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Accelerated Stability Study with SestakBerggren R Package: Impact of Statistics for Quicker Access to New Vaccines

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The recent pandemic surged the emergency for quick access to new drugs and vaccines for the patients. Stability assessment of the product may represent a bottleneck when it is based on real-time data covering 2 or 3 years. To accelerate the decisions and ultimately the time-to-market, accelerated stability studies may be used with data obtained for 6 months. We show that the kinetic Arrhenius model is oversimplified to extrapolate the critical quality attribute over time.

On the other hand, the Ordinary Differential Equation (ODE) from Sestak-Berggren model gives one overall model allowing the extrapolation of the degradation both in time and temperature. The statistical modeling of the ODE model (including bias and coverage probabilities, from asymptotic theory and bootstrap) is here evaluated by simulations. Finally, real world data from vaccines development are analysed with the new R package SestakBerggren. This will include decreasing and increasing trends like antigenicity, residual moisture and pH.

Keywords

Differential Equation, Bootstrap, Stability

Classification

Both methodology and application

Primary authors: FRANCQ, Bernard (GSK); Dr SCHMIT, Olivier (GSK); SANCHEZ, Raymundo (GSK); PALUDI, Marilena (GSK)

Presenters: FRANCQ, Bernard (GSK); Dr SCHMIT, Olivier (GSK)

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