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A STUDY REPORT FROM PHARMACEUTICAL INDUSTRIES WHICH CROs PLAYS A VITAL ROLE IN RESEARCH & DEVELOPMENT

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ABSTRACT

A contract research organization is a third party service provider organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services for both drugs and medical devices. The CRO will provide up-to-date technical information which is a big support for pharmaceutical industries for extinction of knowledge on the current regulations. Outsourcing will save time, which is often critical because any delay in production processes, batch releases, or obtaining approvals from regulatory bodies can severely damage a company's prospects. CROs will be work in close collaboration with their clients, providing smart solutions to their needs, establishing and transferring methods quickly, and ensuring that information transfer is efficient, secure, and confidential. The study included of about 40 pharmaceutical R & D outsourcing companies. Survey was conducted from 2009 to 2012. Out of 40 pharmaceutical outsourcing companies selected of which 25 pharmaceutical R & D outsourcing companies were from India and remaining 15 pharmaceutical R & D outsourcing companies were from outside of the India mostly from USA. Among the 25 Indian pharmaceutical R & D outsourcing companies, of which 10 pharmaceutical companies were blend for both R& D outsourcing and R & D in sourcing. Survey may help the pharmaceutical companies to increase the outsourcing and insourcing their products to faster the out-come.

Keywords: R & D, Outsourcing, CROs, Pharmaceutical industries.

INTRODUCTION

A contract research organization (CRO) is a third party service provider organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services for both drugs and medical devices. CROs range from large, international full service organizations to small, niche specialty groups and can offer their clients the experience of moving a new drug or device from its conception to FDA marketing approval without the drug sponsor having to maintain a staff for these services. In the Code of Federal Regulations (CFR), the U.S. Food and Drug Administration regulations state that a CRO is "a person [i.e., a legal person, which may be a corporation] that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

Merits of CRO

As on today pharmaceutical companies are concentrating more on their core –activities such as drug discovery, marketing and sales. They are directly or indirectly depending on the third party service providers (CROs) for their R & D, analytical and manufacturing support requirements. The CRO can provide expertise using up-to-date technology supported by an extensive knowledge of the current regulations. Outsourcing can save time, which is often critical because any delay in production processes, batch releases, or obtaining approvals from regulatory bodies can severely damage a company's prospects. CROs should work in close collaboration with their clients, providing smart solutions to their needs, establishing and transferring methods quickly, and ensuring that information transfer is efficient, secure, and confidential [1].

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Advantages of CRO

(1) Capability or Experience: The most important criterion is capability and it plays a predominant role. Can the CRO provide the needed services? Are the personnel are well qualified, and do they experience in therapeutic area? These are simple questions to be asked before considering a CRO. A CRO must have the requisite experience in performing rapid methods development, validation, transfer, and routine sample testing. Experience has shown that when biological products are involved, even fully validated assays and products are often not as robust as initially perceived when transferred to another laboratory. In regulatory issues the CRO must update with latest requirements. Before initiation of the project the CRO must discuss with the client about the parameters and acceptance criteria for validation and acceptable inter-laboratory variation limits for the comparative analysis for method transfer [2].

(2) Compatibility: A CRO must be compatible with its client there should be co-ordination between the CRO and Client.

(3) Cost: Taking into consideration the huge costs involved in developing a new drug, pharmaceutical companies can save a lot of money by outsourcing some part of their activities to third party vendors.

(4) Continuing Support: A CRO must be continuous support to the client. It should act as an extension of client. By obtaining equivalent materials, equipment for the methods-transfer exercises, and many changes to the project scope after initiation many problem will overcome with the client. Even after completion of project, the CRO should provide continuous support during the manufacturing process to the client. Continuous support which finally leads to good long-term relationship and mutual understanding between Client and a CRO. Building a good relationship between the CRO and the client will lead to time and cost savings, providing added value to both businesses.

Selecting a CRO

Based on three most important criteria for selecting a CRO follows:

(1) Capability
(2) Compatibility
(3) Cost

Disadvantages of CRO

(1) Extreme high R & D Cost: The disadvantage to using CROs, however, is that short term R&D costs can become extremely high. CROs set prices to not only cover their costs plus a healthy profit margin; they also include provisions that penalize sponsors in the event of unforeseen occurrences such as early termination of a project, delays, additional requirements, etc. This results in relatively high fees for CRO services.

(2) Loss of intellectual property: Security is an issue to be, considered when selecting a CRO, as intellectual property and data exchanged between client and service provider.

(3) Loss of project control: By outsourcing, a project to a CRO there is a possibility of loss of project control from the client. So sometimes, it is a disadvantage to a CRO.

(4) Loss of in-house expertise: In insourcing arrangements, the insourced staffs are not employees of the pharmaceutical company. A third-party supplier retains responsibility as the employer of the insourced staff, while the pharmaceutical customer is responsible for their day-to-day supervision during the project.

(5) Delays in the projects: A CRO might not be only providing services for one organization. Since CRO might be catering to the needs of several companies, there might be not be complete devotion to one company, it will take several projects for different companies and it won't spend time on each projects concurrently. That will leads to delays in the projects.

