EARLY ONCOLOGY • BAYESIAN DECISION SCIENCE

Bayesian Lalonde Go/No-Go Framework for Early Oncology

Selecting neutral priors and controlling decision risk

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A transparent path from evidence to action

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A Three-outcome Bayesian Framework To Guide Early Oncology Development

EARLY ONCOLOGY

Small studies increase decision uncertainty

Early oncology often relies on small, single-arm studies. Objective Response Rate (ORR) is a common efficacy endpoint.

EVIDENCE BENCHMARKS[2]

LRV (Lower Reference Value) — Minimal clinically meaningful ORR

Below this level, efficacy is insufficient.

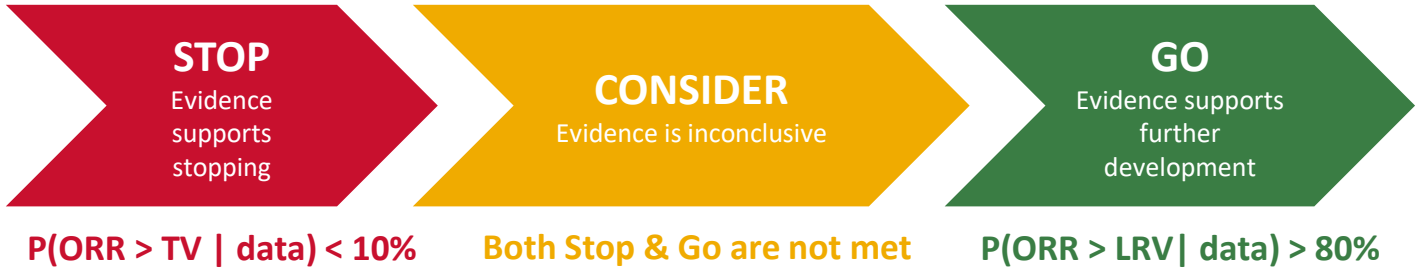
TV (Target Value) — Desired/Target ORR

At this level, efficacy is promising.

FROM EVIDENCE TO ACTION

The Bayesian Lalonde framework extends the approach proposed by Lalonde et al.[1]

POSTERIOR EVIDENCE FOR TREATMENT ACTIVITY →



CONTROL TWO COMPETING RISKS



Advance an ineffective treatment

End a promising treatment too soon

[1] Lalonde RL, Kowalski KG, Hutmacher MM, et al. (2007). Model-based Drug Development. Clinical Pharmacology & Therapeutics, 82, 21–32. https://doi.org/10.1038/sj.clpt.6100235

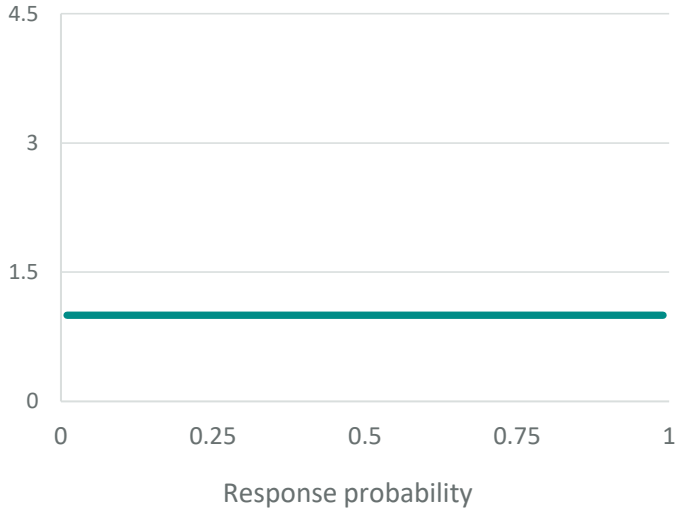
[2] Frewer P, Mitchell P, Watkins C, Matcham J. (2016). Decision-making in early clinical drug development. Pharmaceutical Statistics, 15(3), 255–263. https://doi.org/10.1002/pst.1746

Same Prior Mean, Different Dispersion—and Potentially Different Decision Risk

Same prior mean: 0.5 • Decreasing prior effective sample size (α + β) from left to right →

