Type: Assignments
Subject: nurse role in clinical trial
Subject area: Nursing
Education Level: Masters Program
Length: 4 pages
Referencing style: Harvard - standard
Preferred English: US English
Spacing Option: Double
Title: Please use data from below link of phase 3 clinical trial of given drug by study details, study results and describe Research nurse roles, responsibilities and what the procedure is carried by Research nurse to conduct phase 3 clinical trials of given below drug.
Instructions: this is drug detail.
https://www.clinicaltrials.gov/ct2/show/study/nct[removed]?term=b[removed]&draw=2&rank=1
**** you will find all the detail and information about the drug in this link above****** this link provide you study detail and study result must consider points from11(staff training) to 20 (mile stone-3 placebo trail completed) please see below the picture. plsease use the timeline as mentioned in the picture below (start time and finished time). please describe the role of research nurse in these points of phase three clinical trial of given drug. all detail you wil find by click on the link above. plsease see picture below. also give details by using tables or flow chart like drugs administration and or any adverse drug reactions monitored by researchers nurse.

Research Nurse

Student's Name

University

Course

Professor

Date

A research nurse is determined to explore the measure to enhance patient safety and quality of care. For this study, the research nurse was determined to explore the safety of using Abrocitinib in patients 12 years and above suffering from severe Atopic Dermatitis. The main goal of the research is to identify the safety associated with using the specific drug and whether there are any side effects and possibility for impairing the health and well-being of the patient rather than fostering a quick recovery. Phase III of the clinical trial involves different aspects that will ensure the safety and quality of care for the patient is achieved. The trial process is meant to ensure the entire goal of nursing, to keep the patients healthy and enhance their recovery, is met.

A research nurse is dedicated to ensuring the staff have adequate knowledge and competency on the specific condition and administering the clinical trial on the staff training. The research nurse educates the staff on the guidelines and procedures to be followed during the clinical trial. Staff training is conducted by the research nurse, considering the vast knowledge and experiences on the disease and the drug and the ability to administer and follow clinical trial guidelines.

Site in clinical trial refers to the location where the drug is tested on human beings. The site startup involves processes and procedures that ensure the area is well equipped and ready for the human experiment. The research nurse is obligated to ensure the site for the clinical trial is well equipped. The environment is set as per the standards of the FDA and other health agencies related to the ethics and safety of human research subjects. All the equipment in the setup is desired to be safe and standardized for human subject's research. The nurse also seeks the relevant approvals from health departments and other stakeholders, including the drug developers, to conduct the trial.

The recruitment of participants is also a critical part of the clinical trial. There are various factors to consider, including the age of the participants and the severity of the condition. It is also critical to review the possibility that the subjects might be suffering from other conditions that do not align with the tested drug (MacArthur, Hill & Callister, 2014). These are some of the inclusion and exclusion criteria that need to be considered during the clinical trial to ensure the results attained give the best conclusive information about the drug. There are instances where individuals recruited without considering some of these elements give different results regarding the drug's safety. Their condition or preexisting conditions might expose the trial to different results such as allergic reaction and nullify the conclusion.

Informed consent is an important part of the clinical trial that the research nurse should not dismiss. The participants need to give their approval to be involved in the study as an ethical requirement. The research nurse should explain to the participants the research process, the activities involved, and possible dangers, side effects, or benefits that come with the participation (Kadam, 2017). Every bit of the clinical trial should be explained precisely, and the participants allowed the opportunity to continue or drop their interest in the clinical trial. The research nurse can be exposed to ethical liabilities when a participant declares that they are involved in the study without knowledge or consent.

In a clinical trial, there are certain aspects that a participant ought to meet before engaging in the process. The inclusion and exclusion measures need to be taken keenly to ensure the participants will give reliable results concerning the drug. The important part of ensuring the results will be reliable would be to screen the participants during their enrollment in the clinical trial site. The patients have to be suffering from the identified disease to be sure the drug will be administered to a patient who deserves the treatment. The screening will also ensure the patients

do not have any other conditions that might compromise their health during the trial and render the results inefficient or attract legal and ethical lawsuits.

The research nurse initiates phase 3 of the clinical trial after the participants are ready and the site is all equipped for the study. The nurse should be the overall supervisor of the process and ensure that everything in the trial is initiated. The research nurse ensures that the staff follows the protocol and guidelines given for the trial. The nurse acts as a supervisor and avails any questions or consultations by the staff during the trial (Eckardt et al., 2017). In case of an adverse event, the staff must address the issue immediately. They should inform the research nurse, who is expected to have another team on standby to deal with such a situation. The team designated to respond to such events must be experienced clinicians with adequate knowledge of how they can handle these situations and conduct emergency first aid and response to the patient.

The milestones for the drug are the main part of the clinical trial to show whether the drug is effective with the patient, and it can be recommended to patients without any doubts. As per the results, the first milestone is to explore the efficiency of 100mg of the drug. This is the minimum quantity that is administered to the participants during the first periods of the trial. The experiment should inform whether this dosage is adequate to fight the condition or it is weak and the patients need additional dosage. The research nurses recommend the experiment to use 200mg of the drug and observe the patient's reactions. This should determine whether the dosage is adequate for an overdose based on the patients' response to this drug. The third milestone is completing the experiment, where the research notes the most appropriate dosage that should be used with the patients. The findings should guide the research nurse to give recommendations to clinicians and practitioners on the dosage that should be used for the patients across the age groups.

References

Eckardt, P., Hammer, M. J., Barton-Burke, M., McCabe, M., Kovner, C. T., Behrens, L., … Coller, B. S. (2017). *All nurses need to be research nurses. Journal of Clinical and Translational Science, 1(05), 269–270.* doi:10.1017/cts.2017.294

Kadam R. A. (2017). Informed consent process: A step further towards making it meaningful! *Perspectives in clinical research*, *8*(3), 107–112. https://doi.org/10.4103/picr.PICR_147_16

MacArthur, J., Hill, G., & Callister, D. (2014). Professional issues associated with the clinical research nurse role. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)*, *29*(14), 37–43. https://doi.org/10.7748/ns.29.14.37.e9216