Bayes Bayesian Biostatistics Leiden, NL 2026

PANEL DISCUSSION

Bayes in Regulatory Science

John Scott, FDA

James Travis, FDA

Juan Jose Abellan, EMA

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Sebastian Weber, Novartis

MODERATORS

Brad Carlin, PhaseV Trials · Sofia Villar, University of Cambridge

FDA

John Scott & James Travis

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The FDA traditionally avoids highly prescriptive guidance to preserve flexibility for trial sponsors. Yet this new Bayesian guidance contains over 70 uses of the word “should”, and devotes four pages just to reporting and documentation requirements. Is this detailed “steer” intended to provide rare regulatory predictability for complex designs, or should sponsors read this level of prescriptiveness as a warning that Bayesian submissions will face a much higher level of scrutiny than traditional designs (perhaps discouraging Bayesian submissions)?

EMA

Juan Jose Abellan & Peter van de Ven

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You've both been active in the development of the EMA concept paper for the development of a reflection paper on the use of Bayes in clinical development. That document brings up the idea of “how to assess error control ... in the absence of frequentist inference.” What does acceptable alternative calibration look like in practice? Are regulators open to average (prior-weighted) Type I error, or a higher worst-case α (e.g., 10% or 15%) in high-unmet-need settings? Or does “uncalibrated” imply moving to a pure decision-theoretic or health-economic framework?

FOLLOW-UP — for John and James: *What is FDA's current take on this issue?*

ACADEMIA

Yuan Ji

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Recent work like the Schneider et al. paper suggests we may have reached a point of diminishing returns in trying to invent new dynamic borrowing tuning parameters to boost power while strictly capping worst-case Type I error. Given that this space is becoming so crowded, is it time for the methodological community to push regulators toward alternative metrics (e.g., Nicky Best's average Type I error frameworks, Andy Grieve's pre-posterior/EVSI decision-theoretic approach, etc.)? Beyond these (and your own talk), where do you see the biggest needs for new methodological development?

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Sebastian Weber

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Alongside developing packages such as RBesT and OncoBayes2, you maintain the Bayesian Applied Modelling in Drug Development website, which presents worked case studies across drug development. What motivated you to develop this resource, and what does it tell us about the topics that Bayesian guidance documents and the wider community should address more explicitly? Does a lack of practical modelling expertise among sponsors continue to hamper the use of Bayesian methods in regulatory settings?

FDA

John Scott & James Travis

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The Bayesian guidance provides extensive discussion on the development of prior distributions, especially those derived from historical data, adaptive borrowing, discounting, and effective sample size (ESS). These methods for cautious borrowing are helpful, but the document stops short of discussing causal inference techniques (such as propensity matching) for correcting bias. Can you say a bit more about the agency's position on causal tools and related techniques for bias correction (e.g., via propensity matched power priors)?

FOLLOW-UP — for Juanjo and Peter: *How does EMA view causal inference, and do you see causal tools being included in the EMA reflection paper?*

EMA

Juan Jose Abellan & Peter van de Ven

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Critics sometimes worry that adaptive or Bayesian approaches create opportunities for operational bias or excessive flexibility. How should regulators (and sponsors) distinguish principled adaptation from “moving the goalposts”?

FOLLOW-UP — for Sebastian: *How do those concerns look from the sponsor side?*

ACADEMIA

Yuan Ji

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Bayesian borrowing and adaptive designs can dramatically accelerate learning, especially when incorporating external or real-world data. Where do you think the statistical community still lacks consensus about when these methods are trustworthy?

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Sebastian Weber

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From the perspective of a large pharmaceutical company, where are you seeing genuine enthusiasm for Bayesian and AI-assisted workflows and innovative trial designs, and where are organizations still hesitant?

John Scott & James Travis

The guidance is just one of several big changes announced by FDA in the past year, including “one good trial”, the use of agentic AI by FDA reviewers, and the pilot program in real-time clinical trials (RTCTs). Do you see the Bayesian guidance as part of a broader agencywide effort to further streamline drug and device approvals?

EMA

Juan Jose Abellan & Peter van de Ven

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Last year's Bayesian guidance from ICH seems to restrict the use of Bayes to settings "when the reasons for their use are clear and when the resulting conclusions are sufficiently robust". Many Bayesians were unhappy with this wording, since it seems to codify the old-fashioned thinking that Bayes is only sensible as a “last resort.” Can you say a little about your vision for handling this issue in the EMA reflection paper?

Full Panel

There's growing concern that AI systems may become operationally useful before we fully understand how to validate them statistically. How should regulators and sponsors handle that tension? Are current validation frameworks adequate for these systems?

