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Regulatory considerations related to the development of filovirus vaccines

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The licensure pathway for most viral vaccines includes the development and validation of the vaccine manufacturing process along with well defined clinical studies to support vaccine use to prevent disease. Product development under IND includes the establishment and validation of the manufacturing process leading to a well qualified commercial scale process. In parallel, clinical studies are performed to define the potency of product that will be safe and effective in the prevention of disease in the intended population. While this is a complex, often lengthy process, this overall scheme has led to the licensure of many safe and effective vaccines. The complexity of how to develop a licensed vaccine increases when those vaccines are used to prevent diseases such as those caused by Filoviruses, where a correlate of protection has not been clearly developed, there is a paucity of information about natural history of disease in humans, and the feasibility of performing human efficacy studies is low due to a low, unpredictable incidence of disease, typically in developing countries with less well-developed national regulatory authorities and laboratory frameworks. While well characterized vaccines can be produced and clinical trials can be performed to support vaccine safety in the intended population, it is difficult to show efficacy when disease is episodic or when the total numbers of individuals exposed to disease is limited. To overcome these obstacles in clinical development, the agency has developed an alternative pathway to show vaccine efficacy. This pathway, informally termed "The Animal Rule", and discussed in the "Draft Guidance for Industry: Animal Models – Essential Elements to Address Efficacy Under the Animal Rule" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078923.pdf) utilizes efficacy data generated in animals where a relevant disease model can be demonstrated and these data establish that the product is reasonably likely to predict clinical benefit in humans. Information on the Animal Rule and other regulatory concerns for the licensure of Filovirus vaccines will be presented.

Biography

Dr Levis completed her PhD at Washington University in St Louis in 1988. She conducted post doctoral studies in laboratories at the National Cancer Institute and the Uniformed Services University of Health Sciences in Bethesda, MD prior to coming to the FDA's Office of Vaccines Research and Review in 1995. Dr. Levis is currently the Deputy Director of the Division of Viral Products and is involved in the review and support of viral vaccines already licensed for use or currently under development.

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