

## **ADJUVANTS IN PRECLINICAL AND CLINICAL DEVELOPMENT: THE DO AND DON'T**

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It is clearly accepted that all vaccines are adjuvanted (endogenously: part of the pathogen or exogenously: added to the antigen formulation) except for a few vaccines such as liquid Hib or non aluminiac Meningitis vaccines. It is also recognized that the vast majority of recombinant vaccines if not all, will require an adjuvant to induce an immune response which will be adequate in quality and quantity. Over the past 3 decades, adjuvants have become increasingly important and central to the development of new and improved vaccines. Although the introduction of exogenously adjuvanted vaccine has been slow and steady, 7 licensed vaccines based in the adjuvanted approach are now licensed, and the number eaching late development phase continue to increase.

Their introduction into vaccines has added complexity to the development of vaccines in terms of formulation, preclinical and safety evaluation both preclinically and clinically.

Challenges however remain and should be understood and overcome when embarking in the development of a new adjuvant antigen combination. It is only the combination of the right antigen and the right adjuvant that will lead to an efficacious vaccine, in that sense, one cannot be assessed without the other, in particular in the context of the formulation. Special consideration need to be taken when defining and evaluating the formulation aspect of the vaccine. The preclinical evaluation needs to take into account the nature of the adjuvant used and its potential differences between species. Understanding adjuvant mode of action has therefore become crucial, with the realization that differences existed between animals and humans making extrapolation between preclinical and clinical not always possible. The use of adjuvants in new vaccines has highlighted the need to define preclinical and clinical safety evaluation methods as compared to therapeutic small molecules

This presentation will review the challenges faced with the development of adjuvanted vaccines, from their inception to current days, and path that could be followed.