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Collaboration versus conflict: building successful working relationships

Diana Stuart, Cmed, Horsham, UK

ABSTRACT

Since 2000, there have been considerable changes in the Pharmaceutical industry including the approach to resourcing. This in turn has led to an increased use of CROs and an evolvement in the services and technology offered by them. As a result, there are more external collaborations and subsequently more emphasis is being given both by CROs and Pharmaceutical companies to the importance of building successful working relationships when projects are outsourced. Inevitably, companies are also gaining more experience in this area, so why is it that some project teams work well together, and others are troubled?

From ground level upwards, many people have an important role to play in the success of these relationships. Given from the perspective of a lead statistical programmer, I will focus on what individuals can do, whether overseeing the outsourcing or the recipient of the work, to achieve greater probability of successful delivery of studies, whilst building effective and collaborative relationships.

INTRODUCTION

According to Tufts Center for the Study of Drug Development 2010 Outlook, despite the number of clinical projects worldwide increasing by 80% between 2000 and 2008, biotech and pharmaceutical companies Research and Development headcounts have remained static. The additional resource required has been provided by CROs.

When planning for outsourcing, various strategies will be considered. For example, whether full service; or functional service provider contract is most appropriate. Whatever the strategy decided upon, all require a need to build a working relationship at all levels.

There are many benefits to outsourcing:

- Flexibility of resources – by outsourcing it takes the guesswork out of resourcing a project and the company is not exposed to peaks and troughs in workflow.
- Access to expertise – whether working for a large pharmaceutical company split by therapeutic area or a small biotech, it is likely that only a small number of studies will be conducted each year, whilst CROs with multiple clients will be exposed to a much greater number of studies.
- Better control over budget – many pharmaceutical companies do not keep track of the exact cost of resourcing a particular function to complete a particular task in-house, and by outsourcing there is more opportunity to fix the cost.
- Faster delivery – CROs complete clinical trials on average 30% quicker than those conducted in-house

Of course there are disadvantages to outsourcing, most of which relate to the relinquishing of control of a study to a third party. Most pharmaceutical companies would like to keep studies in-house, conducted by their own employees where any issues and difficulties can be seen and dealt with internally.

CREATING A SUCCESSFUL RELATIONSHIP

In a world where outsourcing has become an oft used resourcing strategy by pharmaceutical companies, rather than a last resort as was more usual in the 1990's, establishing long term relationships between pharmaceutical companies and CROs is necessary for better outcomes of the deliverable.

Outsourcing the programming of a study, is not like taking your clothes to be dry-cleaned, or having someone service your car, it is not a straight forward relationship whereby one party pays and the other does, the former if they so desire being able to live in ignorant bliss and relinquish all responsibility. The main reason for this of course is that in most cases the pharmaceutical company does actually know how to do the job themselves. More importantly they primarily have the knowledge of what the purpose of a study is and know what they expect to achieve from it. They also have to pass that knowledge along to the CRO. Finally they are ultimately responsible for the study, and must play some part in the overseeing of it. With this in mind, it is important that both parties make an effort to form a good working relation, the main components of which are going to be good communication, and mutual trust and respect.

Easier said than done, creating successful long term working relationships is not dissimilar to trying to establish success in a personal relationship. There are similar milestones within the relationship that require effort from both parties to achieve.

COURTSHIP

Just like the questions on a dating questionnaire, there are a few questions to be considered before moving forward:

- What sort of partner am I looking for?
  - Size matters
  - Location
- What factors are most important?
  - Ability to cope with quantity/volume of work
  - Quality
  - Simplicity
  - A specialist
- Where do I look for this other?
- How will I make my selection?
- Am I being overly keen and misreading the signals?

It is preferable that both parties in this search know what they are looking for, and what they are capable of providing. Punching above your weight might seem exciting in the short term, but not delivering what is promised is ultimately humiliating.
The programmer overseeing a study or a project wants to have confidence that their counterpart in the CRO along with their team is capable of delivering, whilst the lead programmer in the CRO needs to also have confidence in this. There will be observation of each party's behavior and potential abilities to deliver and follow good practice.
At a higher level, senior management will ensure that work bidded for is appropriate for the CRO, that there is sufficient resource and experience.

