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Assignment 1: mRNA-1273 Vaccine Trial Questions

In this clinical trial evaluating the mRNA-1273 vaccine for COVID-19 prevention, the population comprises adults aged 18 years and older who are considered at risk of SARS-CoV-2 infection.

The sample specifically refers to the subset of this population enrolled in the study, randomly assigned to receive either the mRNA-1273 vaccine or a placebo across different phases (Parts A, B, and C). This randomization helps ensure that the results can be generalized to the broader adult population at risk of COVID-19.

Regarding confounding variables, three notable factors include age, health status, and geographical location. Age diversity among participants may influence immune response variability, potentially impacting vaccine efficacy and safety evaluations. Variations in underlying health conditions among participants could also affect outcomes, as those with certain comorbidities might respond differently to the vaccine or be more susceptible to severe COVID-19 outcomes. Moreover, differences in regional prevalence of COVID-19 and exposure to various viral strains may impact infection rates and vaccine effectiveness, thus posing challenges in interpreting study outcomes if not properly controlled.

If these confounding variables are not effectively managed through study design (e.g., randomization, stratification) and analytical techniques (e.g., statistical adjustments), the validity and reliability of the study findings regarding the mRNA-1273 vaccine's efficacy, safety, and immunogenicity could be compromised. For instance, if age as a confounding variable is not managed and say, a non-representative amount of the sample was relatively old, then the results regarding efficacy of the vaccine may not necessarily apply to a relatively young person.