Abstract

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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. 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.

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Biography

Dr. Nalini Kumari's career spans over 11 years in medicine, consulting, and pharma research. She brings her comprehensive knowledge to accelerate the clinical development process by designing and implementing innovative, adaptive, platform trials and clinical studies across several therapeutic areas. Currently, she is working at Apollo Sugar Clinics as Senior Manager, Medical Affairs & Research, where she is responsible for conducting scientific studies for various therapeutics areas and medical products. Before this, Dr. Nalini served as Principal Investigator at leading CROs – ZenRise CRO and Sipra Labs and has led numerous research studies and projects. In the past, Dr. Nalini has worked in various government and private hospitals as Medical Officer and Consulting Physician. Dr. Nalini has obtained M.D. (Pharmacology) degree from Government Medical College (GMC), Nagpur, one of the premier medical institutions of India. She did her M.B.B.S. from Rajendra Institute of Medical Science (RIMS), Ranchi, India.

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