Paper PP12

SPEED BREAKER, TRAFFIC SIGNAL AND TOLL GATES OF HIGHWAY JOURNEY OF SPONSOR-VENDOR RELATIONSHIP

Anusuiya Ghanghas, Novartis Healthcare Private Limited, Hyderabad, India

ABSTRACT

An increasing number of clinical trials and their enhanced complexity makes it burdensome for most sponsor companies to handle their entire portfolio in an effective manner. As a result, most try to find a helping hand in the form of CROs or third-party vendors.

For a long relationship journey, thorough planning before signing the contract is needed rather than simply jumping on the execution. Hence, it is important to come up with the proper vendor management strategy upfront. This should be developed with the end in mind, right at the beginning. Along with the strategy, the below are some important points for managing the relationship effectively:

- Selecting the right vendor
- Preparing and understanding the contract
- Managing the vendor relationship
- Audit
- Vendor monitoring and control

This paper will highlight some of the main points, which will be helpful in building a proper relationship between a CRO and sponsor company, and in helping both parties to achieve the desired results. Good Clinical Practice (ICH E6, section 5.2.1 & 5.2.2) defines a sponsor as the owner of the trial and accountable for ensuring quality, integrity and compliance. Equal ownership and sharing of responsibility with vendors help both sponsors and vendors understand the importance of this partnership, making it better and long-lasting.

INTRODUCTION

In today's competitive world, sponsor companies often seek services of vendor's for routine tasks, allowing them to focus on clinical aspects. With more services being outsourced, a strong sponsor–vendor relationship is essential for a successful partnership. The key lies in developing a contract with clear roles & responsibilities, communication frameworks, well-defined KPIs and a strong sponsor governance mechanism. Lack of any of them often leads to mismanagement, additional workload and more spends.

