



Bayes 2023, Utrecht, October 25-27, 2023

## Hype, Not Hope: Using Bayesian Methods in Drug Development

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## Motivation

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- **Advocacy for use of Bayesian statistics** in drug development (eg Ruberg et al., 2023)
- **Slow adoption of Bayesian methods by regulators** (and hence drug developers) in spite of repeated advocacy with similar arguments in the past
- **Discussion of main issues** (cf Igl & Constant, 2023)



## Main Issues

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1. **Overstatements:** Bayesian statistics is not fundamentally distinct with enormous consequences (cf Gill, 2011)
2. **Miscommunication** to target audience: Regulator's priority is to be conservative and consistent and not innovative (cf Campbell, 2020)
3. **Inappropriate Bayesian methods:** Bayesian methods may show massive inflation of risk for false positive conclusion (cf Berry et al., 2013; Chu & Yuan, 2018)
4. **Poor empirical examples:** questionable assumptions, no added value (cf Senn, 2022)



# Recommendation

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1. **Balance** the presentation of differences and (!) similarities
2. **Target communication** to audience
3. **Evaluate operating characteristics** based on regulatory standards
4. **Promote Bayesian studies** which actually show added value

## References

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