U.S. FOOD & DRUG ADMINISTRATION

GUIDANCE SNAPSHOT

Use of Bayesian Methodology in Clinical Trials of Drugs and Biologics

DRAFT GUIDANCE FOR INDUSTRY (JANUARY 2026)

What is covered in this guidance?

This guidance provides recommendations on the appropriate use of Bayesian statistical methods to support primary inference in clinical trials that evaluate the effectiveness and safety of new drugs (human drugs and biological products). The guidance offers general and specific examples of Bayesian methods used in drug development programs. Examples include the use of "borrowing" or "leveraging" data from previously available trials or from information across populations within a trial. The guidance also provides recommendations on the choice of success criteria, evaluation of trial operating characteristics, determination of the prior distribution, handling of missing data, and software usage.

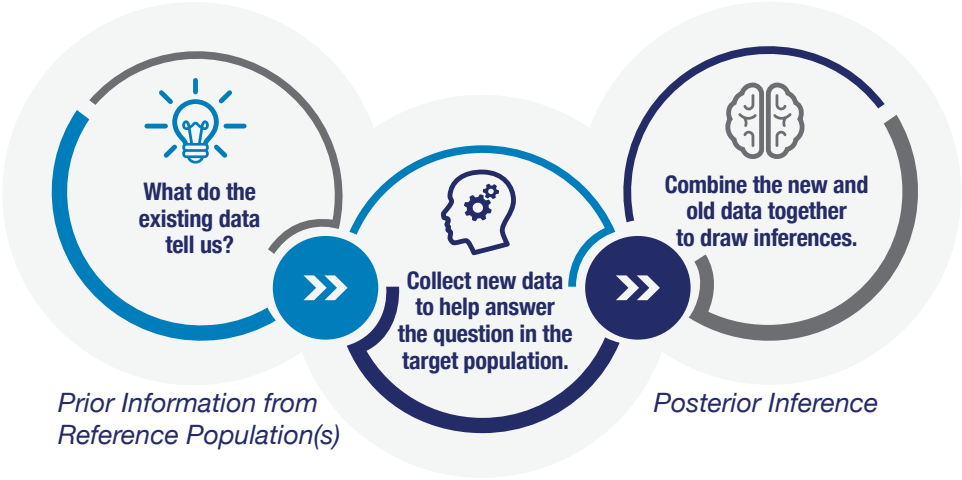
What are Bayesian statistical methods?

Bayesian approaches use a different statistical framework from the frequentist approaches more commonly used in clinical trials. Bayesian statistics provide an approach to estimation or hypothesis testing based on the use of Bayes' theorem, a mathematical rule for combining a prior distribution and likelihood together to form a posterior distribution. In a Bayesian analysis, the prior distribution captures the pre-study information about the parameter of interest, and the likelihood summarizes the data collected in a study. The posterior distribution expresses the updated, post-study information about the parameter of interest.

Why is this guidance important?

Bayesian methods have been used and can be considered in various clinical trial settings, and the recommendations in this guidance are important to ensure the methods are used appropriately.

Bayesian Inference Framework



Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about using Bayesian methodology in clinical trials, read the guidance.