ENGAGEMENT

After establishing a mutual liking and a feeling that there can be a working relationship with a future, there is an initial engagement of work, a test. How much of test, the number studies and what size varies. This decision will be made by the pharmaceutical company selecting the CRO. Being selected is obviously a good thing for the CRO and this is when the practical swing of things is set in motion. Observation of the CRO is ongoing, so each step of the way it is measured and assessed.

Lead statisticians and lead programmers in the pharmaceutical company can be asked to provide input into specifying what work needs to be carried out by the CRO, and this can form part of the final contract. The more accurate and unambiguous this is, the less likely there is to be dispute later on. This is also a good time to establish some other basics, for example what SOPs from the pharmaceutical company does the CRO need to comply with? Does the pharmaceutical company have any standards or templates they wish to be taken into account in documentation or outputs? Do communication and escalation plans need to be put in place? Are there shared project plans? Do metrics need to be defined?

TAKING THE BIG JUMP - GETTING MARRIED

It is in both parties interest to have a tight contract. The pharmaceutical company will need to decide on what type of contract is most suitable for the work they wish to outsource, and then what they wish to be included in the scope. The dreaded phrase "out of scope" that Pharmaceutical companies dislike hearing so much, and CRO programmers

are dismayed to deliver, can be avoided when proper consideration has been given to the deliverable and its purpose. Taking the marriage analogy further; a bride and groom usually have clear expectations from aspects of their wedding day that they have researched and discussed together. For example, if the decision of the type of wedding cake is left to the groom, the bride may well end up disappointed, not because of the quality of the cake but because it is simply not to her liking in flavour or shape. This brings into play the importance of communication in the relationship, and the setting clear expectations right from the beginning. Expectations must be realistic from day one.

Communication is the key to the success of any relationship. Once the contract has been agreed and signed, work begins. A meeting is a good way for the team to introduce themselves to each other, ensure that everyone is clear on the details of the contract, and begin the process of managing everyone's expectations. Agreeing upon good programming practice at the beginning ensures that the pharmaceutical company knows what to expect in terms of quality.

A communication plan may be decided upon. In general, whilst having one point of contact within the team may work well for data management and other functions such as clinical, often for programming and statistics it is preferable to have counterpart contact so that methods of derivations can be discussed freely. The benefits of good communication between programmers are going to be building mutual trust, openness, understanding and respect. Or to put it another way, when facing a major challenge mid-study, the programming teams will work together to resolve it, there will an exchange of ideas and respect for the boundaries of the contract.

It is just as important at a higher level that a rapport is established so that both serious issues and positive feedback are communicated effectively. Other considerations could be for example, how a submission file will be put together. What is the cost impact? Are there benefits of using standards such as CDISC? Is there an impact of shared resources on multiple projects? What is the cascade effect of delayed timelines. The bigger the contract, the more has to be monitored and reported back. Be prepared to show metrics and report on performance.

There are going to be difficult times, and instances of miscommunication. It will be necessary to work at the relationship. Regular health checks will help, starting with the kick-off meeting, having interim meetings and finishing with an assessment of lessons learned. The minutes of a lessons learned meeting should record constructive points and any intended actions. These minutes could then be revisited at the beginning of the kick off meeting for the next study so that any matters of contention are not repeated.

THE FIRST CHILD

In this case looking after the first awarded study, and getting it right. If the pharmaceutical company represent parents, they need to decide how much or little supervision of the nannying of their child is required. This will be down to the resource constraints of the pharmaceutical company, and what internal processes they have in place. Care of the study has been given to someone with experience and expertise, this is where the building of trust continues. No parent would like to think that someone else can do their job better than themselves, but given the challenges of the modern world childcare has become necessary. The advantage is that your child is exposed to people with greater experience and specific talent. In general CROs will work on a much greater number of studies than a pharmaceutical company and they have greater awareness of metrics. These things mean that they are often able to produce deliverables quicker without affecting quality.

