

PERFORMING CLINICAL RESEARCH IN PRIVATE PRACTICE

Three tips for getting started.

BY KEVIN LAMARCHE



The pharmaceutical and medical device industry continues to advance technology at breakneck speed, creating an array of clinical trials and opportunity for today's medical community. The number one question I hear from people at private practices regards how to get involved in clinical research. It is no coincidence that many of the same practices

participate in trial after trial across the ophthalmology industry. Simply put: they earned it!

Sponsors today must enroll clinical trials quickly and efficiently while maintaining a high ethical standard and fiscal responsibility. It is understandable why they consistently choose proven clinical investigational sites to participate when the average monthly budget to sponsor a trial can be in the millions of dollars. People at the premier investigational sites have worked very hard to get to where they are. New research sites are always needed to refresh and replenish the ranks from which sponsors choose, however, so how do you earn a seat at the table?

No. 1. MAKE CONNECTIONS

Networking and communicating with industry in your subspecialty will help you to demonstrate your commitment to making clinical research a new part of your practice. I recommend first developing an understanding of the clinical trials underway and those that are coming down the pike. Talk to your industry representatives, make inquiries at your local and national meetings, and speak to the investigators who are currently participating in trials you would be interested in conducting. Learn as much as you can from peers and industry so that you can smoothly establish your clinical research.

No. 2. PROVE THAT YOU HAVE THE PATIENTS

You must prove to the study sponsors that you have the subjects. A large patient population that matches with the clinical trial's inclusion and exclusion criteria *and* who is

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willing to participate will go a long way toward your practice's selection. Understanding what the sponsor is seeking and establishing a realistic assessment of potential enrollment at your practice are extremely important. Through database queries, you can establish a “like trial” subject pool within your practice and begin to identify potential subjects, but this is only one part of the equation.

Knowing which of your patients may be willing to participate in a given trial is equally important. One way to prepopulate a list of potential subjects is to add a question to your intake form that asks patients if they would be



AT A GLANCE

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- Demonstrating what you can contribute and supporting that impression with statistics will open doors. Honesty and realism are essential.
- Not allocating the necessary time and resources will doom your research practice to failure.

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interested in participating in research. Another approach is to discuss with your patients your participation in clinical trials as a practice offering within your office. Posters and plaques in your office and a clinical research corner in your newsletter or website can support these efforts.

Demonstrating what you can contribute and supporting that impression with statistics will open doors. Honesty and realism are essential. The sponsor will be making a large investment in your practice. *Underpromise* and *overdeliver* should be your mantra. The last thing you want to do when getting started is to underdeliver on your commitment.

No. 3. ALLOCATE THE RESOURCES

Dedicate the time and the resources necessary for conducting and overseeing a clinical trial within your practice. Effectively running a clinical trial requires staff, space, equipment, training, and time. A piecemeal approach is a huge mistake. Your practice will need a dedicated research coordinator who can effectively navigate the sea of paperwork, protocol changes, Investigational Review Board questions, equipment, and inventory management as well as interactions with the sponsor and subjects. The coordinator can make or break your research department, so choose wisely. Then, ensure that this person has enough time to effectively fulfill his or her responsibilities.

Clinical research takes a great deal of time, it is tedious, and it can be quite frustrating. Not allocating the necessary time and resources will doom your practice to failure.

CONCLUSION

Participating in clinical research can be extremely rewarding, but it can become an unwelcome obligation if all of the necessary internal systems are not in place. There really is no easy way to get started. You must decide that clinical research is going to be a big part of your practice, and then, you must demonstrate the know-how, dedication, and resources to see a trial through. ■

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