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TITLE: From Antiquated Frequentist Methods to the Bayesian Revolution: Driving Innovation and Approval in Non-Clinical Statistics

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ABSTRACT: Historically, non-clinical statistical analyses in the pharmaceutical industry have predominantly relied on frequentist methodologies. The subsequent emergence of resampling or bootstrap techniques offered new avenues to calculate statistical intervals for complex situations. However, common resampling methods often underperform, yielding coverage probabilities below the nominal level. This presentation argues that a paradigm shift towards Bayesian statistics offers significant advantages for non-clinical drug development. Real striking examples will be showcased including statistical intervals for ratios, prediction intervals for multiple observations, tolerance intervals in mixed models, or probability to pass specifications in multi-stages procedure (e.g. dissolution tests).

We will demonstrate that Bayesian methods are highly effective even with uninformative priors, delivering robust and interpretable results. Furthermore, advanced Bayesian techniques, including methods that leverage mixture priors and dynamically borrow prior information, can optimally utilize both weak and strong prior knowledge, enhancing inferential power and efficiency.

Through compelling real-world examples from successful projects within our company, we will showcase how Bayesian statistics has been instrumental in supporting the approval of novel vaccines and drugs by health authorities.