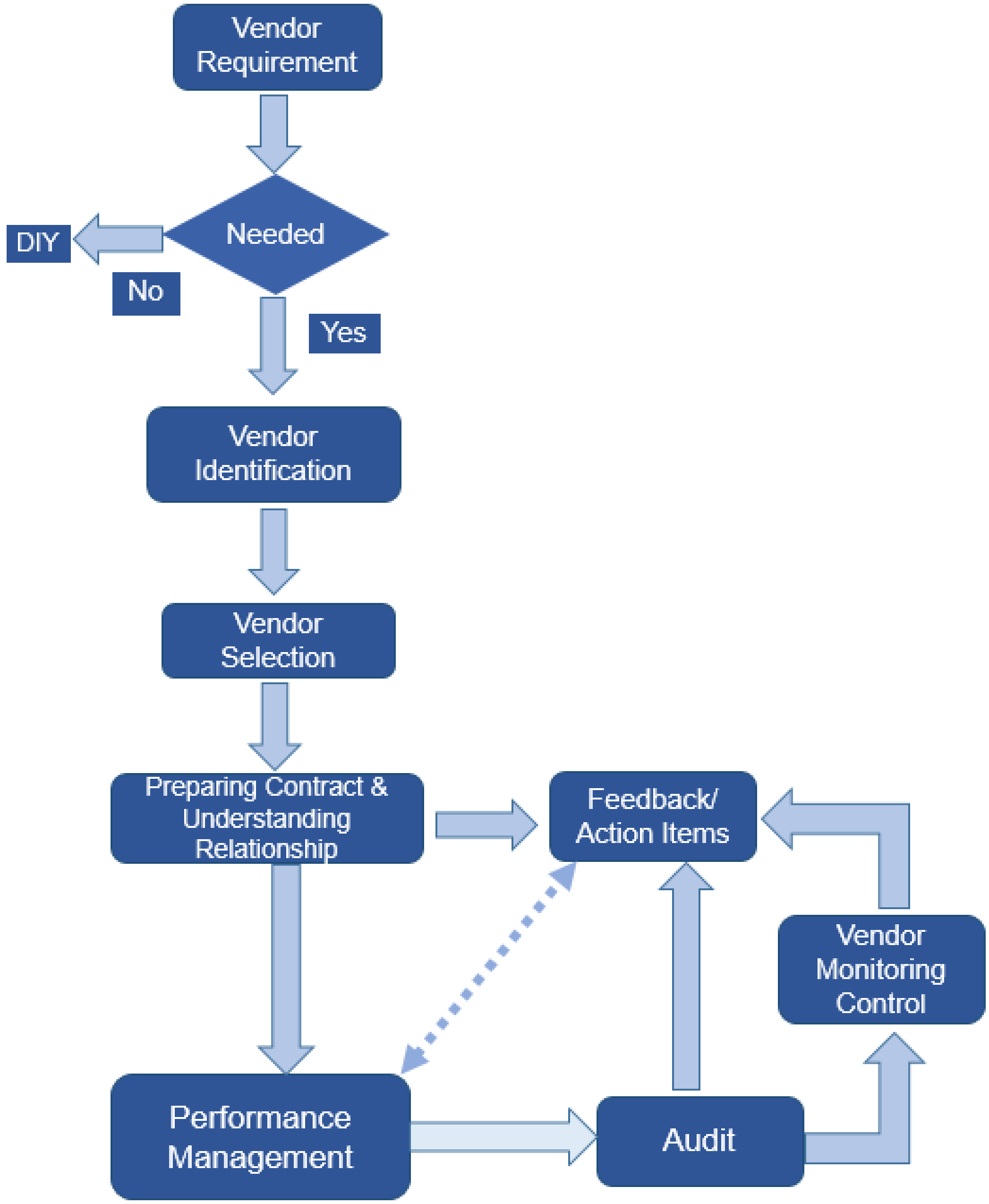
OBJECTIVE

Main objective of this poster is to identify the key areas for vendor–sponsor relationship building. Identifying and selecting a right vendor is most important one and then managing the performance, timely audits, feedback sharing and trainings are key areas to focus.

It looks very simple and straightforward. However when it comes to implementation, it has its own challenges. That is one of the reason, many of the major pharmaceutical companies find it difficult to go with same vendor for long time. As a result, after few years, most of the Pharma giants start thinking about doing everything in-house and then after few years of handling it in-house again think about taking support from vendors. This is a vicious cycle, which is difficult to avoid. Although if timely proper measures are taken and vendor-sponsorship relations are maintained as per initial contract or with time and change of requirement, by revisiting the contract if expectations are made clear, realistic and up to date then it is helpful in keeping the relationship in check and make it last for long time.

VENDOR-SPONSOR JOURNEY

Before commenting on the relationship and suggesting something about it, it would be good to know different stages of the vendor-sponsor journey.



Flow chart: Journey with traffic signal and toll gates

Based on the size of organization, type of work and expertise available internally, it is decided whether there is a requirement for a vendor or not? If Vendor is not needed then Sponsor Company can get it all done internally and need not to visit below points. If this is not the case then vendor is needed and further steps have their importance.

VENDOR IDENTIFICATION

Identifying the right vendors for selection is key to the success. Based on the requirement of sponsor, size and expertise of vendor is important. Based on prior experience and industry reputation, 3-5 vendors are invited for bidding.

VENDOR SELECTION

Based on presentations and audit/visit for invited vendors, final vendor needs to be selected. Some of the key points for making this decision are vendor rating, industry reputation, timeliness, onboarding and training time for new or replacement staff, cost, expertise and prior experience etc. Few sponsors try to rush through this phase, but it is one the important step for long relationship. **Abraham Lincoln** was quoted as saying “Give me six hours to chop down a tree and I will spend the first four sharpening the axe.” This is one-step before sharpening the axe, you should select the right axe. Selection should not be based on low cost alone. Because if that is the base then it is bound to backfire soon.

