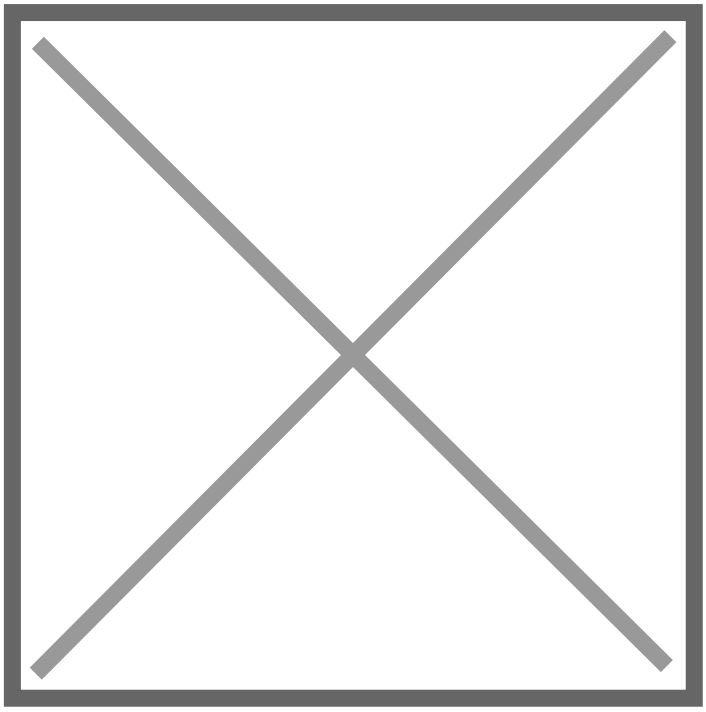
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Managing clinical research business in modern times

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Each area in a CRO operation requires different type of investment and skills—it has a long term bearing on future earnings and business growth

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Clinical research business, like any other business has its own nuances. There are a variety of activities and skills required for each activity. It is always a challenge to build a sustainable long-term business model, and a proper infrastructure planning at a formative stage will help to achieve this.

If we look at the successful clinical research organizations (CRO) in the US and Europe, they offer a wide range of services starting from early phase development, proof of concept, phase I–IV clinical trials, clinical data management and software services in life sciences.

Majority of the CROs in India are feeling the heat of overcapacity, large manpower and very few lines of business operations. They have invested heavily in just one of the areas of clinical research such as BA/BE studies or phase III clinical trials or data management. They are caught in the web of sustaining current business/concentrating on capacity utilization and managing shrinking profitability by cost-cutting/downsizing, rather than growth and expansions.

Some of the questions constantly asked by the CEOs of CROs are:- (a) how do you address a situation where profitability starts shrinking from a high of 40 percent? (b) how do you retain talent in this highly competitive market where employees are offered 100 percent hikes in salaries year-on-year to a more realistic 10 to 15 percent increase? (c) how do you keep abreast of growing regulatory requirements? (d) how do you stay ahead of competition?

Strategies

There are some important considerations, which owners/CEOs should address at a very early stage. Each area in a CRO operation requires different type of investment and skills, and has a long term bearing on future earnings/ growth of business.

Risk mitigation

In every business, the first strategy is to identify business risks and work out a risk mitigation plan. First risk is to reduce dependence on a single or few clients. Most CROs are dependent on a single or few clients rendering themselves vulnerable to the fortunes of those clients.

The second most important risk is disproportionate expansion in a particular area of operation. This seems very attractive in the short term. But CROs will be caught in the vicious cycle of overcapacity, price war, and unwieldy manpower. It is important to draw a limit for each line of activity and concentrate on diversification into other areas of clinical research. The best models can be obtained from the CROs in the West.

Productivity

Keep an eye on the productivity of each employee on the basis of volume of activity and not on the rupee value of projects. Initially, all CROs will see a growth in the value per project as they graduate from local clients to foreign clients, pilot studies to pivotal studies, and zero regulatory track record to several FDA approvals. The value graph will flatten out due to competition as more and more CROs start catching up.

Training

Invest on people constantly. Companies invest on people in two ways. One way is to compartmentalize employees into certain departments, and train them well in only one area of operation. Large corporations adopt this strategy when they have a sustainable order pipeline, clear employee lay off contracts in case of business loss. On one hand, this is detrimental to the interests of the employee, and inflationary for the company on the other.
Medium sized CROs should adopt a multi-tasking training strategy. The training programs should be designed in such a way that 25 percent of the training component in a year should support future business expansions or diversification plans. The employee should be allowed to learn different sets of skills, which the company can make use of in future. This strategy may lead to a percentage of people leaving the organization for better prospects due to skills they acquire from this training. However, a CRO can always strike a balance of such variability based on its business plans and growth.

Networking

CRO industry is highly skewed towards technical skills and regulatory compliance. It requires huge amount of time, effort and money to set-up, expand and maintain the same. One way of being ahead of competition is to network and compliment efforts than set up everything under one roof. It is an accepted fact that a CRO is not expected to be an expert in every therapeutic area under the sun, and is abreast of every regulatory requirement laid down.

Macro Economic Factors

It is important to periodically review the benefits emerging markets offer as a country in terms of pricing and patient load in comparison to other low cost countries. A strategy to go global should be in place to mitigate risks related to economic factors.

Social Factors

CRO business cannot ignore the benefits it derives from the lower strata of the society. Most of the patients who participate in clinical trials are from low economic background, and who cannot afford quality medicine. CROs should actively pursue development of better infrastructure by reaching out to hospitals which have never heard about clinical trials. This will help modern techniques of treatment available to a larger population.
A CRO can succeed only when its vision is a blend of three factors – commercial gain, employee welfare and social benefits. No CRO can succeed without skilled people and active participation of the society. CRO industry carries a huge responsibility to the society. The focus should be on delivering quality service by developing people and building good infrastructure.