

WHY OUTSOURCING PATIENT ENROLLMENT TO A SPECIALIST Makes Sense

Disruptive change is needed in clinical trial management, an industry where inadequate enrollment has become the biggest driver of wasted dollars. The cost of patient enrollment is now the single largest part of the total trial budget, representing 32% of the cost. Among CROs and sponsors, this expense has been accepted as the inevitable cost of trial management, but it no longer should be. What impact will the emerging CRO/sponsor strategic partnerships trend have on patient enrollment?

Sponsors are forging these partnerships to save money and make clinical trial management more efficient. The alliances have been trumpeted as a mutually beneficial solution for both the sponsor and the CRO. The sponsor purportedly wins by being able to negotiate aggressive pricing discounts, offload more responsibilities, and reduce the staff it once needed for trial management. By working with one or two large CROs for multiple trials, the sponsor supposedly will have fewer CROs to manage and will gain a tighter control over activities. The CRO benefits from this strategic relationship because it is guaranteed a larger volume of work over the long term, although with significantly reduced profit margins.

But in recent years, clinical trials have been delayed because there aren't enough patients at individual sites to enroll in the studies. The longer it takes to complete a trial, the more money a sponsor has to spend. When the need for more patients arises, CROs are quick to add change orders for more sites. Sponsors continue to spend hundreds of 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. This old model with CROs having dual responsibility of running the trials and recruiting patients isn't producing the needed results anymore. They have limited expertise in patient enrollment; they often simply represent what sites say they can deliver.

Because sponsors are signing long-term

contracts with CROs that do not predict or even guarantee the actual cost of patient enrollment, they find themselves locked into a system where they must keep their checkbooks open to pay for the inevitable change orders.

Outsource to the Correct Expert to Improve Efficiencies

It's highly unlikely that real transformative changes in patient enrollment will come from these new partnerships. CROs have been running clinical trials in some fashion since the 1970s, yet site productivity continues to plummet.

Change is needed in clinical trial management because inadequate enrollment has become the biggest driver of wasted dollars. Sponsors need to build into the clinical trial the tools for efficient patient enrollment. Think about it: if 85% of trials are late, the CRO site selection processes are an inadequate solution. The needed solution is to improve the enrollment productivity of each site rather than adding more sites and time. Sponsors need to start planning and budgeting for out-of-practice patient recruitment to meet enrollment goals and require CROs to provide best-in-class services in this area.

Trial managers need to ask themselves: Why reward CROs with additional monies to choose new sites with the same flawed approach? Specialty providers of patient enrollment can step in and improve this part of the cycle of a clinical trial.

These improvements start with an updated view of the role of sites. This model for selecting sites is to use the ones that:

- Want and accept externally-recruited patients.
- Previously had success in randomization of external patients.
- Exist in a disease-predominant geographic area.
- Run clinical trials as a business.

This model should include paying sites for the additional pre-consent workload of exter-

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nal patients to motivate them to perform. If they are given well-qualified potential candidates, sites will aggressively recruit patients.

The reality is that you hire sites for access to patients and if you could hire fewer sites and still reach your enrollment goals, you would. Outsourcing to a specialty patient recruitment and retention company that has quantifiable experience working with sites and prices on measurable enrollment milestones can help achieve this goal. The greater the number of patients from each site, the more financially efficient the overall study becomes. **PV**


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