Full Panel

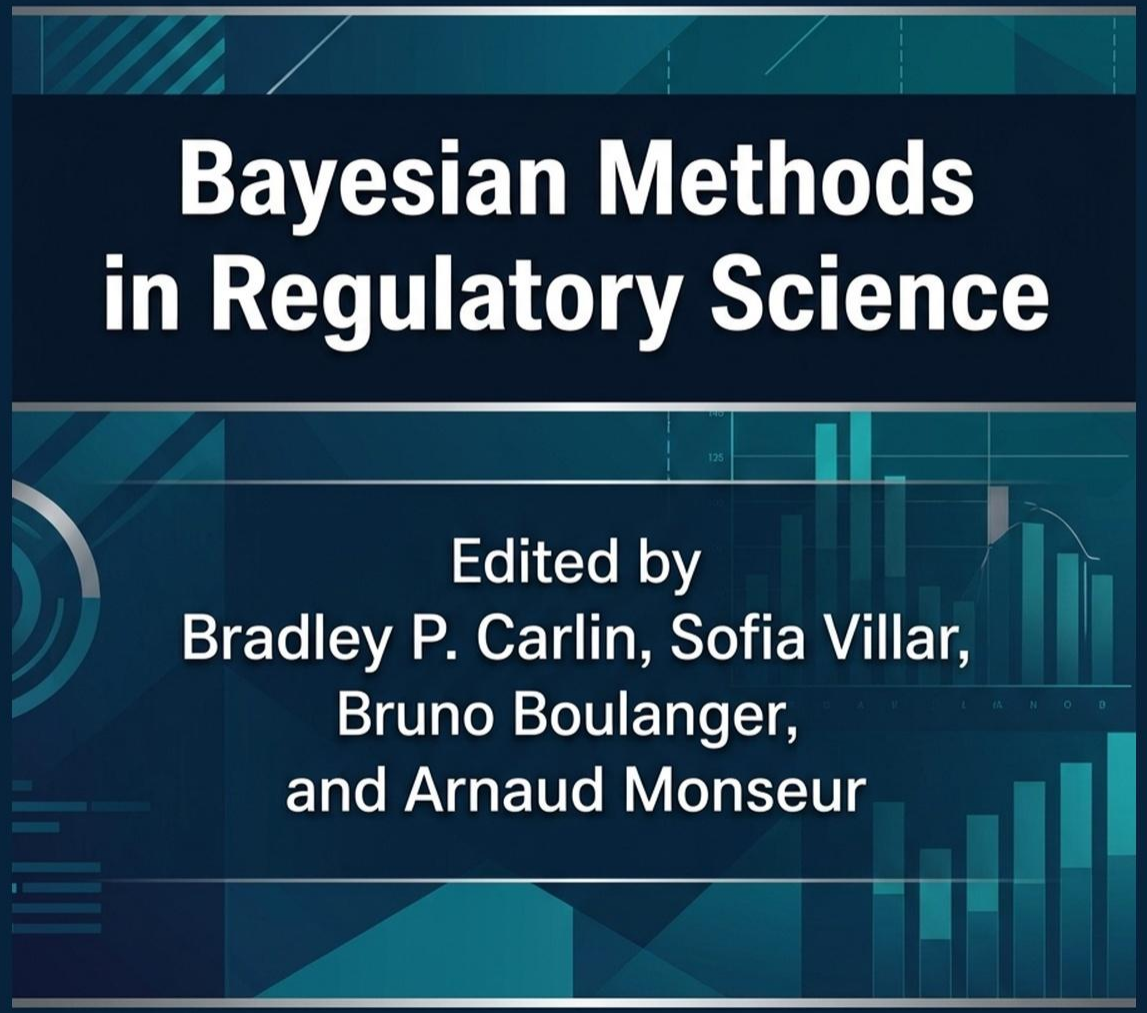
AI-assisted optimization and simulation tools are increasingly influencing trial planning and execution. What parts of the clinical development pipeline do you think are most ready for automation, and which parts still require substantial human judgment?

Full Panel

Some critics argue that current regulatory processes are too slow for modern AI-enabled development, while others worry they're moving too quickly without sufficient deliberation. From your perspective, which concern feels more real right now?

FOLLOW-UP: *The US state of Utah and several AI-health companies are already experimenting with models of AI-enabled healthcare delivery that move well beyond traditional regulatory review paradigms. Are regulators not keeping pace with innovation, or appropriately cautious given the risks involved?*

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