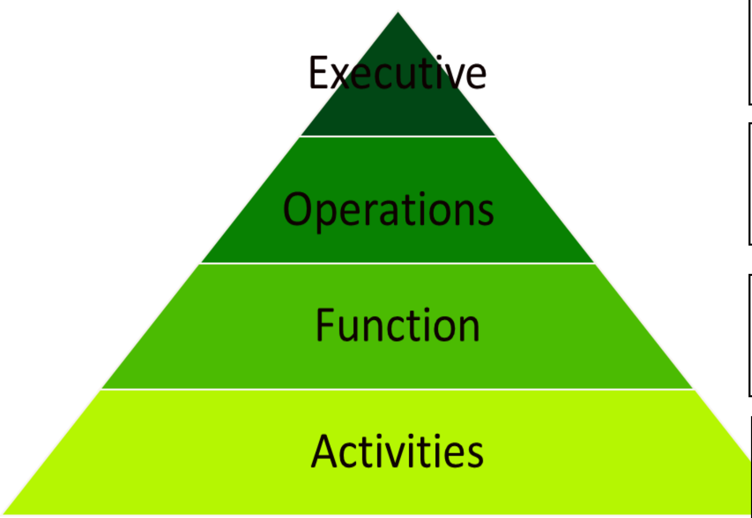
KOM agenda topics will likely include:

- Partnership working agreements
    - Budgets and Master Service Agreement (MSA) finalisation
    - Partnership scope/scale
    - Communication and culture
- Agreement of Governance Structure
- Metrics and monitoring
    - KPIs
    - Surveys
- Next steps planning

Consideration should also be given to how the meeting is structured. Break-out groups can be useful to discuss more topics, brainstorm ideas in different teams or where there are different functions involved in a FSP to have some function-specific focus time. However, it is important to share and pull these ideas back together, as topics can be relevant to all.

STRUCTURAL GOVERNANCE

The methods for governing the partnership should be established as a priority. This would usually consist of 2-3 levels in both organisations, to include Functional Management, Operational Oversight (optionally if a mid-level needed) and Executive Oversight. The purposes of these levels need to be agreed and documented. They ultimately oversee the success of the partnership and should be established with clear processes and aims that will enable the work to get done, but then to oversee progress, quality, issues and future goals for the partnership.



Executive oversight provides vision and goals for the partnership. Ensures overall success of the partnership for both parties.

Operations oversight oversees performance and goals for the partnership. Resolves any issues coming from the functions.

Function oversight sets out and executes the FSP plans. Oversees work task performance, risks and quality.

Activities line managers and team members conduct the FSP work tasks. Monitor and escalate any issues or risks.

PROCESSES AND DOCUMENTATION

At the start of the partnership many decisions are needed for the tasks to go ahead. Changes will occur along the way after work has started, so it should be ensured that there are processes to allow for that, where it is appropriate. The following topics should be looked at to ensure work can commence. Changes later can have a bigger impact depending on the topic, so it should be ensured sufficient time is spent to align on the main pillars of the partnership from the beginning.

SERVICE ORDER

Master Service Agreements / Work or Service Orders must be put in place in order for work to begin.

PARTNERSHIP AGREEMENTS

A Partnership agreement or manual should be created to document the main agreements and philosophies of the partnership. This may be in one document or may include multiple additional guidance documents to cover all the information needed. This document must be a required training for all members of the partnership, to ensure alignment across both Sponsor and CRO teams and should contain information from the following topics to document decisions made.

Agreements should also be made on any Key Performance Indicators (KPIs) for the partnership including details of expectations on both sides that will lead to success.

A successful partnership is very dependent on the people within it. It is important to ensure feedback is obtained and acted upon throughout the life of the partnership. Some provision for this, for example in the form of surveys done on either side or at a partnership level at regular agreed intervals, should be explored and documented.

IT CONSIDERATIONS

An immediate question is where processing of the data should take place? How do Stats Programmers get access to the data sources? These sources include Data Management data (CRF data and external sources) as well as any sponsor standards to be used. Does the CRO process data on their own platform or on the Sponsors? Will all programming be in SAS® or will there be any open-source coding in addition? If data are processed on the CRO platform, how is it transferred to the Sponsor? Are there any requirements for code to be executable on Sponsor systems with any direct match of the Sponsor directory structure needed? If data are processed on sponsor systems how is a gateway to their platform established?

The Sponsor may have a preference to perform activities on their systems. This has the benefits of ease of access and familiarity for the Sponsor team. It can also allow for more consistency between in-house studies and those processed by potentially multiple CROs. For the CRO, use of their own in-house system enables use of established processes and standard costing mechanisms. Both come with their own IT challenges to access the sponsor system or transfer data between systems.

Decisions at this stage have a clear impact for how things are set-up on both sides. Changing from Sponsor or CRO systems or vice versa after the initial set-up is usually still feasible but will require additional time and effort for re-work.