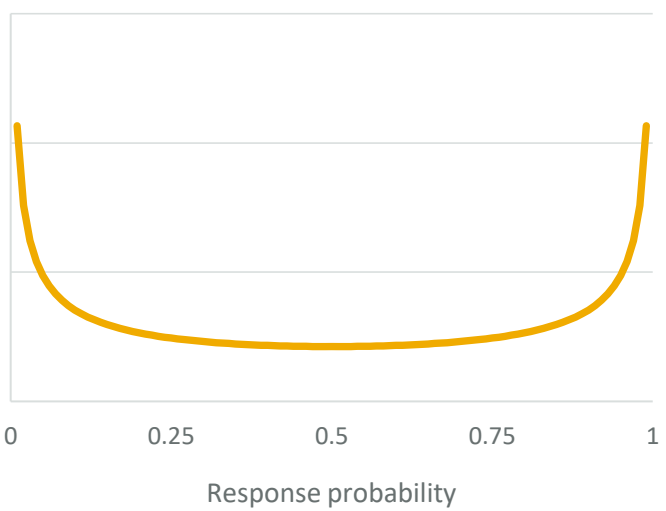
UNIFORM PRIOR

Beta(1, 1) α + β = 2.0



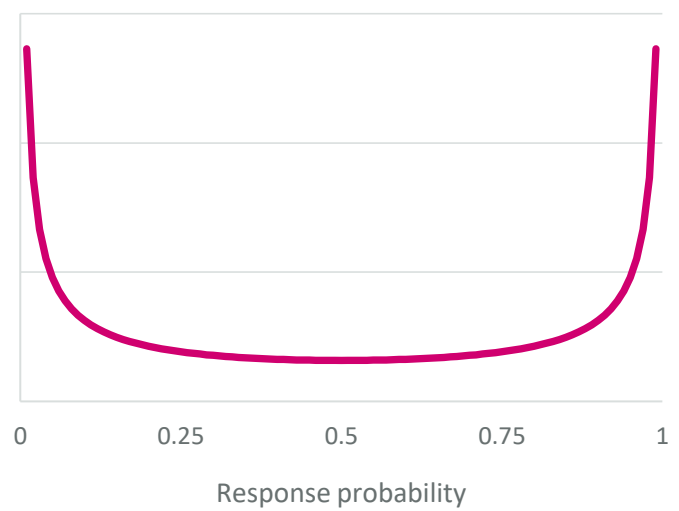
JEFFREYS PRIOR

Beta(0.5, 0.5) α + β = 1.0



WEAKLY INFORMATIVE PRIOR

Beta(1/3, 1/3) α + β = 0.67



WHAT WE TEST NEXT

Which prior best balances false Go and false Stop risks?

FALSE GO • GO GIVEN TRUE ORR = LRV

FALSE STOP • STOP GIVEN TRUE ORR = TV

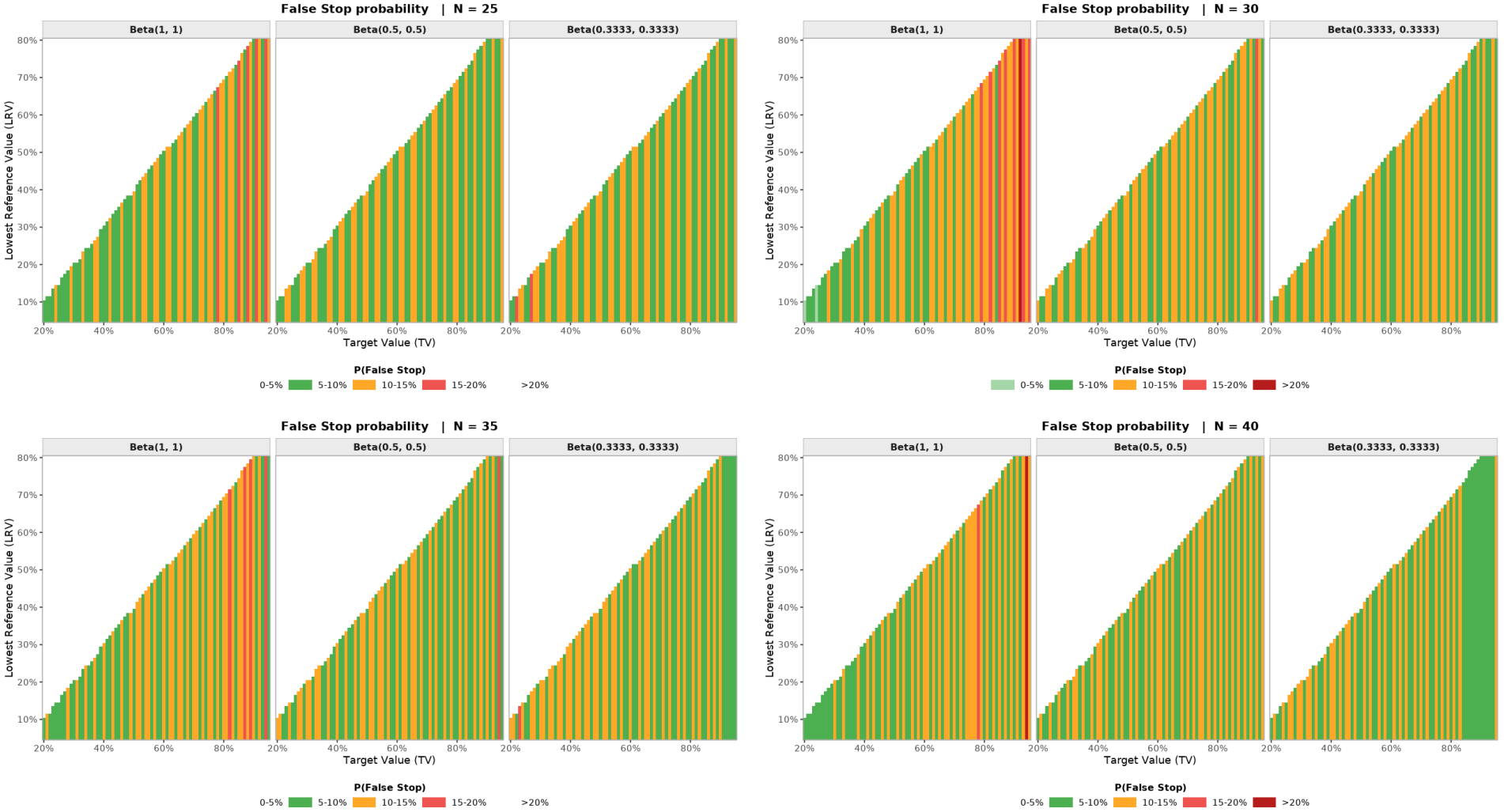
Simulation—not prior shape alone—reveals the impact on decision risks

