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Parallelism Testing Methods for Potency Bioassay Curves - Meiyu Shen, PhD, Office of Biostatistics, Center for Drug Evaluation and Research, FDA

FDA announced plans to phase out animal testing requirement for monoclonal antibodies and other drugs in April 2025. Since then, significant development in statistical methods has made for supporting the FDA initiative to promote use of non-animal bioassay. For instance, a cell-based bioassay not requiring animals might offer an attractive alternative to a mouse LD50 bioassay testing for biological products potency (a critical quality attribute). To reduce measurement variability, the relative potency methodology is adopted for testing the reference material and test material concurrently. Criteria for accuracy, linearity, parallelism should be met for determining a cell-based bioassay as a fit-for-use analytical method. Assuming a test material behaves like dilution or concentration of a reference, we propose assessing the parallelism of dose-response curves of a test material against a reference with parameter difference-based equivalence tests with margins determined from historical data analyzed with the four-parameter logistic model. Simulation studies are conducted to evaluate the proposed method's ability to identify parallelism and non-parallelism across various scenarios.

