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LSC541

Module 1 Assignment

mRNA-1273 Vaccine Trial

1. **Identify the population and sample in this clinical trial.**
   Population: Adults 18 years of age or older.
   Sample: 30,000 adults 18 years of age or older
2. **Identify three confounding variables in this clinical trial.**
   i. Underlying health conditions
   ii. Changing COVID-19 strains
   iii. Unknown previous COVID-19 infection
3. **Discuss the potential effects of the confounding variables if not handled correctly.**
   If not handled correctly, it could become difficult/unclear if this vaccine aided in resistance to COVID-19. It will especially become difficult to quantify that. For instance, if people included in the study had unknown exposure to COVID-19 before the trial, they have more baseline immunity than the average person in the sample. Another important aspect is that some vaccines are more effective for certain strains of COVID-19 than others. Due to this, researchers may find that the vaccine could not prevent reinfection for long, but will be unsure if that is due to the way the vaccine was developed, or if it is because subjects in the sample are being infected with new strains with different antigens than the ones in the vaccine. Underlying health conditions were briefly mentioned in the exclusion criteria, but only for people currently in a known immunosuppressive state. In order to avoid these confounding variables, an antigen test should be conducted at the start of the study to determine if the subject has already had a prior infection, then at the end of the study to determine what strain of COVID-19 they were infected with (if they did get sick). A blood test may also be important to conduct at the beginning of the study to determine the immunocompetency of the subjects in the population. Of course this adds much more cost to the clinical trial, but can ensure that the sample is a better representation of the target population.