Sensitivity of False Stop Risk to Prior Choice

Larger ‘green zones’ indicate better control of ‘false stop risk’

Stop criteria: P(ORR > TV | data) < 10%

Promising scenario: true ORR = TV • Sample sizes: N = 25, 30, 35, 40



KEY READOUT

Beta(1/3, 1/3) shows the most favorable ‘false stop risk’ pattern across sample size

WHERE IT SEPARATES

Differences in Green zone size across priors are clearest when true ORR (=TV) exceeds the prior median (50%)

IMPLICATION

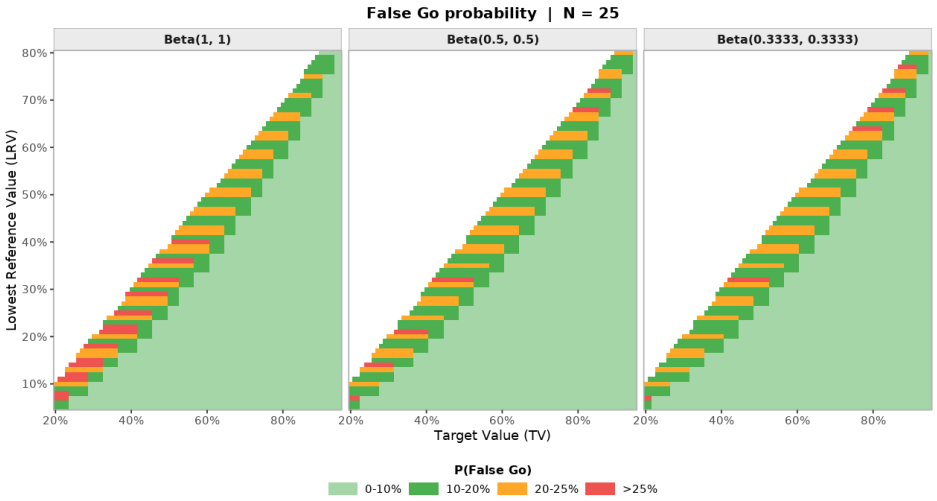
Understand differences in ‘false stop risk’ pattern alongside ‘false go risk’

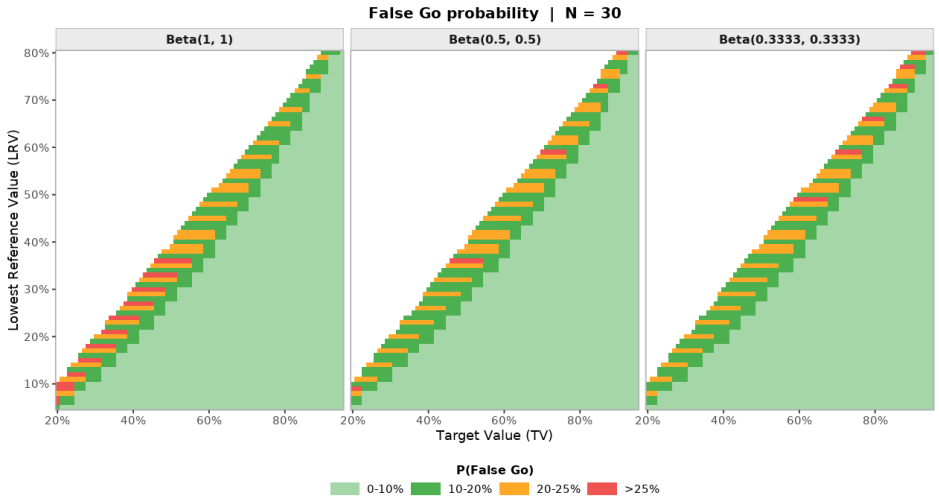
Sensitivity of False-Go Risk to Prior Choice

