The Challenges of Conducting Clinical Research: The Investigators Perspective

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Introduction:

As new drugs/devices are developed and the demands for evidence based care increase, the need for qualified nurses to serve as investigators in clinical trials will likewise grow. Some nurses have extensive experience serving as investigators for various types of clinical research; however, many nurses participated as investigators for clinical research have a unique insight into challenges provided by the various types of research in a recent clinical trial were asked to share their perspective.

Objective:

To share the experience and insight gained by participating as a site investigator for a clinical trial and to educate ETs and WOC nurses on the challenges encountered and opportunities presented.

Methods:

A recent industry-sponsored multi-site medical device research gained from the experience was obtained through interviews

Investigators who participated in this study were interested in conducting clinical research to expand their knowledge of research for advancement of their professional practice and to improve quality of life for their patients. Most investigators had no experience with conducting a clinical research study in have limited to no experience in this area. Those who have their institution. Some had experience with product placement trials but most of their exposure to clinical research was through coursework. As with most clinical trials, these investigators study. Nurse investigators who participated as site investigators had enthusiastic expectations for enrollment which resulted in several sites not meeting their recruitment goals or reduced the goals prior to or during the study. Limited time was the most common challenge amongst study staff, which was confounded with a large amount of study paperwork, difficulty locating patients that qualified for the study, long approval periods for institutional legal or ethics departments and communication challenges between site (UK) and sponsor (US) time zones. Several investigators felt that there was a steep learning curve to start the study, while a few felt that start-up was relatively easy. All investigators found that collecting the study information from study was conducted in the United Kingdom. Many of the subjects was challenging and demanded a significant amount nurse investigators for this study had experience with case of time. Investigators felt that hospitals could provide more local studies and/or product evaluations but had limited experience support so that "critical reflexivity is both nurtured and valued". with clinical trials. The challenges they discovered, the impact

Some investigators also felt that the sponsor should provide a this type of research had on their subject care, and what they study day to review the study and meet with potential patients.



Investigators reported gaining a better understanding of the research process, ethics and those responsible for research related processes at their institutions. These investigators proposed recommendations for other new investigators as:

- Gain a clear understanding of the expectations and limitations of the project and each investigator
- Establish a good understanding of the study methodology
- Identify a designated clinical study area
- Ensure good rapport with patients/clients
- Consider advertisements for subject recruitment
- Keep in mind that many patients may have changed products in the community
- Don't underestimate the amount of time the study will take
- Clearly explain what the sponsor requires on data collection tools to all subjects

There is also a degree of commitment and staying power required to see the project finished.

While clinical research is challenging and time consuming, especially for new investigators, a majority of investigators found their time and effort towards the larger project goal to be rewarding. Investigators also greatly value the experience they gained and look forward to applying their lessons learned for future research studies.

Conclusion:

Nurses are well positioned to undertake research studies due to their clinical skills and access to patients. However, nurses undertaking this research felt that they needed more clinical research education. To better prepare nurses for the challenges of clinical research, formal and informal training needs to be provided; along with a more structured support system in the hospital and recognition of the value research provides. These changes may increase nurse participation in clinical studies resulting in improved patient care and evidence based practice due to the results of these studies.

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