

TITLE: Statistical Foundations of AI: From Predictive Models to Credible Evidence in Drug Development**AUTHORS:**

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ABSTRACT: Artificial intelligence (AI) is increasingly being used across drug development, clinical trials, endpoint assessment, digital health technologies, real-world evidence, safety monitoring, and operational decision-making. However, the credibility of AI in regulated life sciences does not rest only on model architecture or predictive performance. It depends on whether the model is statistically well-defined, fit for its context of use, transparent in its assumptions, reproducible in implementation, and interpretable for scientific and regulatory decision-making.

This presentation will discuss the statistical foundations required for responsible and regulator-ready AI. Key concepts include defining the AI objective and context of use, understanding the data-generating process, addressing bias and dataset shift, evaluating calibration and discrimination, quantifying uncertainty, assessing robustness, prespecifying decision thresholds, and maintaining traceability from data input to model output. Bayesian thinking provides a natural framework for many of these needs by making uncertainty explicit, enabling incorporation of prior or external information, supporting posterior predictive checks, and facilitating decision-making under uncertainty.

The session will take a practical life-sciences perspective, moving from scientific objective to programming implementation and communication. It will outline how statisticians and programmers can support AI development through analysis specifications, validation datasets, reproducible code, version control, audit trails, sensitivity analyses, model monitoring, and clear reporting. The discussion will also connect these practices to emerging expectations from AI reporting guidelines, uncertainty quantification literature, and regulatory guidance emphasizing risk-based credibility, lifecycle management, data governance, performance assessment, and clear context of use.

The central message is that AI should not replace statistical discipline; it should be strengthened by it. In regulated clinical research, trustworthy AI requires the same foundations that support credible evidence: prespecification, validation, transparency, uncertainty assessment, quality control, and scientifically defensible interpretation.

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