

## **A Bayesian Perspective on the Two-Trial Rule**

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The two-trials rule for drug approval requires "at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness". This is usually employed by requiring two significant pivotal trials and is the standard regulatory requirement to provide evidence for a new drug's efficacy. Recently some alternatives to the two trials rule have been suggested, such as the 2-of-3 rule (Rosenkranz, 2023) and Edgington's p-value combination method (Held, 2023). However, all these methods are based on p-values but the direct statistical approach to quantify evidence is the Bayes factor. I will compare the two-trials rule and some alternative approaches in terms of their Bayes factors based on suitable transformations of p-values into Bayes factors (Held and Ott, 2018).

Held, L. (2023). Beyond the two-trials rule. Soon available as preprint.

Held, L. and Ott, M. (2018). On p-values and Bayes factors. *Annual Review of Statistics and Its Application* 5, 393-419.

Rosenkranz, G. (2023). A generalization of the two trials paradigm. *Therapeutic Innovation & Regulatory Science*, 57:316–320.