(6) Poor Quality: As CRO caters to several companies sometime due heavy load of completion of projects; they do not concentrate their time and manpower on the projects**.** Eventually they end up with poor quality of work.

(7) Incompatibility: Due to improper understanding about the projects CRO s becomes incompatible with their clients.

Review of Literature

Our study were also correlated with the other studies carried out by,

Nick Taylor as per his reports on CROs Phase I-II, Phase III-IV, Preclinical, Clinical Development CROs pipeline growth & price rises encouraging signs for CROs. A year-on-year increase in active drug development projects and improving pricing will drive business to CROs, a survey was found. John Kreger, equity analyst at William Blair, said: "Budget cuts may be more geared towards reducing infrastructure and internal resources rather than decreasing the number of projects in the research and development pipeline." US-based investment firm William Blair commissioned the survey [2].

Wai Lang Chu, reported that CRO's drug R&D contribution never been more significant**.** Contract Research Organisations' (CROs) contribution to drug development has never been more crucial with faster development, earlier decisions on project failures, and higher approval success rates becoming the norm amongst outsourcing partnerships [1].

Stacy Pritt studies reported that Working with Contract Research Organizations (CROs) are companies with a base business of providing clients (known as Sponsors) with research services on a project or contractual basis [3].

Nina Flanagan Knowing When to Rely on In-House Capabilities and When to Outsource is Critical to Success" the objective of this article was that before going for outsourcing, the pharmaceutical companies must aware of the Contract Research Organizations (CRO). There are certain steps companies can follow to help choose the right CRO for a specific study. These include the life cycle of

the study (timing, study management strategy), RFP, protocol synthesis, vendor contract, study maintenance, site closing, and database lock [4].

The author also explained that the company's decision-making plan focuses on balancing costs and quality and consists of three key elements: clinical development (studies required, timeline completion), capabilities assessment (resource assessment, clinical expertise), and financial and human resource (buy or build) considerations. She also stated some of the main challenges for sponsors include high expectations, competition for sites and subjects, data and regulatory requirements, unexpected costs, personnel turnover mid-project, and development time.

The author conveyed that it very important that the pharmaceutical companies should know the three c's of CRO such as capability, compatibility and cost.

Nick Taylor, Forming CRO spin-out can help big pharma; research. The objective of this article was large biopharma's getting the benefit to concentrate and focus on their core activities, research found. From 1997 to 2003 ten service providers were created by spinning-out assets owned by biopharm companies. He also reported that shedding assets allows the parent company to cut costs and focus on its core activities, while potentially gaining a stake in a new growth business [2].

The researchers also wrote in "Journal of Business Chemistry" that "If an internal project is spun-out and has the opportunity to commercialise its technology and knowledge for a broader customer base [there is potential for growth]" The researchers also cited that Accovion, formed in 2002, as an example of a successful CRO (contract research organisation) spin-out. Accovion was formed from clinical research, pharmacovigilance and medical writing assets at Aventis, itself a spin-out created after the merger of Hoechst and Rhone Poulenc.

Accovion has grown operations, setting up subsidiaries in the UK, Czech Republic and Russia in the past year, by commercialising the technology and knowledge possessed by Aventis. However, the researchers warn that the benefits of this type of spin-out can be uneven. The researcher finally concluded that "Overall, research and development spin-outs do seem to have a positive impact for both the parent organisation and the spin-out team, in terms of flexibility, motivation and overall performance".

Andrea Charles explained about the selection process, minimum risks invoiced, the size, attention received to pharmaceutical Industries and contracts involved in the CRO [5].

Objectives

1) To examine why pharmaceutical companies are outsourcing to CROs
2) To identify the reasons for selection a CRO
3) To identify the reasons for not selecting a CRO

Hypothesis

Will CROs benefit pharmaceutical industries?

Methodology

a. **Data Collection Method**
b. **Data Collection Method**
c. **Source of the Data**

The study depends on primary and secondary source.

Primary Source

- Direct personal investigation in the form of the questionnaire.
- Indirect oral investigation in the form of interview.

The data has driven mostly by R & D heads such as Managing Directors, Directors, Chief Executive Officers, Vice Presidents, Assistant Vice Presidents, General Managers, Assistant General Managers and managers. Normally Managing Directors, Directors, Chief Executive Officers were responsible selection of projects.

Secondary Data

Secondary Data will be driven from,

- Books
- Journals
- Company Records
- Company Web Sites

Sampling Techniques

Two different techniques were used in this study, they are,

Simple Random sampling

Simple Random technique was adopted to choose the Pharmaceutical R & D outsourcing companies. This technique was used to keep in view the scope of the study which tries to cover different Pharmaceutical R & D outsourcing companies.

Systematic Sampling

The other technique which we used was systematic sampling. Here from the list of Pharmaceutical R & D outsourcing companies. We randomly picked some of the pharmaceutical R & D companies which were into outsourcing, their products to third party service providers.

Research Design

As this study aims to find out how the Outsourcing will be going on in pharmaceutical R & D companies.

