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Clinical Trials – A Bayesian Approach

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Introduction

Bayesian approach in the design and analysis of clinical trials is gaining wide application in the industry

Bayesian statistics uses a mathematical approach to effectively utilize prior and current information

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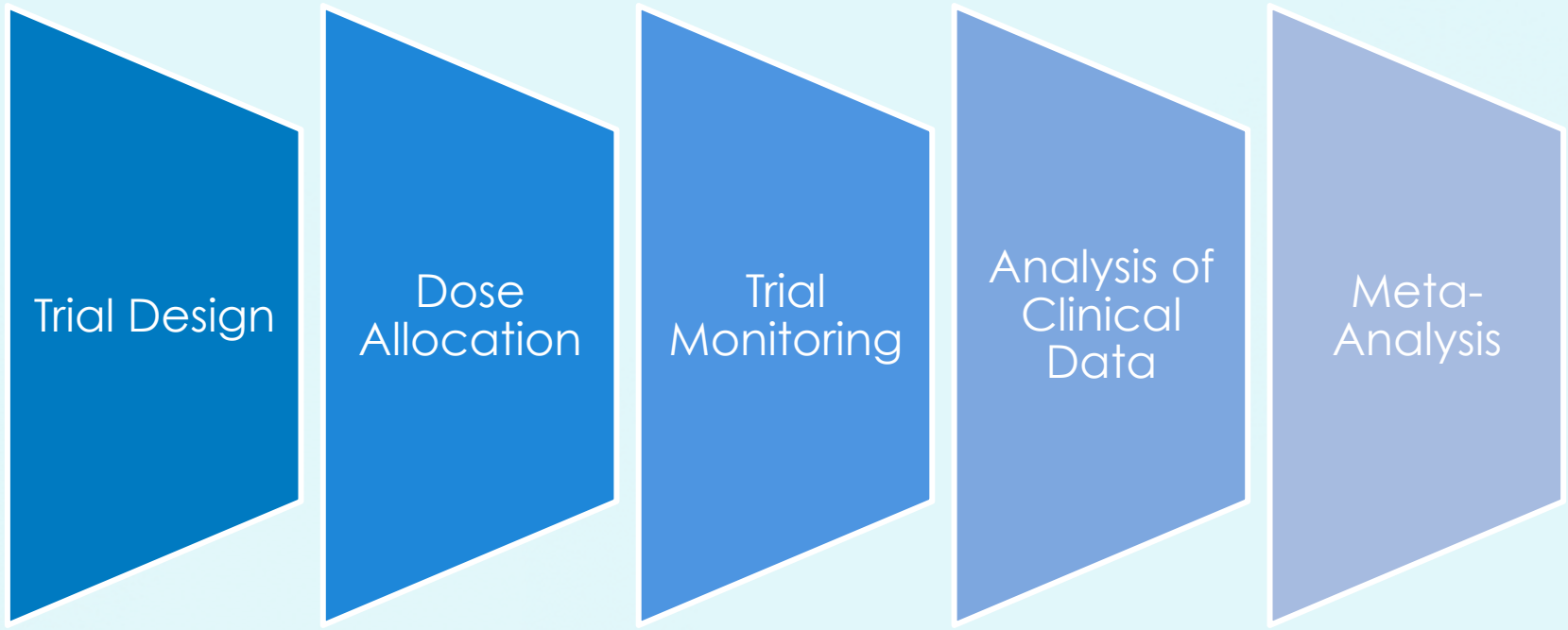
Where does it find its application?



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Bayes' Theorem

The roots of Bayesian Statistics lies in Bayes' theorem

Bayes' Theorem is a rule about probabilities which is used in any analysis describing random variables

Thus for two events A and B...

