

TITLE: Bayesian Methods in Registered Clinical Trials: A Systematic Review of Studies Registered on ClinicalTrials.gov

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ABSTRACT: Bayesian methods are increasingly used in clinical trial design and analysis for their ability to incorporate prior information, enable flexible decision-making, and support complex inference. Previous reviews by Lee and Chu (2012)[1], Biswas et al. (2009)[2] and Tidwell et al. (2019)[3] examined the implementation of Bayesian analyses in published trials. However, no systematic review has characterised how Bayesian methods are reported in publicly registered interventional studies.

Therefore, we performed an updated review of clinical trials self-referencing as having Bayesian components, a review of freely available information on *clinicaltrials.gov*.

All trials within *clinicaltrials.gov* in December 2024 were searched using terms relating to Bayesian methods or terms likely mentioned by trials using Bayesian methods (e.g. Bayes, prior, posterior, continuous reassessment).

Of 6,293 trials found within the search criteria on *clinicaltrials.gov*, 115 met eligibility criteria of using Bayesian methods either in design or analysis of the trial. We extracted data for each included trial characteristics such as phase, therapeutic area, Bayesian design features (e.g. endpoints analyzed, prior type, decision criteria), adaptive components, and regulatory context.

We will present descriptive results of trial characteristics, and will compare these findings to the 122 published trials summarized by Lee and Chu (2012) to analyse current patterns to historic trends, highlighting if there has been a recent uptake in adoption of Bayesian methods and if there has been any change in the types of trials utilising Bayesian methods and if there are still areas of underutilisation.

[1] Lee JJ, Chu CT. Bayesian clinical trials in action. *Stat Med.* 2012;31(25):2955-2972. doi:10.1002/sim.5404

[2] Biswas S, Liu D, Lee J, Berry D. Bayesian clinical trials at the University of Texas M.D. Anderson Cancer Centre. *Clin Trials.* 2009 Jun;6(3):205-16 doi:10.1177/1740774509104992

[3] Tidwell R, Peng S, Chen M, Liu D, Yuan Y, Lee J. Bayesian clinical trials at the University of Texas MD Anderson Cancer Centre: An Update. *Clin Trials* 2019 Dec;16(6):645-656. Doi: 10.1177/1740774519871471

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