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Hype, Not Hope: Using Bayesian Methods in Drug Development

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OBJECTIVES: The application of Bayesian methods in drug development has been controversially discussed on the basis of theoretical, empirical, and practical arguments. This debate has gained new momentum by a recent publication by Ruberg et al. (2023) [1] who proposed that Bayesian approaches have the potential to be "the single most impactful tool for accelerating the development of new medicines". Here, I discuss the various arguments in favor of Bayesian methods in drug development and explain why these arguments may make Bayesian analysis actually less attractive to drug developers and regulators, thereby, creating hype, not hope for their adoption.

METHODS: The presented arguments in favour of Bayesian methods which have been presented in selected influential publications, e.g. Ruberg et al. (2023), are critically discussed and if possible, solutions to the raised issues are proposed.

RESULTS: For example, fundamental distinctions between frequentist and Bayesian approaches with enormous consequences are stated. However, the priority for regulators is more on being conservative and consistent and less on being innovative. Therefore, such a statement may make the application of Bayesian methods less likely. In addition, this statement is exaggerated. Bayesian and (likelihood-based) frequentist approaches will give similar if not identical results if a non-informative prior distribution is used. They will also converge towards identical results as more data are collected. Therefore, it may be wiser to emphasize the similarities of frequentist and Bayesian approaches rather than the (presumed) differences.

CONCLUSIONS:

Although the author initially stated that he expected “hype, not hope” for Bayesian methods in drug development, his hope actually is that by addressing the raised issues the advantages, which Bayesian statistical rethinking has to offer, become clearer to drug developers and regulators.

REFERENCES: [1] Ruberg, S. J. *et al.* Application of Bayesian approaches in drug development: starting a virtuous cycle. *Nat Rev Drug Discov* 1–16 (2023) doi:10.1038/s41573-023-00638-0.

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Program Selection:
Research

Preferred Presentation Format:
Either poster or podium

Research Study Approach:
Conceptual Papers

Main Topic/Taxonomy:
Methodological & Statistical Research

Subtopics:
Does Not Apply: Does Not Apply
Health Policy & Regulatory: Approval & Labeling
Health Policy & Regulatory: Coverage with Evidence Development & Adaptive Pathways
Methodological & Statistical Research: Confounding, Selection Bias Correction, Causal Inference

Primary Specific Diseases & Cond./Specialized Treatment Areas:
No Additional Disease & Conditions/Specialized Treatment Areas

Additional Diseases & Conditions/Specialized Treatment Areas:
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