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Choose Studies Wisely to Increase Your Site's Clinical Research Capacity

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Many institutional sites take three months — and often much longer — to start up a study. During most of this time, nothing is happening — the paperwork is just sitting on someone's desk waiting its turn. Shoving more studies into the front of the pipeline does not mean more will come out the other end. In fact, the opposite will occur, and everything will take longer.

Once a study is initiated, it must compete for resources with other studies and uses other than clinical research. In fact, open studies consume resources even when patients are not enrolling or coming to study visits. Opening more studies does not increase capacity; it just makes everything take longer.

Clinical research labor, facility, equipment and other resources are expensive and largely fixed costs, so it is uneconomical to reserve extra capacity.

Maximizing throughput takes a fine balance, which is complicated by the fact that studies use many different types of resources and every study places different demands on those resources. In many respects, clinical research is not an assembly line operation; it is more like a custom furniture workshop in which individual craftspeople work on individual sets of furniture, each with its own design.

There are two ways to increase capacity:

- Hire more people, expand facilities, etc.
- Increase efficiency with new technology or better processes.

The first approach directly increases costs. The second approach can also be expensive, at least initially, and will certainly take time and incur risks.

But there is a third way to increase capacity: unclog the works by being selective when accepting new studies. This method just takes the discipline to set priorities.

However, "just" setting priorities may not be that simple, especially when every study has a unique set of attributes and its own champions (e.g., department heads, faculty members, etc.) What is needed is an objective, fair and practical way to make the hard decisions that generate the desired results in a manner acceptable to the stakeholders.

Numerous factors, such as the following, can enter into the priority calculation:

- Scientific importance
- Benefit to the local, served community
- Importance to the investigator and the importance of the investigator to the institution
- Benefits and risks to the institution (e.g., "cutting-edge research")
- Ethical validity
- Revenue generation
- Resource requirements (especially the bottlenecks)
- Availability of patients (e.g., due to competing studies)
- Availability of study personnel

- Availability of other resources
- Current and potential relationship with the sponsor or CRO

Every research site will define and weight these factors differently. Specifying the calculation may be arduous but will certainly be very revealing. It might be expedient to retain a certain level of ambiguity, but at the cost of decreasing transparency and the defensibility of specific decisions.

A proper calculation of priority will help management intelligently decide which studies to accept and which to decline, speeding performance of the accepted studies and increasing capacity so studies that were "on the bubble" can now be completed.

Conclusion

Not overloading the "factory" is a condition of lean production, as popularized by the Toyota Production System. In addition to increasing capacity, it avoids the inevitable problems of delay and poor quality caused by trying to do too much with too little.

Industry-sponsored studies have paying customers. Meeting their expectations is good for business and leads to new opportunities. All studies have the public as a customer, and nobody wants to disappoint the public by delaying important medical treatments. Setting priorities and managing to capacity helps satisfy these customers and other stakeholders. Overloading capacity serves nobody's interests except the manufacturers of inboxes.

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