Survey Instrument and Questionnaire

In order to gather the information from the research participants of the 40 pharmaceutical companies the questionnaire method was adopted, the questionnaires were developed in consultation with my Research Guide, my MD and my colleagues.

Data Collection and Field Work Plan

25 Pharmaceutical Industries located within India and 15 Pharmaceutical Industries located mostly in USA.

Research Design

Sample Size

For the purpose of the study, a sample of 40 pharmaceutical R & D outsourcing companies taken into consideration, 25 pharmaceutical R & D outsourcing companies taken out of which there 10 pharmaceutical companies they were into blend of both R& D outsourcing

and R & D in sourcing within the India and 15 pharmaceutical R & D outsourcing companies taken from outside of the India mostly from USA.

- Pharmaceutical Industry Profile
- Data Interpretation & Analysis

Table 1. Selection of a CRO

Particulars	Number of Companies	Percentage
Capability	40	100
Compatibility	36	90
Cost	40	100
Continuous Support	34	85
No of Companies To Be Studied	**40**	**100**

Table 2. Reasons for not choosing a CRO

Particulars	Number of Companies	Percentage
Extreme high R & D Cost	10	25
Loss of intellectual property	30	75
Loss of project control	20	50
Loss of in-house expertise	10	25
Delays in the projects	18	45
Poor Quality	10	25
Incompatibility	20	50
No of Companies To Be Studied	**40**	**100**

Figure 1. Selection of a CRO

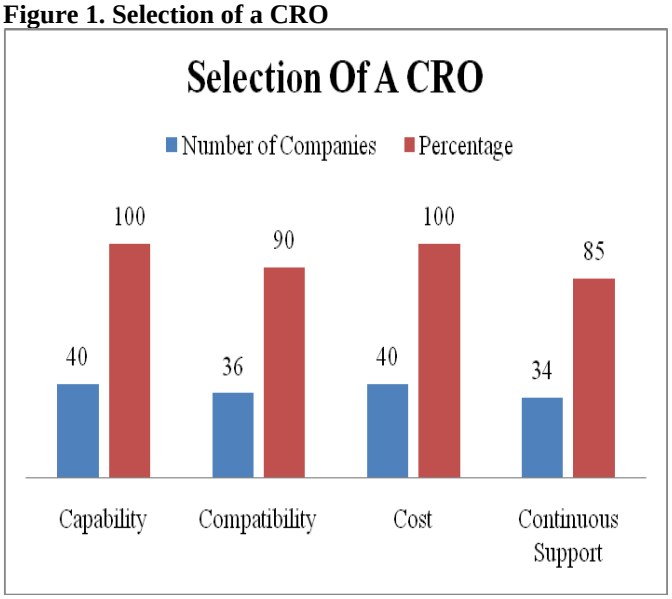
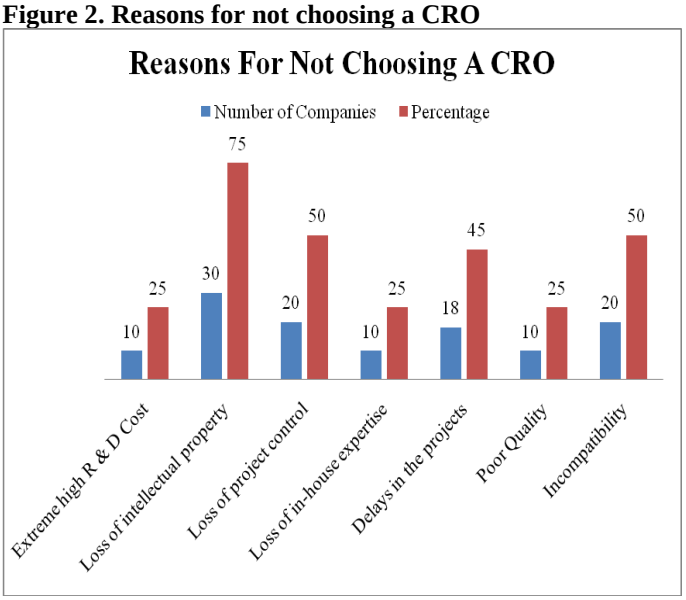


Figure 2. Reasons for not choosing a CRO



RESULTS AND DISCUSSION

In our study we would like to report that different companies were representing in a different ways for the selection of CRO for outsourcing their R & D. 40 companies were showing capability & cost, 36 companies were showing compatibility and 34 companies were showing continuous support for selecting a CRO for outsourcing their products.

It is evident that different companies were representing why they do not prefer a Contract Research Organization for outsource their R & D. Out of 40 companies, 75 % of the companies were showing loss of intellectual property, 50 % of the companies were showing for loss of project control & incompatibility, 45 % of the companies were showing for Delays in the projects and 25 % of the companies were showing for Extreme high R & D Cost, Loss of in-house expertise and poor quality.

CONCLUSION

We would like to conclude that CROs are playing an important role in providing a big support to the research and development in pharmaceutical and biotechnology industries for rapid completion of their projects.

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