$P[A | B] = P[A \text{ and } B] / P[B] = P[B | A] \, (P[A] / P[B])$

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Bayesian Approach

Starts with a prior belief and then uses new evidence to attain a posterior belief

Provides a mathematical method for calculating the likelihood of a future event based on prior knowledge

Uses the 'language' of probability to describe what is known about parameters

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Components of Bayesian Approach

- Prior distribution
- Likelihood principle
- Posterior probabilities
- Predictive probability
- Exchangeability of trials
- Decision rules

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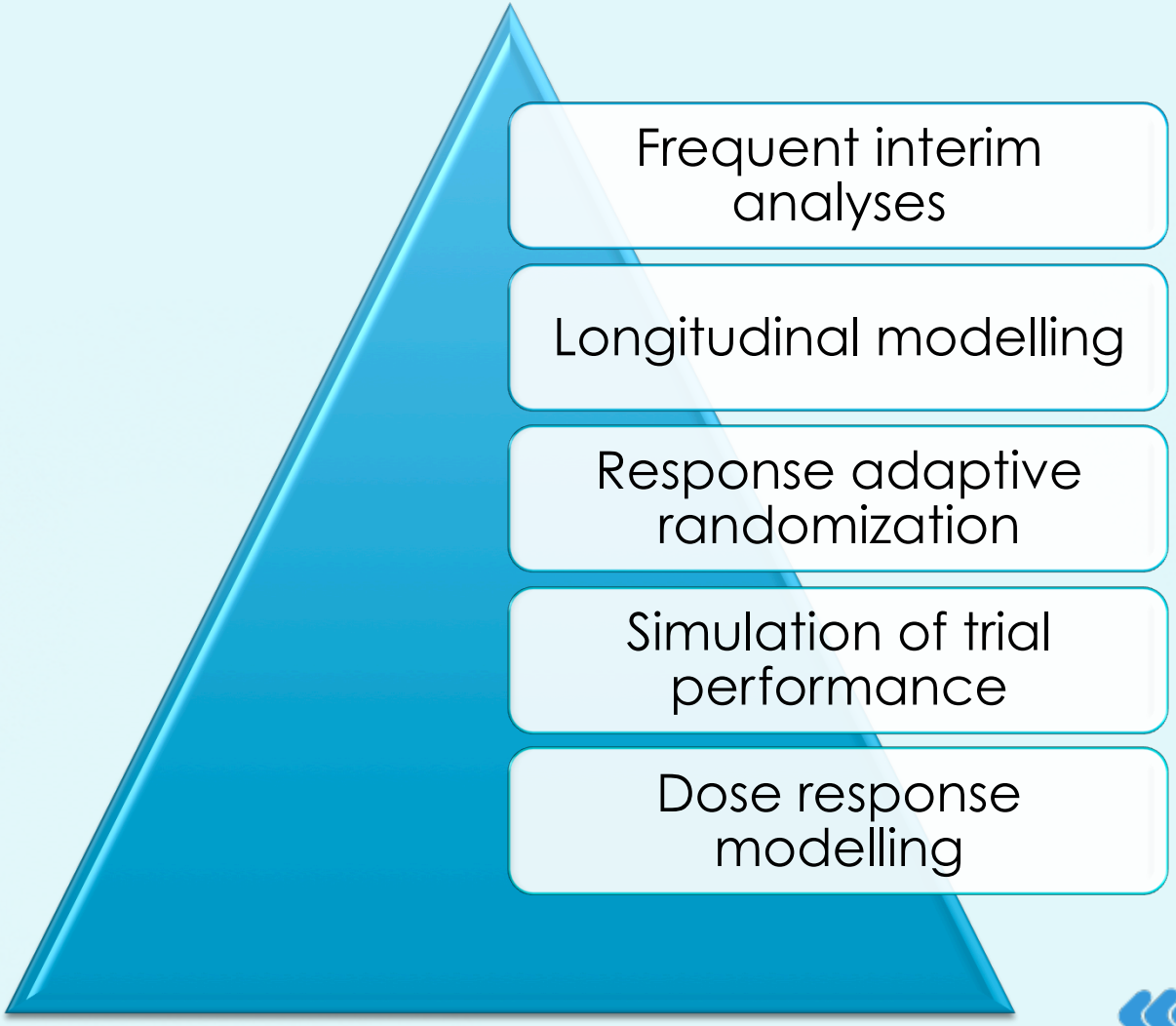
Bayesian Strategies



