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A New Trend in the industry – Partnership between CROs and Pharma. Do we know how to work in this new relationship?

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ABSTRACT

There is a new trend in the working relationships between CROs and Drug companies. The relationships evolve from the traditional transactional model to a partnership in the recent years. The partnership in the pharmaceutical industry is a new adventure to both CROs and Drug companies, and it also impacts programmers.

The partnership will bring the new challenges and opportunities to programmers. We will work with not only our colleagues, but also employees from other vendors and clients. The partnership working environments will require the new set of rules and behaviors. The paper will discuss what kind of challenges and opportunities we will encounter and how we will resolve and succeed in the partnership working environments. The paper will specifically discuss the role of a project leader in CRO who are working directly with the clients and other vendors in the partnership environments. It will emphasize how important the culture is in the partnership environments and how the project leader helps to build the right cultures in the partnership environments.

TYPES OF SERVICE AGREEMENTS

The CRO and Drug companies can have various working relationships. Below are examples of service agreements.

- Transactional model
 - Drug companies outsource one or more projects at a time, so after each project, the Drug companies and CRO will go through another service agreement.
 - CROs usually work in their own infrastructure.
 - Drug companies provide “thinking” and providers provide “doing”.
 - Cost-based agreement
 - Short-Term
- Functional service provider model (FSP)
 - Drug companies outsource functions to CROs.
 - Drug companies will work with many different vendors which provide the different functions.
 - Cost- or Value-focused agreement
 - Short-Term or Long-Term
- Strategic partnership model
 - Drug companies outsource projects for the agreed-duration.
 - Drug companies and CROs work in the same infrastructure. (e.g., in the same SAS® working environment rather than in their own SAS working environment)
 - CROs provide “doing” as well as “thinking”.
 - Strategy-focused agreement (e.g., value, expertise, flexibility in resources and finance or location)
 - Long-Term

GOALS OF STRATEGIC PARTNERSHIP

The partnership between Drug Companies and CRO could be formed due to the following reasons.

- Knowledge Sharing: The provider and sponsor can benefit from each other. They can share their strengths and expertise to achieve a common goal.
- Increased Productivity: They can work together to improve the performance. The partnership last longer than FSP or Transactional model, so it has enough time to improve the performance.
- Future: They can prepare the future plan.
- Cost Effective: They will have a time to build a trust, so the sponsor will be able to reduce the oversight cost.

CHALLENGES IN PARTNERSHIP

There are a couple of issues or concerns from both sponsor and service providers.

- All parties are in the same page? - Usually, the partnership is formed in executive levels, so sometimes functional and operation level are not fully informed and communicated to.
- Different corporate cultures – This could be a big challenge, but at the same time, it will bring a huge advantage. The effective leadership will take an advantage of it, rather than take it as issues.
- Different geographic locations – not much face time.
- Different time zone – a limited communication time.
- Poor Communication : Different locations, time zones and cultures could hinder a good communication process.
- Changed roles for both sponsors and service providers: For example, some of programmers in sponsors get involved more in managing projects and processes rather than programming.

OPPORTUNITIES IN PARTNERSHIP

Any new environment will bring challenges, but at the same time, it will bring opportunities. The partnership can bring new opportunities to programmers.

- More learning opportunities – The Drug Companies and Service Providers will be able to learn from each other.
 - Different SAS programming techniques and process
 - Macros
 - Standards (e.g., CDISC)
 - Process flow
 - Software
- Exposure to more functions (e.g., Data Management, Statistics, Standard, and Regulatory)
- Exposure to different cultures (e.g., working cultures and geographic cultures)
- Chance to achieve excellence together
- Chance to learn new ideas and different perspective

ROLE OF PROGRAM LEADS IN PARTNERSHIP

The program leads could be a main communication hub for all the functions (e.g., Data Managers, Statisticians, Regulatory, Standard Groups, Medical Writers and more). So, below technical skills could be helpful to have.

