

TITLE: Setting and Reporting the Bayesian Decision Threshold under the FDA 2026 Draft Guidance: A Practical Workflow

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ABSTRACT:

The FDA's 2026 draft guidance on Bayesian methods for drugs and biologics endorses three ways to choose the posterior probability cutoff in a Bayesian success rule: a direct posterior probability statement, a benefit/risk loss, and frequentist calibration. We show how to put all three on the same operating-characteristic display so that the prior, the cutoff, the implied false-positive rate, and the implied power can be reviewed together before the design is locked. In a single-arm trial, once the cutoff is set to control type I error, the reject/accept boundary is the standard one-sided test for any reasonable prior; the prior still drives the numerical cutoff and the posterior summary, but not the binary decision. The conventional fixed cutoff $c = 0.975$ does not have this property and, across the prior configurations we examined, implies a type I error rate from near zero under skeptical priors up to 10.2% under optimistic ones. In a two-arm trial that borrows from a historical control, no single cutoff aligns the Bayesian rule with the standard test, and the false-positive rate depends on the true control effect; we cap it over a prespecified plausible interval and compare against no-borrowing and several common borrowing rules. We illustrate the workflow on a hypertension trial and provide a short Decision Charter that documents the prior, the cutoff rationale, and the operating-characteristic translation for the statistical analysis plan.