Selecting A Right Patient Recruitment Company: The Key To Success
With current global economic uncertainty, intense global competition, aggressive financial targets and reduced R & D budget, drug industry is facing major challenges in achieving their objectives to ensure drug’s successful path through development. The risk may be high if they fail to manage. Hence to overcome such challenges, outsourcing is a powerful option for achieving these operational objectives which can be accomplished by selecting & utilizing right expertise. The Pharma, biotech and medical device companies can achieve efficiency; reduce operating cost and time by outsourcing key functions or entire processes to a right partner.

Patient recruitment is one of the most important aspect of clinical trials and a key determinant for success of drug development program. Patient recruitment has always been a challenge and it has been observed that more than two thirds clinical trials fail to achieve their original recruitment target. It is becoming more challenging with the increased complexity of clinical trial design, stringent eligibility criteria and the trend toward more targeted patient population.

In the last two decades, investigational sites use to provide their total patient enrollment by reaching into their own databases of patients. However, due to complexity of the current protocols, rigorous eligibility criteria and rarity of disease condition, sites need to go beyond their practice to achieve their recruitment targets on time. The longer it takes to complete the recruitment, the more money & resources sponsors have to spend to complete the trial. If the study is outsourced to CRO, sponsors continue to spend millions of dollars on change orders for extended enrollment timelines, more sites, and more countries when initial in-practice recruitment fails to reach the goal. Moreover, due to delays in patient recruitment, sponsors fail to achieve their important, planned milestone of “time to reach market” and each day delay in reaching market costs a lot to sponsors.

The old model with CROs having dual responsibility of running the trials and recruiting patients is not producing the needed results anymore, especially for “difficult to recruit” kind of protocols and indications. CROs have limited expertise and limitations in patient enrollment activities in virtue of their responsibilities for management of a clinical trial. They often simply represent what investigational sites say they can deliver. Therefore, it is very crucial for success of clinical trials and drug development program, that sponsor has to reach agreement internally to select and use
Selecting a Right Patient Recruitment Company: The Key to Success

right patient recruitment company for managing complex and “difficult to recruit” protocols in different therapeutic area and orphan disease indications. Most of the times the protocols in therapeutic area like Oncology, CNS and CVS have stringent eligibility criteria and it is difficult to find protocol specific patients. Apart from these complex indications, some of the simple indications like pain study also pose challenges in patient recruitment either due to just use of narcotic drug which is already available in the market but in the different form or due to some specific study procedures or restriction on use of other medications.

Keeping in mind complexities and challenges in some of the clinical trials, it is advisable to have a right patient recruitment company on board right from the start of clinical trials instead of waiting to see the progress on patient enrollment and then go into rescue mode and thereby avoid losing significant time & money. Moreover, sponsor can get better insight in selection of right countries, sites for their study protocols, from the patient recruitment companies based on their earlier experience in managing similar kind of studies. Thus, selecting a right partner as patient recruitment company helps the sponsor in fulfilling their operational objectives, reducing timelines & costs and cutting down the amount of stress that is associated with complex coordination and thereby improving overall efficiency & quality in clinical trial management.

Patient recruitment service is offered by different firms like dedicated patient recruitment companies, advertising firms, call centers and some of the clinical research organizations. Partnership and outsourcing to appropriate firm can prevent unnecessary spending, loss of time tactical blundering and will continue to be a strategic trend that sponsors has to leverage from the partner’s expertise in patient recruitment.

With the expertise and experience in therapeutic and geographic area of a planned study, an experienced patient recruitment partner helps to effectively overcome the hurdles in patient enrollment which otherwise is seen as the major challenge by sponsor/CRO and sites. However, the key is selecting the right partner to ensure success. Selecting a specialty patient recruitment company that has quantifiable experience in working with sites and the company, who can price on measurable enrollment milestones, can help to achieve sponsor’s goal.
While choosing or selecting a patient recruitment partner, few aspects need to be taken into consideration to ensure right selection.

