



**TITLE: Bayesian dynamic borrowing applied to stability and accelerated stability - Regulatory insights from health authority submissions**

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**ABSTRACT:** In the development of new vaccine or drug products, stability assessments typically require several years of data collection. Statistical innovation is therefore key to accelerate stability evaluation and reduce time-to-market. In this talk, two statistical methodologies will be reviewed, assessed and compared.

First, accelerated stability studies can be conducted using data collected at temperatures exceeding the standard storage temperature, over shortened periods of up to 4 or 6 months. Such models enable the extrapolation of drug product degradation over both time and temperature. A range of statistical methods will be assessed, including analytical, resampling, and Bayesian techniques, with a focus on a novel semi-Bayesian approach implemented in our R package AccelStab. Second, Bayesian Dynamic Borrowing (BDB) is a promising statistical method to leverage prior knowledge of long-term stability data from a previous formulation to model the new formulation at storage conditions. This technique is based on a robust mixture prior comprised of an informative (strong) component and a conservative (weak) component.

In this talk, the strengths and weaknesses of both approaches will be discussed and nuanced with respect to the non-clinical framework. Finally, we will review two internal projects from vaccine and drug developments submitted to health authorities where lessons and insights will be shared. Ultimately, this talk will illustrate how advanced statistical methodologies can significantly accelerate drug development timelines and enhance regulatory success for new pharmaceutical products.