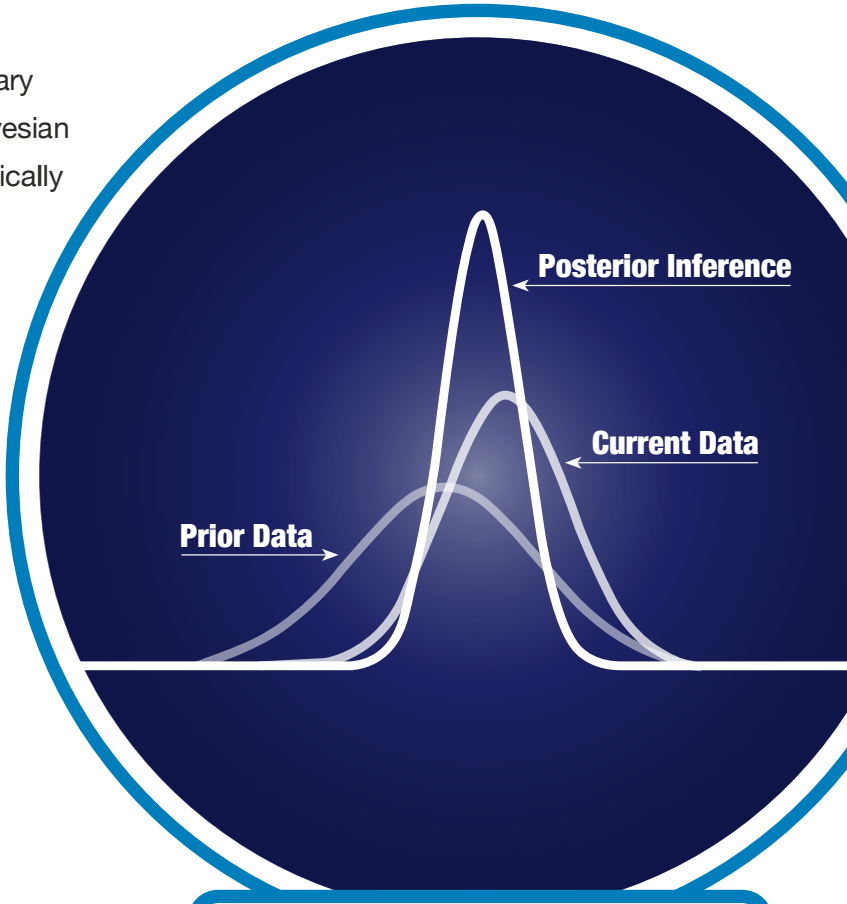
SUCCESS CRITERIA AND OPERATING CHARACTERISTICS IN CLINICAL TRIALS

Success criteria

Success criteria help in determining whether the primary objectives of the clinical trial are met. When using Bayesian inference for the primary analysis, success criteria typically used in frequentist statistical analysis plans may not be applicable or appropriate. Sponsors should carefully specify success criteria in Bayesian designs and analyses.

Operating characteristics

Operating characteristics summarize how a planned trial is likely to perform in terms of supporting correct conclusions and reliable estimation of treatment effects. Clinical trial simulations are generally used to estimate or demonstrate control of operating characteristics.



PRIOR DISTRIBUTIONS

Use of a prior distribution is the main feature distinguishing Bayesian from frequentist approaches. Such prior distributions allow an analysis to leverage the available information.

Sponsors should pre-specify and justify the proposed prior distribution in the protocol. The justification should address the prior distribution's influence on results and the operating characteristics of the design. Sponsors should design, implement, and document their process for constructing the prior in a systematic and transparent manner.

When evaluating whether and how much to leverage external information to ensure that conclusions relying on such information are reliable and interpretable, sponsors should consider several factors such as data quality and reliability, pre-specification, relevance, design of studies providing the information, and the availability of patient-level data.

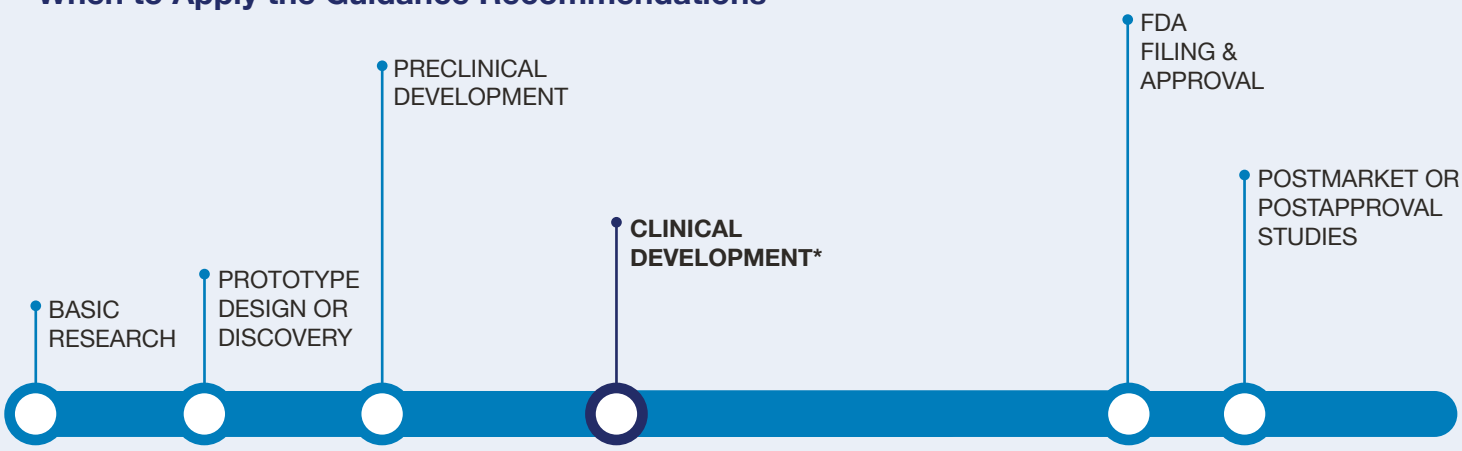
Timing of Design Proposals

Clear documentation and transparency about a trial's design, analysis plan, and assumptions are critical when using a Bayesian approach, particularly when using external information to construct the prior distribution. The guidance recommends detailed information that should be pre-specified and submitted to FDA prior to trial initiation to ensure adequate time for discussion and feedback. The guidance also provides specific recommendations on the content of clinical study reports to ensure adequate transparency after a completed trial.

DRUG DEVELOPMENT TIMELINE: WHEN TO APPLY THE GUIDANCE RECOMMENDATIONS

MEDICAL PRODUCT DEVELOPMENT TIMELINE

*** When to Apply the Guidance Recommendations**



Recommendations from this guidance typically apply during clinical development, but many of the recommendations can apply to any phase of medical product development.

Guidance Recap Podcast

Hear highlights from FDA staff

Speaker:

James Travis, PhD, Master Mathematical Statistician
Division of Biometrics II, Office of Biostatistics
Office of Translational Sciences

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Continue the Conversation

Share your thoughts on the draft guidance (docket opened on 1/12/2026)

Click here to provide official comments to the FDA Docket

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