STANDARD OPERATING PROCEDURES (SOPS) AND PROCESSES

Similar to the IT considerations, the decision on whose processes to be followed has a broad impact on the set-up of the SOPs. Whilst the decision on the IT location for the processing of the data may have an impact on the choice of whether to follow Sponsor or CROs SOPs, it does not necessarily need to be aligned. Standards can also be more important than processes as adherence to the same standards will minimize integration issues when working towards submission.

Process decisions will need to be made for the functional Stats Programming activities, but in addition consideration should be given to peripheral activities and the SOPs that govern them. This can include dealing with Quality oversight, Serious Adverse Event processing, Trial Master File (TMF) and Training activities. Potentially the ideal solution may be a mixture of Sponsor and CRO SOPs.

The decision on the SOPs to be followed should be documented. Both sides may have processes requiring a documented evaluation of the suitability of those SOPs. It should be ensured time is allowed for those processes. If the CRO will follow any Sponsor SOPs, arrangements also need to be made to ensure the team are trained on those SOPs and are kept informed and trained on any subsequent SOP updates.

RACI

Once the major IT and Process decisions have been made, it is important to settle on the detail. Both the Sponsor and CRO may make assumptions on planned processes, according to how they conventionally function. Those assumptions may be conflicting. It is therefore important to go through all the process that are part of the work contracted and discuss and agree on responsibilities. In addition to standard Statistical Programming tasks, peripheral activities should also be included, such as interaction with Standards teams, training, TMF. These can be documented in a RACI or similar document (an example section is given below):

Responsible:	The party who performs the task (may be multiple roles involved).
Accountable:	One role that has the overall accountability for the task.
Consulted:	Any others that are consulted, for example for input or review, who may be from other functions at the CRO or Sponsor.
Informed:	Roles that are notified as the task progresses and/or is completed.

R=Responsible, A=Accountable, C=Consulted, I=Informed

Task Family	Task	Sponsor Stat/Prog	CRO Stat	CRO Prog	DM
	Prepare SDTM Specifications	C	C	A/R	C
	Review/Approve SDTM Specifications	A/R	I	C	
	Produce SDTM datasets	I	I	A/R	
	Produce SDTM annotated CRF	I	I	A/R	
	Review SDTM datasets and annotated CRF	A/R	C	C	
SDTM	**Produce SDRG and Define.xml**	C	I	A/R	

FINANCE

All aspects of the partnership Finance should be considered, both those where there are interactions with the Sponsor and some internal only to the CRO:

MSA and Work Orders

Overall financial agreements for the partnership. Unitised or FTE model? Any agreements/restrictions on locations?

Standard budget worksheets and pricing

Pricing for specific activities and/or roles and/or locations

Initial Engagement Agreement?

Will a Work Order for a contracted activity be agreed and approved before work needs to commence? If not should Early Engagement Agreements be considered as part of the process?

Change Order process

How are changes to budgets tracked? Thresholds for submitting a change order? Process for approval of changes before proceeding with additional work?

Invoice process

What is the process for issuing invoices? When are invoices issued? If using milestone billing, agree timepoints

Revenue recognition and forecasting tools

Develop internally required financial tools related to revenue recognition and reporting as well as forecasting

TEAM

To have a successful partnership, it does not matter how good your governance and documentation may be – the team working in that partnership are critical. First to be identified will be the leaders at the different governance levels. As soon as the details of the expected work level becomes clear the leaders will also start to build a team in preparation. To ensure readiness to proceed this will need to be pushed forward with a degree of calculated risk whilst the agreements are put into place.

How we seed the partnership is critical. Consideration to the existing team may be given as this has the benefit that they are already known for their performance and will be familiar with ways of working in the company. It is usual that a new FSP is an expansion of work, so current employees that are moved to it will need to be backfilled in their original position and additional staff brought in. Moving existing team members can provide interesting developmental moves for those involved as well as giving a secure base for the partnership. However, care will also need to be taken on how they are moved on from their existing roles to minimize impact to ongoing work.

To determine recruitment needs, a portfolio forecast is needed. The requirements should be passed to a recruiting team. To ensure efficient screening of candidates by recruitment teams, any specific needs (levels, location, TA requirements) should be detailed. Timelines and needs can change, so the CRO also must keep this in mind when bringing on new people. It is important to have an effective onboarding plan including all relevant training including any specific processes for this FSP partnership. As the team grows Subject Matter Experts (SMEs) can also be identified to help develop team knowledge and help team training.

CONCLUSION

The start of a new FSP partnership is exciting but may be daunting. With comprehensive planning covering culture, governance, systems, processes and finance and a collaborative relationship between Sponsor and CRO the path to success becomes clear. As the portfolio forecast is clarified, the full team can be established. With effective execution the goals can be achieved. By monitoring metrics, gathering feedback and innovating further, this success can be continued to ensure an effective collaboration across multiple years and projects.

CONTACT INFORMATION

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

Author Name: Nicky Lawrence
Company: Fortrea
Address: 5 Foundation Park, Roxborough Way, Maidenhead, England, SL6 3UD
Work Phone: +44 (0)7920 463952
Email: Nicky.Lawrence@Fortrea.com
Website: www.fortrea.com

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