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TITLE: Bayesian vs. Frequentist Methods: Implications for Preclinical Vaccine Research

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ABSTRACT: Preclinical in vivo studies are guided by established principles of good practice. The implementation of robust statistical methodologies is essential for minimizing bias in these studies. Vaccine research utilizing animal models involves specific experimental designs, requirements, and readouts that necessitate the consideration of multiple endpoints and often require longitudinal analyses across multiple time points. Although the application of parametric approaches can be challenging, these methods offer significant advantages over non-parametric alternatives, particularly by enabling the estimation of effect sizes and their corresponding 95% confidence intervals.

Typically, the estimation of boost and adjuvant effects is performed using ANOVA (both one-way and two-way), and, when feasible, using repeated measures or mixed models that account for the animal as a random effect. Ensuring the validity of these models is essential, particularly by evaluating the normality of residuals, which can be problematic in the presence of small sample sizes and non-responders (i.e value below the LOQ or first dilution).

Preclinical research is often constrained by a limited number of animals per group, in accordance with the 3Rs principle aimed at reducing animal use. This constraint poses challenges for maximizing the interpretability of results obtained from small sample sizes. To address this, we propose the use of Bayesian methods, which offer a probabilistic and more flexible framework for characterizing the distribution of parameters of interest, rather than relying solely on p-values.

In contrast to frequentist approaches, which typically emphasize hypothesis testing and yield binary conclusions based on p-value—potentially leading to the exclusion of relevant groups due to arbitrary or overly stringent significance thresholds—Bayesian methods enable a more nuanced interpretation of data and integration of prior knowledge. These approaches allow researchers to quantify the probability of a true vaccine effect given the observed data, thereby supporting more informed decision-making.

Our findings, based on the probability that the observed difference exceeds a predefined margin, demonstrate the advantages of this Bayesian approach, showing that parameter evaluation can yield meaningful probabilities. Overall, this method improves the interpretability of results in preclinical vaccine studies and enhances the use of in vivo data, enabling researchers to draw more informative conclusions.

BRIEF SPEAKER BIO: Alice Raillard is currently the Head of Preclinical Biostatistics in the R&D Vaccine division at Sanofi. Since joining Sanofi in 2015, Alice has focused on optimizing vaccine production through modeling and process control strategies. In 2020, she advanced to her current position, where she leads a team dedicated to applying statistical methods to preclinical studies for vaccines. Before her tenure at Sanofi, Alice worked at GSK as a statistical coordinator on several pan-European studies, which enhanced her expertise in market access. She also contributed to clinical trials and regulatory submissions at a clinical research organization.

Alice began her career at the Nîmes University Hospital (CHU de Nîmes), collaborating on public health projects. Her experience also includes time at CIRAD, where she worked on agricultural research and statistical modeling, contributing to projects that addressed food security and sustainable development.
Additionally, she has a background in climate modeling, focusing on reconstructing past climate conditions, which has enriched her understanding of the environmental impacts on public health.