

A Perspective on Human Challenge Trials for Vaccines Development

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Abstract

Introduction

A human challenge study is a type of clinical trial for vaccines or other pharmaceuticals that intentionally exposes test subjects (whether or not they have been vaccinated) to the condition being tested. The challenge organism could be any of these: close to wild type and pathogenic; adapted and/or attenuated from its original form with less or no disease symptoms, or genetically modified.

Discussion

When conducting human challenge trials, researchers must consider the value of information and risks to subjects. The trials should be undertaken with ample foresight, attention, and oversight. The trials should be conducted within an ethical framework in which genuinely informed consent is given.

Human challenge trials serve as a model for evaluating and representing one possible approach to vaccine development. To protect this vulnerable group, all principles of clinical evaluation should be applied, including the need for approval under a Clinical Trial Authorization (CTA) by the National Regulatory Authorities (NRA) or ethical committees in addition to compliance with Good

Clinical Practice (GCP). These trials are often a type of efficacy-indicating study, but most would not be pivotal. Almost all could qualify as a pilot and performed to gain helpful information for vaccine development; several might even occur during vaccine development.

The following points could be considered as the purpose for the study:

- The stock and model system of the challenge is characterized in terms of titration, symptoms, kinetics, shedding, and transmissibility.
- A precise understanding of the pathogenesis and immunity to an organism is needed for vaccine design.
- Identifying the optimal design for traditional pivotal efficacy trials such as case definitions, endpoints, and other study design aspects.
- The study tests to see if a potential vaccine candidate would protect against disease.

Conclusion

The vaccine development process is more complex than the traditional drug process, so the regulatory assessment of vaccines takes longer. The approval process for a vaccine can be lengthy and consequently impact the overall development timeline.