Advantages of using the Bayesian Framework for Modelling the relationship between Volume, Freezing Rate, Supercooling and Aggregation in Vaccines

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In the field of vaccine development, understanding the causes and mechanisms of instability is crucial to maximize shelf-life and immunogenic potential. Aggregation causes instability because it reduces vaccine potency, and it is essential to control and minimize aggregation during vaccine formulation and storage.

A split-plot design was developed to study the effect of the factors freezing volume and freezing rate on particle aggregation after storage of a vaccine drug substance for fixed duration in freezing condition. During the analysis of the results, we found out that the studied relationship was more complex than expected and that the model used to generate the design did not fit the data. Furthermore, a phenomenon called supercooling was found to be mediating the relationship between the factors and the outcome.

This presentation shows that the Bayesian framework offered several advantages in studying this complex relationship. The model fitted could incorporate the relevant factors and the confounder/mediator variable. Non-linear and location-scale models were explored. By using the Bayesian framework, we could integrate prior information based on previous studies and handle the reduced number of samples available. Several cross-validation and information criteria were used to select the best model. Based on the selected model the design space was defined.