In Terms of monitoring, the pharmaceutical will want to put in place checks or tests. Like parents, ultimately they are responsible,

If the collaboration is successful, then more studies may follow. With the second child the team may feel more relaxed as there is some familiarity. However, as it is often the case there is possibility of some staff turnover, and with personnel change comes the risk of variance. As always communication is important, ensuring that the team are reassured that there is a plan for handover, and that the team continues to work together accommodating new members.

RELATIONSHIP CHALLENGES

No relationship is trouble free and in our line there will always be plenty of challenges thrown in our path, as subjects are anything but predictable. All long term relationships require maintenance, and a strategy for this should be considered to assess how healthy the relationship is from both sides.

The challenges a team encounters are likely to be caused by changes to the timeline. These could be due to amendments to the protocol or analysis plan, dirty data or subjects staying on study longer than anticipated. Whatever the reason, there are going to be knock on effects. If the study was being conducted in-house these challenges would exist, just as much as they will if the study has been outsourced. The type of contract may have

some part to play in considerations to changes to timelines. Unless the contract is of the type whereby FTEs are tasked full time to a study, consideration should be given to the availability of resource.

Changing a timeline because the pharmaceutical company wants to see its results quicker, lends itself to a whole other range of challenges and risks. Is the pharmaceutical company really listening to what the CRO is telling them when it comes to realistic timelines? What are they willing to compromise in quality to shorten timelines? The reality is that the pharmaceutical company does want a quality deliverable. If a good relationship has been established, then they can trust what they are being told regarding realistic expectations.

Another challenge to the relationship will be when ad hoc requests are made by the pharmaceutical company. Often this is due individuals on the team not understanding the specifics of the contract, or process. It can be a difficult situation, as the CRO will want to accommodate requests in order to preserve a good relationship. However, if it involves a considerable amount of work then the CRO will have no choice but to request a change order. Communication plays its part here as well. Understanding what is being requested and why will enable the CRO to better assess the situation.

There is always the temptation to think that the grass is greener on the other side, and the pharmaceutical company may have its head turned. Competitors will always be waiting for a CRO to make mistakes, and will take their opportunities where they can. We are all flattered by attention from admirers, and as an attractive individual other suitors will be looking for the current partner to put a foot wrong, allowing them to swoop in.

The big picture should be taken into consideration. If a relationship has history then it is better to look at the issues, establish if they are temporary, and work out what needs to change for the relationship to get back on track. This is when you know the importance of pre-built trust and the durability of the relationship.

Non-payment is obviously going to seriously affect the relationship and if not resolved will lead to a tense relationship.

In rare cases, a relationship will irretrievably breakdown. There could be a number of reasons for this, non-payment being just one, but the chances are communication and unreal expectations will be at the core. Failures to meet expectations on quality, timelines and delivery, significant increases in work load or unrealistic timelines could also be contributory.

THE GOLDEN ANNIVERSARY

The longer a pharmaceutical company and CRO collaborate, the more both parties will know about each other. There will be better handling of the unknown, and familiarity can reduce costs and shorten timelines. They will be able to look back and recognize their mutual achievements.

As trust is built upon, there may also be the opportunity of taking the relationship further, as both parties are prepared to share the risk and invest in an opportunity together.

CONCLUSION

Outsourcing is a reality, and making the relationship between the pharmaceutical company and the CRO work is essential to the success of a project. This will be achieved by continuously working together to ensure there is effective communication, and the building of mutual trust and respect.

REFERENCES

http://csdd.tufts.edu/_documents/www/Outlook2010.pdf

CONTACT INFORMATION

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

Diana Stuart
Cmed Clinical Services
Holmwood, Broadlands Business Campus, Langhurstwood Road
Horsham, West Sussex, RH12 4QP, United Kingdom
Work Phone: +44 (0)1403 755432
Fax: +44 (0)1403 755051
Email: dstuart@cmedresearch.com
Web: www.cmedresearch.com

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