- **Selecting patient recruitment company with comprehensive services:** To deliver on patient enrollment commitment, it is necessary to carry out field based activities within and around investigational sites to identify study specific potential patients. Therefore, it is important to select the patient recruitment company which offers powerful field-based activities approach with the provision of targeted media advertising with call center support. The companies which just offer advertisement option or call center support may not be a right option to have a “complete solution” to take up all recruitment challenges. The recruitment company which provides field based resources like clinical enrollment specialists/managers can offer flexible approach options and a variety of innovative solutions by effectively addressing protocol specific challenges and hurdles in patient enrollment.

- **Operational presence with local expertise in the countries of study conduct:** The recruitment company should be able to offer local experienced resources who will be able to formulate country and site specific result oriented strategies and offer targeted, customized methodologies in patient enrollment based on their experience within the framework of local regulatory and ethical environment.

- **Proven track record on enrolling required pool of patients:** Every study protocol is different. However, the proven track record with successful experience in enrolling required patient pool in earlier studies in the same countries increase the chances of success for the study planned.

- **Having experience and past success in getting patients beyond investigational sites’ reach:** Investigational sites can enroll the patients who are there in their database. In order to accelerate and enhance patient enrollment, the key is tapping the patients who are otherwise “out of reach” patients for the sites and this is the real support that any patient recruitment company can offer to sponsor.
• **Past Performance (Key Performance Indicators):** The best way to assess patient recruitment company’s experience and expertise is looking into their past performance on similar studies. The key performance indicators that can be checked before selecting the patient recruitment services such as:
  - Shortening/reducing overall enrollment timeline with regard to planned one
  - Time to randomize first patient after site activation
  - Percentage of patients randomized from sites’ “out of reach patients”

• **Experience in working with CROs assigned by sponsors:** As CROs manage most of the studies on behalf of sponsors, patient recruitment company should have experience and “success stories” in working with CROs. To ensure success in patient enrollment, there is a need to have effective co-ordination and communication with CRO, if the sites are managed by CRO and not by sponsor directly.

• **Performance based pricing:** Sponsors always look at patient recruitment as a “risky business”. If sponsor pays the patient recruitment company as regular monthly payment and if they do not support recruitment; then what? Therefore, sponsor should select patient recruitment company which offers fees structure based on per patient randomized i.e. performance based per randomized patient pricing. This true “risk sharing approach” will benefit sponsors and take away their concerns regarding the non-performance of patient recruitment partner.

A patient recruitment partner should have experience not only in developing right, innovative study, country & sites specific strategies but also should be able to effectively implement those strategies in cost effective manner. Patient recruitment partner should be confident and thorough in its assessment of the enrollment challenges to ensure delivery of patients into the study. These patients should not be the ones that sponsor would have otherwise received from the sites’ own activities. Close collaboration between a patient recruitment company and sponsor makes both parties aware of the each others’ needs and limitations. Patient Recruitment Company should also help sponsor to maintain long-term relationships with sites and Investigators.
Selecting a Right Patient Recruitment Company: The Key to Success

Sponsor should ask their outsourcing representatives to source multiple proposals and look for the company that offers detailed enrollment plan and roadmap to success. With the right partner on board, patient recruitment is a predictable, reproducible process that optimizes site performance and prevents budget overruns caused by adding time, and paying for vendor change orders.

**Conclusion:** Outsourcing can be a cost-efficient option to achieve operational objectives of some important functions of a clinical program and ensures a drug’s successful path through development. Patient recruitment has always been a challenge in a clinical trial, especially for complex and “difficult to recruit” kind of protocols and indications. Selecting a right patient recruitment company is the key to ensure success of a clinical program. The various aspects and qualities of a patient recruitment company like breadth & depth of the services offered, past experiences, expertise of local resources, key performance indicators followed and pricing model need to be assessed thoroughly while selecting right partner for the patient recruitment services. A partnership with patient recruitment company will not only improve efficiency quality, and effectiveness of clinical research by lowering the problems such as low patient enrollment, missed deadlines, language barriers, and other trial related issues but also will create a new paradigm benefiting sponsor, patients and investigational sites.

This information does not constitute a written advisory opinion of the Author, but rather is official information available through up to date literature survey. This information does not necessarily represent the formal position of MCSMO, and does not bind or otherwise obligate or commit the MCSMO to the information presented.