Lessons learned working in the clinical trial industry

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As a resident in psychiatry, I am being trained in the art of diagnosis, treatment, and prevention of mental illness and emotional problems. As part of my training, research and scholarly activities are encouraged—reminding us that clinical medicine is always evolving and that it is every physician's duty to be at the forefront of advancements in medical science.

Last year, I worked in the clinical trial industry under a seasoned principal investigator. I learned several lessons from my time with him and in the industry. Here, I present these lessons as a starting point for residents who are looking to gain experience or contemplating a career as an expert trialist or principal investigator.

Lesson 1: Know the lingo

To make the transition from physician to principal investigator go more smoothly, I recommend taking the time to learn the language of the industry. The good news? Clinical trials involve patients who have a medical history and take medications, which you are well acquainted with. In addition to medical jargon, the industry has developed its own distinctive terminology and abbreviations: *adverse drug reaction* (ADR), *good clinical practice* (GCP), *contract research organization* (CRO), and more.

Don't stop there, however. I recommend that you read FDA research guidelines and guidelines of the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP) to be familiar with the ethics and standard regulations of the industry.

Lesson 2: When in doubt, refer to the Protocol

Every clinical trial has a manual, so to speak, known as the Study Protocol, which outlines approved methods of performing diagnostic tests and procedures; provides information on the study timeline; and specifies patient inclusion and exclusion criteria. This document ensures conformity across all study sites, helps prevent errors, limits bias, and answers questions that might come up during the study. It's worth noting that, in my experience, many of the questions about exclusionary medications arise when psychiatric drugs are involved.

Lesson 3: Document. Document. And document.

The golden rule in clinical practice and research is: "If it isn't documented, it didn't happen." (Recall what I said about reading FDA and ICH-GCP guidelines to learn about regulations.) Documentation of all study-related activities must be meticulous. At any time, your documents might be subject to

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Disclosure
The author reports no financial relationships with any company whose products are mentioned in this article or with manufacturers of competing products.

external or internal audit, conducted to preserve conformity to the protocol and maintain patient safety. Improper documentation can delay, even invalidate, your research.

Lesson 4: Remember that advertising is an art

The real work begins when your site is ready to accept patients. To fill the study, patients need to be aware that you are recruiting participants. A good starting point is to inform likely candidates from your existing patient population about any studies from which they might benefit.

Most times, however, recruiting among your patients is not enough to meet necessary enrollment numbers. You will have to advertise the study to the general public. Advertisements must target the specific patient population, informing them of the study but, at the same time, not be coercive or make false promises. The advertisements must be approved by the study's institutional review board, which is responsible for protecting the rights and welfare of study participants.

Advertising can be tricky. If an advertisement is too vague, you will get a huge response, causing time and resources to be spent screening patients—most of whom might not be suitable for the study. If an advertisement is too specific, on the other hand, the response might be poor or none at all.

Advertising is its own industry. It might be best to hire an advertising expert who can help you decide on the selection of media (radio, television, print, digital) and can design a campaign that best suits your needs. If you decide to hire a professional, I recommend close collaboration with him (her), to help him understand the medical nature of the study.

Clinical Point

When recruiting for the study among your patients is not enough, you will have to advertise to the general public to find participants

Related Resources

- ClinicalTrials.gov. About clinical studies. https://clinicaltrials.gov/ct2/about-studies.
- U.S. Food and Drug Administration. Clinical trials and human subject protection. http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.
- ICH GCP. International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use. http://ichgcp.net/.

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