Considerations on the Nonclinical Safety Evaluation of Vaccines and Adjuvants

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Vaccines are an integral part of the strategy for improving public health. They are typically given to health individuals to prevent disease but may be given in a therapeutic setting as well. Antigens in vaccines may be weakly antigenic and therefore require the co-administration of adjuvants to enhance their immunogenicity. Historically alum has been used but because of an increased need for vaccines that elicit cell-mediated immunity, the search for novel adjuvants has significantly increased. Safety of vaccines and adjuvants is typically evaluated non-clinically and during clinical trials and additional safety evaluations are often conducted during batch release testing. While the vast majority of vaccinated individuals only experience mild symptoms following administration, occasionally there are unexpected adverse events noted in the broader population. This introductory presentation will discuss the regulatory expectations for safety evaluation of vaccines and adjuvants prior to registration and during batch testing and release and will offer thoughts on opportunities for improvement. Additionally, it will explore some recent examples of unanticipated adverse events and the challenges for predicting these de novo and will set the stage for further discussion of immune-related evaluations and systems biology approaches to improve both the efficacy and safety of future vaccines.