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Design of optimal sampling times for pharmacokinetic trials via spline approximation

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Abstract: Understanding and comparison of different drug delivery formulations are based on pharmacokinetic parameters (PKP) such as area under curve, maximum concentration, and time to reach maximum concentration. Accurate estimation of PKP is of critical importance in capturing drug absorption and elimination characteristics and in reaching bioequivalence decisions. Since PKP are estimated from a limited number of samples, the timing of the samples directly influences the accuracy of estimation. Optimization of the sampling times may not only increase the accuracy of PKP estimation, but also reduce the number of samples to be drawn, which in turn lessens the inconvenience to the subjects and the cost of the study. In this study, as an alternative to conventional