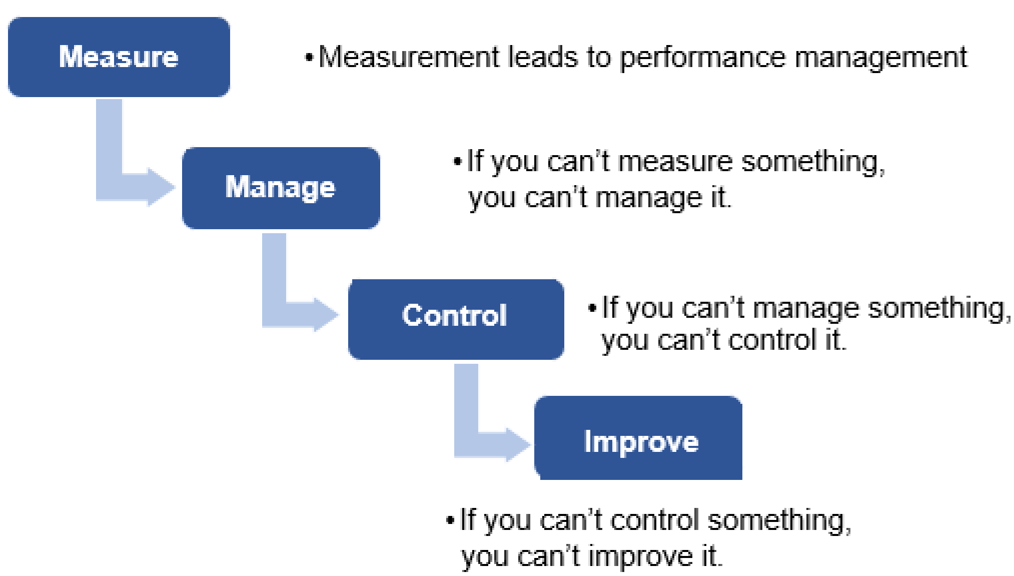
PREPARING CONTRACT

One of the biggest mistake committed by many of the sponsor-vendor partnership is not involving someone from core team for finalizing the contract. End of the day, the team who will be working with vendor knows it very well. If they are included at the time of writing and finalizing the contract then things will be clearer and it will help in avoiding any problem later, when it will come to implementation. Contract should be clear and detailed enough for not leaving any scope of assumption. It is always better to discuss everything at this stage including the pain points and areas of the concerns and in case of any miss, what would be the action and severity of it. Generally sponsor and vendor both are very helping and supportive at this stage, may be interested to discuss many things verbally without documenting and agreeing to unrealistic things as well. This doesn’t work for long time. Hence, it is fine if someone don’t like something at this stage, however clarity of expectations and keeping them realistic is better for the long run. It is highly recommended to discuss everything in detail, document it with examples wherever needed and then finalize the contract. As this is going to be rulebook and roadmap for further journey.

PERFORMANCE MANAGEMENT

For better-improved services, performance of vendor needs to be managed and timely feedback should be shared. For managing the performance, timely audit should be conducted and proper feedback along with findings and action items should be shared. Once a vendor is on boarded, now it becomes responsibility of vendor and sponsor both to ensure they are sharing timely proper feedback, suggestions and training based on audit and performance reviews. Sharing constructive feedback is required for improved performance. It provides the right platform for covering the entire base and making things happen with urgency and maintain high quality. Performance management is not only about escalations. If something is going well, that should be appreciated and highlighted. It encourages in further improvements and bringing innovations.

For better performance management, key performance indicators(KPIs) and key quality indicators(KQIs) should be defined with mutual agreement. Performance management can be divided into four steps as below.



Measuring the performance is key step for performance management. It should be taken in positive way. Its not about doubting your vendor partner, however it is about ensuring everything is on track and any required action can be taken before it is too late. There is a famous quote:

If You Can't Measure It, You Can't manage It.
If you can't manage it, you can't control it.
If you can't control it, you can't improve it.

Consistent improvement is the key for better relationship. From above phrase it is evident that for reaching to improvement, measurement, management and control are key steps to be taken. Measurement helps in gauging the amount of work and resource needs. Which helps in managing the work by timely on-boarding and training the required resources. This provides good control over everything. When you have covered all the bases and still you have some breathing space then you can think about innovative ways of improvements. Otherwise, if one is always in firefighting and damage control mode then it becomes difficult to come out with any creative idea. Rather in such scenarios chance of making blunders are high.

If everything is under control and both vendor and sponsor are discussing more about the innovative ideas for improving the performance than escalation. This itself is a very positive sign of relationship going in right direction. This will help in prosperous relationship, which can last longer.

CONCLUSION

For a successful relationship, bringing in the right vendor is essential. Having a well-defined contract with clear roles, responsibilities and expectations is very important. Following this up with a robust execution of the governance plans ensures there is transparency and trust between both the organizations. A successful partnership means – more time for sponsor to focus on the scientific part of the business, improved / highly efficient processes, improved compliance to regulatory and finally, significant financial benefits for both organizations.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:
Author Name : Anusuiya Ghanghas
Company : Novartis Healthcare Private Limited
Address : Novartis Knowledge City
City / Postcode : Hyderabad
Work Phone: +91 8421484652
Email: this.anusuiya@gmail.com

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