Bayesian Statistics in Medical Device

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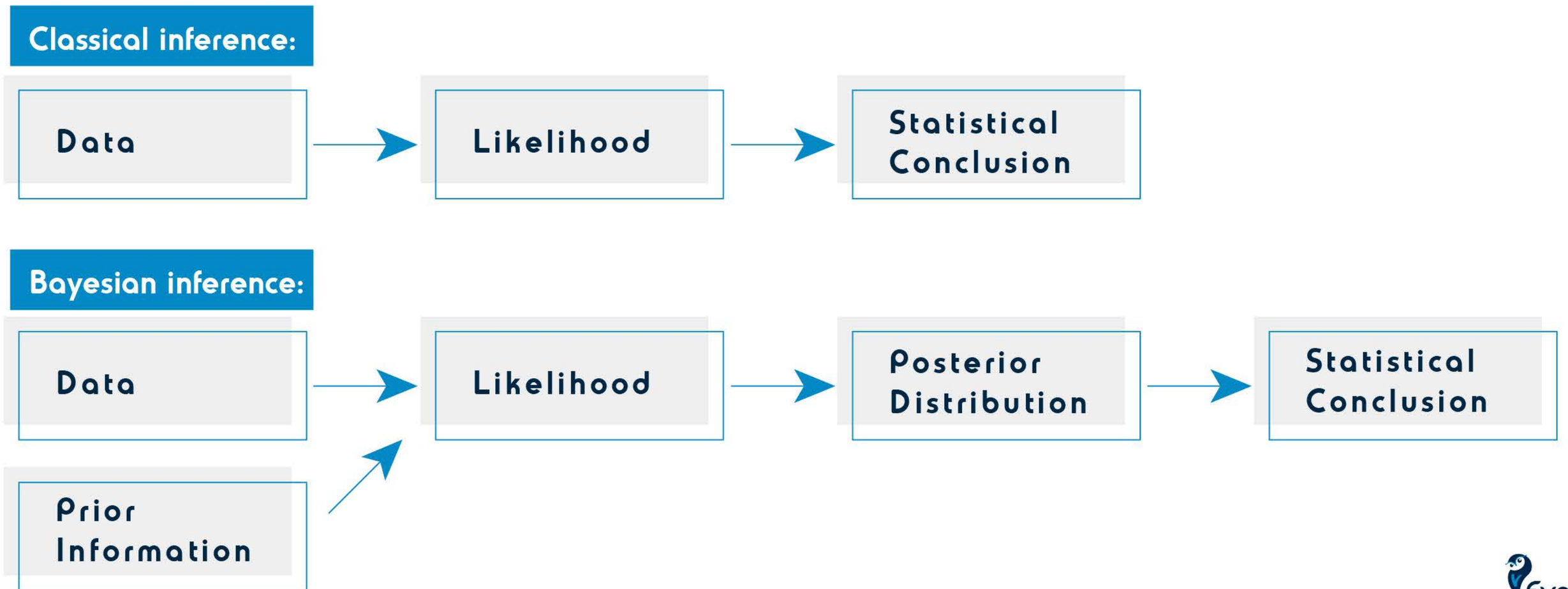
Bayesian statistical analysis incorporates prior probability distribution and observed data to determine an a posterior probability distribution of events.



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- In clinical trials, traditional (frequentist) statistical methods may use information from previous studies only at the design stage.
- In contrast, the Bayesian approach uses Bayes' Theorem to formally combine prior information with current information on a quantity of interest. The Bayesian idea is to consider the prior information and the trial results as part of a continual data stream, in which inferences are being updated each time new data become available.

Why use Bayesian statistics in medical Device field?

Medical device clinical trialists are increasingly confronted with data that feature complex correlation structures, and are costly and difficult to obtain. In such settings, Bayesian trial designs are attractive since they can incorporate historical data or information from published literature. **Prior information** for a device may be a justification for:

1. Minimizing the number of subjects exposed to an inferior treatment
2. Adapt to unexpected changes in the protocol
3. Allow the investigator to explore the plausibility of various outcome scenarios before any patients are enrolled in the trial
4. Sorter duration trials
5. Prior information based on historical control data
6. Adjustment for missing data & sensitivity analysis

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Benefits of using Bayesian methods:

1. More Information for Decision Making
2. Sample size reduction via prior information
3. Sample size reduction via Adaptive Trial Design
4. Flexibility of midcourse changes to a trial
5. Missing data
6. Multiplicity

Potential challenges:

1. Extensive preplanning is especially crucial for a Bayesian trial
2. Extensive model-building
3. Specific statistical and computational expertise
4. Bayesian and frequentist analyses approaches may differ in their conclusions, studies with the same data and a different preplanned analysis could conceivably reach different conclusions that are both scientifically valid
5. Problems with the use of prior studies with using a hierarchical model when only a single prior study is available.(possible solution: power priors)
6. More Bayesian research is needed for the handling of missing data

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FDA Guidance- recommendations:

1

The quantitative basis for prior information, the use of decision rules based on posterior distributions, and the need for prospective well-planned Bayesian designs and analyses.

2

Exchangeability of studies that would be used in the incorporation of prior information by building a hierarchical model.

3

Exhaustive description of the simulations for the Bayesian design.

4

Good prior information: Good prior information is often available for medical devices because of their mechanism of action and evolutionary development. In any case the need of strong and precisely quantified prior information is of hight importance and will be evaluated by the FDA in order to ensure the prior information does not overwhelm the current data.

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YEARS

has been used for more than ten years in medical device pre-market submissions to the FDA

YEARS

at least seven years in post market surveillance of medical products

There is also an increasing number of Bayesian methodological papers and a number of successful Bayesian clinical trials reported. Despite some challenges that require more methodological development, the promise of using Bayesian methods for incorporation of prior information as well as for conducting adaptive trials is great