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Twelve Attributes of a Successful Community Research Site

By Manda Materne and Mary Frances Dobry

How does a community hospital build a successful clinical research program? There are many ingredients, but the following 12 attributes seem to be the most important:

1. Vision

If you want your clinical research program to be successful, you need to know *why* you are conducting clinical research. Is your objective to provide more treatment options for your patients? Is it to support physicians who want to conduct research? Is it to market your hospital as a cutting edge institution? Is it to absorb overhead or generate profits? It might be all these things and more, but you need a coherent vision to serve as the "north star," or organizing principle, for your efforts. For example:

> *Our vision is to make a positive impact on the health of the region as the premier center of clinical research of significance to our patients.*

2. Leadership Commitment

Without full support from the hospital's leadership team, you will struggle to obtain needed resources and essential cooperation from other departments in the hospital. Hospital leadership must see *your clinical research vision* as a key component of *their vision for the entire hospital*, not just a distraction from more important matters. A functioning "research advisory board" is a good indication that leadership is serious about clinical research.

3. Physician-Investigators

You will need a core group of physician-investigators who are passionate about clinical research, with others who are supportive but still significant contributors. Additional physicians will want to join your program over time, and they must be made to understand that clinical research is not for "tourists." Cultivate your physician-investigators by removing obstacles and providing appropriate resources and incentives to conduct research.

4. Team Members

Study coordinators, patient recruiters, regulatory specialists, and other team members will do most of the clinical research work. They need aptitude, education, training, resources, compensation, etc. And, most importantly, they need a dedication to clinical research that will overcome the inevitable stresses and frustrations. If you want to destroy that dedication, overwork your team or give them imbalanced workloads.

5. Standard Policies and Procedures (SOPs)

Solid, up-to-date SOPs that are actually used are essential to a smoothly running clinical research program that consistently delivers high volume and quality, with constant improvement over time. Your SOPs must be realistic and contain just the right level of detail to be useful but not obstructive.

6. Regulatory Compliance and Quality Management

Regulatory compliance consumes roughly one-quarter of the time and effort required to complete a clinical study. Most of the rules are common sense, but some are not, so successful sites have regulatory expertise on site or available from an external IRB, lawyers, consultants or colleagues at other sites. Circumstances, rules and personnel change, so a strong quality management system is essential, including SOPs, training/education, monitoring/auditing, and reporting/metrics.

7. Financial Expertise

Clinical research finances are different than hospital or physician-practice finances. Expertise in research cost structures (including "hidden" costs); coverage analysis; research billing practices; Stark, anti-kickback, Sunshine and other laws; and study budget negotiations are all essential. Balancing a portfolio of well-funded, poorly funded, and unfunded studies — all with their own merits — is a neat trick.

8. Research Information Systems

Comprehensive use of a solid clinical trial management system (CTMS) is no longer optional. eRegulatory binders and other document management systems are emerging necessities. EMR/EHR systems must be accessible to clinical researchers for patient recruiting, source documentation, site monitoring, and safety surveillance purposes.

9. Institutional Review Board

Study sponsors are no longer willing to wait for local IRBs that take months — or even just weeks — to review a protocol. Unless you can find a way to drastically accelerate your IRB's timelines, your only option is to outsource the review of industry-sponsored studies to a central IRB or equivalent. The good news is that many of these IRBs are AHHRPP-accredited and perform at a very high level of human subjects protection (HSP). However, do not lose all your in-house HSP expertise, since clinical researchers will always need a convenient way to get answers to their HSP questions.

10. Patient/Participant Recruitment

Very few community hospitals can rely solely on the investigator's patient database for study participants. Create a patient referral system, both internally and with affiliated physicians and facilities, with competence in marketing and advertising in both traditional and new media, and a community outreach program that lays the ground for specific studies.

11. Business Development

Study sponsors are always complaining about a shortage of good research sites, but that doesn't mean you can just build your research program and new sponsors will automatically come to your door. You need to create a solid reputation in the sponsor and CRO communities and constantly seek out the few studies that best match your capabilities and goals. Sponsors and CROs are very open to working with community hospitals having the above attributes. Without a strong pipeline of new opportunities, any bump in the road can throw your whole program out of kilter. Of course, not just any study will do; carefully assess the feasibility of each opportunity and accept only those likely to support your vision.

12. Resilience

Clinical research is fraught with surprises — investigational product shortages, device malfunctions, rescheduled visits, study participant drop-outs, replacement site monitors, FDA inspections — the list goes on and on. The good news is that sites having the above attributes are naturally resilient; they just bounce back, improve their systems, and keep on rolling. Study sponsors and CROs will notice...and your clinical research program will grow.

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