SAS® MACRO TO EVALUATE STANDARD AND NONSTANDARD STABILITY DATA ACCORDING TO ICH Q1E

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Pharmaceutical products must be intensively tested to guarantee high safety for patients. Quantifying the stability of a drug is one of the objectives to define a shelf life. ICH Guideline Q1E deals with the statistical evaluation of stability studies and gives detailed information for the standard study and statistical analysis. The suggested statistical analysis can be conducted using analyses of covariance techniques by fitting confidence intervals for mean responses represented by regression lines or curves. But, for nonstandard analyses, such as studies including an additional treatment factor or for nonlinear responses, room for interpretation is left. This talk presents a SAS® macro that performs standard and nonstandard statistical analyses and transfers summary output tables and graphs to Word. Different study designs (e.g., common or independent release data) can be analyzed. After checking the appropriateness of a simple linear approach, a model selection process for different response functions (e.g., Exponential) can be conducted. Based on the selected model, a pre-test checks if a formal statistical evaluation is necessary. Shelf-life calculations can be based on one- or two-sided confidence or prediction intervals. This presentation reviews example output tables and graphs, describes the flexibility of the program, and explains the statistical analysis for nonstandard studies and responses.