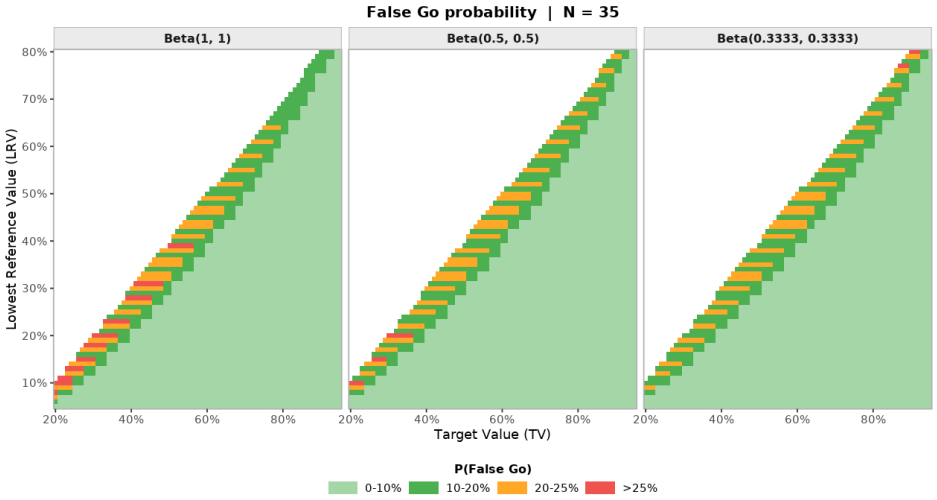
Larger 'green zones' indicate better control of 'false go risk'

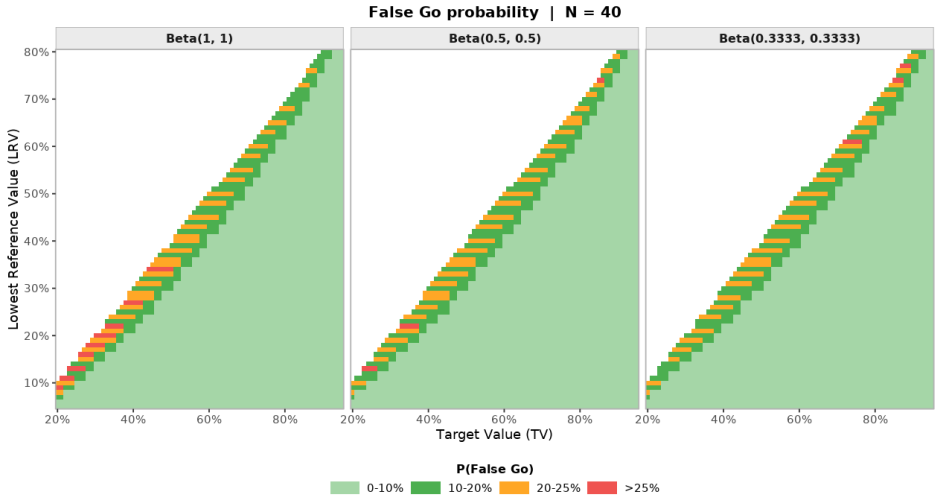
Go criteria: P(ORR > LRV| data) > 80%

Marginal activity scenario: true ORR = LRV • Sample sizes: N = 25, 30, 35, 40









KEY READOUT

False go risk is similar across priors; differences are visible when LRV is close to TV

SAMPLE-SIZE SIGNAL

Larger samples add information, but prior effects remain

IMPLICATION

Beta(1/3, 1/3) does not materially increase false go risk.
When accounting for both false stop and false go risks, Beta(1/3, 1/3) supports a favorable overall risk balance

Prior Choice Influences Decision-Risk Balance

Transparent decision rules define the framework; simulation evaluates how prior choice affects risks

01	**Structure decisions**	The Bayesian three-outcome Go/No-Go framework uses posterior probabilities to translate ORR evidence into actionable decisions
02	**Simulate before confirming a prior**	Different minimal informative prior candidates can produce different operating characteristics, especially in small studies with binary endpoints
03	**Prefer the balanced option**	Beta(1/3, 1/3) shows lower ‘False stop risk’ in the evaluated scenarios, with comparable ‘False go risk’ across sample size

TAKE-HOME **Beta(1/3, 1/3) is a promising candidate prior; confirm its suitability through design-specific simulation and sensitivity analysis.**

References

Lalonde RL, Kowalski KG, Hutmacher MM, et al. (2007).

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