

Type	Section	Line no	Comment	Suggested Changes
minor	II. BACKGR OUND	37		"a framework for" instead of "an approach to"
minor	III.	70		Could add ", which specifies the posterior as proportional to the prior times the likelihood" at the end of the sentence to more reflect the mathematical formula.
minor	III.	78	It would be helpful if the "other settings" could be elaborated--some examples could be added.	
minor	III. A.	89-93	In the REBYOTA study, it would be helpful to indicate whether both the treatment and control data from the Phase 2 were borrowed.	
minor	III. B.	99		Perhaps add ", e.g., in rare diseases," after "limited population"
major	III. C.	126-128	What patient or disease characteristics were considered or used to identify relevant information?	
major	III. D.	138-141	While similarities are leveraged, how can the degree of that similarity be employed to determine degree of borrowing? How is uncertainty due to potential differences quantified?	
minor	IV. A.	191-194		A reference to the "Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products" guidance after the last sentence would be helpful.
minor	V. B.	394-396		Could add that minimally informative priors are also termed "vague" or "diffuse" priors
minor	V. B.	401-403	I'm not sure if "tend to be overwhelmed by the observed data" is the best wording. Noninformative priors are designed to have minimal influence on the posterior distribution such that results are more data driven; they allow for Bayesian inference and interpretation of results.	
minor	V. D. 2	526-529	Could mention the use of propensity score approaches (incorporated in construction of priors) to help identify subjects to borrow from and adjust for potential differences in patient characteristics in external subjects.	
minor	V. D. 4	684-695	Could indicate that the meta-analytic predictive prior is an example of such a mixture prior.	Cite Nuenschwander et al. (2010): Summarizing historical information on controls in clinical trials Schmidli et al. (2014): Robust meta-analytic-predictive priors in clinical trials with historical control information
minor	II.B.	62	Posterior median is also widely used in lots of situations.	Posterior mean or median
minor	V.F.	771	The parameters of the prior distributions should also be tested.	add it to "utilize a range of alternative reasonable choices with different parameters for the prior distribution".
major	VI.	778	More details and strategies should be provided on how to deal with missing data.	The strategy should be given when dealing with different situations of missing completely at random, missing at random, and missing not at random.
major	V.	372	The priors of the time-varying covariates haven't been discussed.	In the prior section, general suggestions are given on how to choose regular priors. When dealing with time-varying covariates, which are widely observed in real-world healthcare studies, strategies should be given in setting up the priors for them.
major	V.	372	In Bayesian analysis, the likelihood functions are very important, but the likelihood functions haven't been discussed in this draft.	With different types of outcomes, such as continuous, binary, and time-to-event, Guidance should be given on how to set up the likelihood functions. When the sample size is large, the likelihood tends to put more weight than the priors. While with a limited sample size, the priors put more weight than the likelihood. Also, there are lots of choices of likelihood, like the normal distribution or the robust likelihood function. More discussion should be given.

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minor	F.	764	Other issues, like extreme observations and outliers in continuous outcomes, competing risk in survival data, and strong correlation among features, haven't been discussed.	More strategies should be given on how to choose priors when dealing with these situations.
minor	III.	73	Consider including examples demonstrating approaches for borrowing information from Real-World Data or other non-trial data sources	
minor	V.D.2	483-486	Some clarifications on whether any prioritization is suggested among the listed sources of evidence	
minor	VI.	780-788	Considerations regarding patterns of missingness and their impact on Bayesian methods should be discussed	
minor	F.	766-775	any standardized frameworks should be considered when conducting and reporting sensitivity analyses	
minor	VII	833	clarify whether any mandate-specific standardized diagnostic reports are required or expected	