- SAS programming skills
- CDISC knowledge
- Data Management Understanding
- Statistical Analysis
- Regulatory
- Medical Writing
- Project Management – workload, resource, budget, timeline and so on

However, the roles of program lead could go beyond the technical skill sets. Since programmer leads are working with so many functions, they have opportunities to influence and lead a certain part of or whole projects. The program leads should be able to build a great partnership with clients or other vendors with below skill sets.

- Open minded and understanding
- Strong communication skills
 - Listening (Inquiry, listen and confirm)
 - Writing and Reading
- Building a relationship – There are many stake holders (e.g., clients and operation teams), so building a good working relationship is very critical for a successful partnership.
- Crisis Management.
- Trust (Who do you trust? You trust people who care about your well-being.)
- Contributing and/or executing a strategy for a successful partnership.
- Building a great culture for the team.

STRATEGY FOR SUCCESSFUL PARTNERSHIP

In order to succeed in the partnership, the drug companies and Service Provider need to plan and implement a strategy.

- Joint Steering Committee (i.e., for executive or management levels)
- Joint Operation Committee (i.e., for functional or operation group levels)
- Communication Plan – who will communicate with whom and escalation process.
- Governance structure : Key Performance Index (KPI)
 - % of in time project
 - % of error rate
 - Duration of project (e.g., programming hours)
 - Response time
- Specified roles and responsibilities for all the participants
- Clear expectation from each partner

CULTURE EATS STRATEGY FOR LUNCH

When two or more companies work as partners, the first thing that they focus on developing is the strategy. How we will communicate, what are the roles of each company, what are the expectations, who will be responsible for what, and etc. The well thought-out strategy is very important to form a partnership, but we can't ignore building a great culture in the partnership. As a matter of fact, I believe that the culture is much more important than the strategy. A great culture will bind everyone together, and it helps everyone to work cohesively and collaboratively. It will make all the strategies work better and more effectively.

The culture won't be able to be measured, but it will impact all the aspects of process. A good collaborative culture makes everyone to help each other and to resolve the issues together. No one will blame anyone in a great culture, but lift and help each other.

Building a strong culture between sponsors and providers take hard work and true commitment. The culture cannot be planned nor monetized. The culture is the behavior of each individual. So, building the culture should start from the top and come down to all the levels. All the people who are working in the partnership should practice and behave as partners. It will be extremely difficult to build a great working culture in a transactional or short-term relationship. However, a great culture can be built in partnership relationship.

BUILDING STRONG WORKING RELATIONSHIP

So, how do partners build a great working? The most important part of a great collaborative culture is people. You need to have right people. You need to have everyone to believe about your culture and behave according to the culture.

There are major key behaviors to help building a strong culture in partnership between sponsors and providers.

- Focus - The focus is not on my company, nor on vendors or clients, but on our goals like projects.
- Commit to excellence – All the participants need to understand why we build a partnership. The partnership is formed to provide a better product, so we should work toward better, faster, more efficient way to do a business.
- Trust – In order to gain a trust from people, we need to show that we care of their well-being. If we don't care for our partner's well-being, we don't get their trust.
- Win Win cultures – It is not about who win or who lose. The partnership does not last forever unless both parties are winning.

CONCLUSION

In order to succeed in the partnership, the drug companies and service providers need to have a great strategy - open communication, joint problem solving, clear goals and expectations, agreed metrics and so. But, most importantly, they should trust and understand each other. The ultimate partnership in our society is a marriage. A marriage is not about to prove who is right and who is wrong. In order to keep a great marriage, one needs to understand and trust his or her spouse whether the spouse is right or wrong. Then, this partnership will achieve the common goal. This principle will apply to any partnership, especially partnerships between CROs and Drug companies.

A great partnership will make everyone involved more efficient, productive, and happier than working individually.

Working together is much better than working ... alone.

CONTACT INFORMATION

Your comments and questions are valued and welcomed. Please contact the author at

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