The Challenges of Conducting Clinical Research: The Investigators Perspective

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 have limited to no experience in this area. Those who have participated as investigators for clinical research have a unique insight into challenges provided by the various types of research.

Methods:
A recent industry-sponsored multi-site medical device research study was conducted in the United Kingdom. Many of the nurse investigators who participated as site investigators in a recent clinical trial were asked to share their perspective. 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 number of patients that qualified for the study, long approval periods for institutional legal or ethics departments and communication and collection tools to all subjects. As with most clinical trials, these investigators had limited experience with product placement trials but most of their exposure to clinical research was through coursework. As most clinical trials, these investigators had enthusiastic expectations for enrollment which resulted in several sites not meeting their recruitment goals or reduced the number of patients that qualified for the study, long approval periods for institutional legal or ethics departments and communication and collection tools to all subjects. As with most clinical trials, these investigators had enthusiastic expectations for enrollment which resulted in several sites not meeting their recruitment goals or reduced the number of patients that qualified for the study, long approval periods for institutional legal or ethics departments and communication and collection tools to all subjects.

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

Methods:
A recent industry-sponsored multi-site medical device research study was conducted in the United Kingdom. Many of the nurse investigators for this study had experience with case studies and/or product evaluations but had limited experience with clinical trials. The challenges they discovered, the impact this type of research had on their subject care, and what they gained from the experience was obtained through interviews.

Summary:
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 their institution. Some had experience with product placement trials but most of their exposure to clinical research was through coursework. As most clinical trials, these investigators had enthusiasm for enrollment which resulted in several sites not meeting their recruitment goals or reduced the number of 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 understand the project and its requirements, some investigators felt that the sponsor should provide a clear understanding of the expectations and limitations of the project and each investigator. Establishing a good understanding of the study methodology and identifying a designated clinical study area were common challenges amongst study staff, which were 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.

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.

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.

Quotes:

“We have enjoyed undertaking this challenge and are keen to keep abreast with new developments in the field.”

“The time spent was enormously rewarding.”

“The largest challenge was time constraints and the ability to manage several tasks at once, not only within the research project but our own clinical practice.”

“We have gained invaluable knowledge and skills in clinical research which was able to be applied to future studies.”

“The study was welloverallwas an enjoyable experience.”

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

“The time spent was enormously rewarding.”

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“The study was well overall was an enjoyable experience.”

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Footnotes: