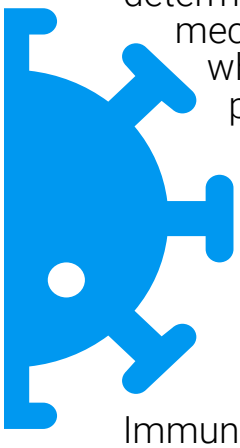
Statistical Significance

Statistics Improves Vaccine Development

Assessing vaccines

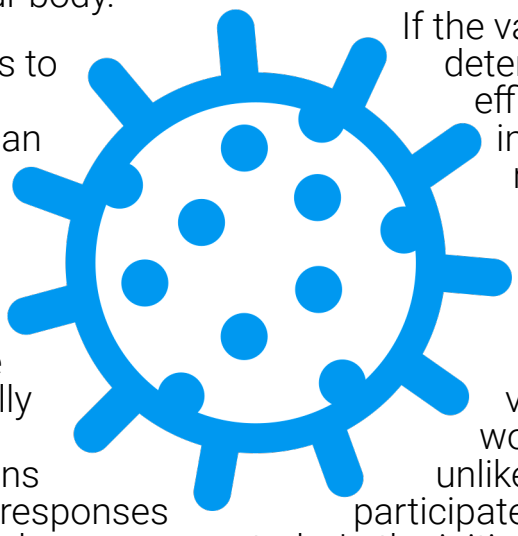
One of the most effective strategies for preventing the spread of infectious diseases is to create vaccines that provide strong protection. However, testing if a potential vaccine is efficacious with a clinical trial can be costly and time-consuming. These trials can require thousands of participants, last multiple years, and cost millions of dollars. For these trials, the most important consideration is if individuals who receive treatment become infected at a lower rate than those on placebo. Some of the most important outcomes used to determine the mechanism by which the vaccine protects against infection are the immune responses that it elicits.



Immune responses

Immune responses are your body's reaction to what it perceives as a harmful foreign invader. Immune responses can occur when you become infected by an actual pathogen, or when you are given a vaccine. These responses include changes in the adaptive immune system, including the generation of antibodies, killer T-cells, and memory T and B cells.

The goal of many vaccines is to cause an immune response similar to what would be seen if you were infected with the pathogen, but without causing you to become ill. This will prepare your immune system for when the pathogen actually enters your body.



Immune responses to vaccines are complicated and can be different for different individuals. To better understand the means by which the immune system successfully protects against disease, statisticians compare immune responses between vaccinated individuals who become infected and vaccinated individuals who do not become infected. They can first determine if there are differences in immune responses between these two groups and, if any exist, decipher where they occur.

Using immune responses to shape future studies

Regardless of whether the vaccine is determined to be efficacious, the immune responses measured during the clinical trial can be used to inform future studies.

If the vaccine is determined to be insufficiently efficacious, the observed immune responses can provide useful information for future studies. The immune responses among the few individuals who were protected can help inform future vaccines that will aim to elicit these same immune responses, but for everyone.

If the vaccine is determined to be efficacious, the immune response observed can be used to better understand whether the vaccine will work in people unlike those who participated in the study. In the initial trial, to determine whether the vaccine is efficacious, a sufficient number of individuals need to become infected. This can require many participants and long follow-up periods, especially when the disease is rare. Studying the vaccine immune responses of individuals outside the original study population and comparing them to the protective immune responses of individuals in the original trial can inform as to whether the vaccine will work in the new population. Because immune responses can be measured on every participant soon after they receive the vaccine, these secondary studies can be conducted more quickly and at a far lower cost.