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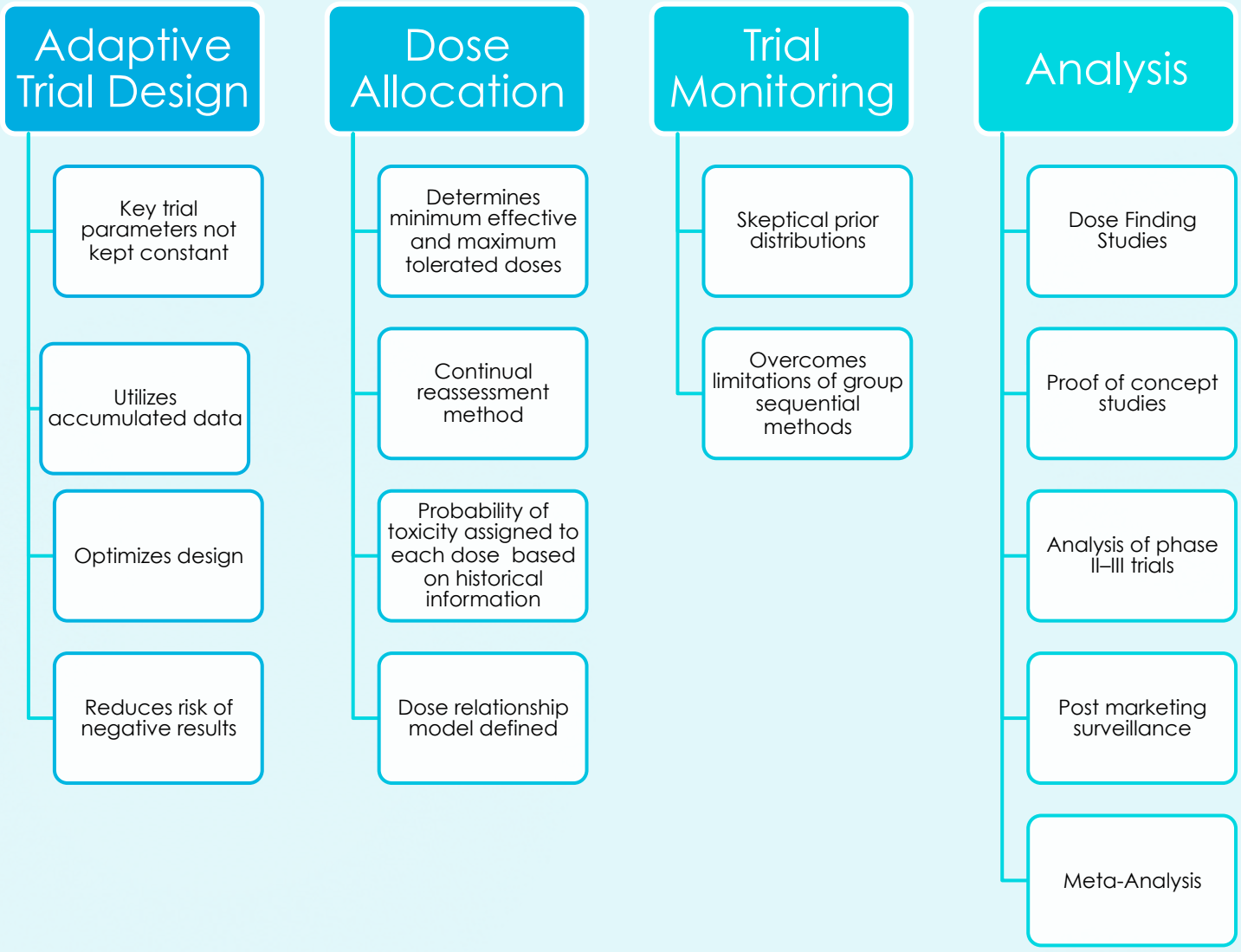
Applications of Bayesian Approach



Advantages of Bayesian Approach

- Provides formal mechanism for using prior information
- Places emphasis on estimation and graphical presentation rather than hypothesis testing
- Avoids the confusion over use of 1–tailed/2–tailed test
- Allows use accumulating information from current well as other trials

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Limitations of Bayesian Approach

- Posterior probabilities may be hard to compute
- Requires good statistical knowledge to choose the prior distribution
- Choice of data inclusion from other trials should be done carefully
- Adherence to regulatory requirements
- Ethical considerations

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Case Studies

Sample Size Calculation

Safety Analysis

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References

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- An Overview of Bayesian Adaptive Clinical Trial Design, Roger J. Lewis, MD, PhD, Department of Emergency Medicine, Berry Consultants, LLC

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THANK YOU

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