› CASE STUDY

VERISTAT

Advancing Dose Escalation Strategies with Bayesian Modeling

How Veristat Enabled Real-Time Decision Making in a Complex Phase 1/2 Oncology Study

Background

A biotechnology sponsor developing an oncology therapy engaged Veristat to support the design and execution of a multicenter, open-label Phase 1/2 dose escalation and expansion study. The objective: to determine the optimal dose while maintaining patient safety and enabling rapid, data-driven decision making. Veristat implemented a Bayesian continual reassessment method (CRM) to guide escalation decisions across multiple cycles and dose levels.

Sponsor Challenge

Balancing Dose Escalation Speed with Patient Safety

The sponsor aimed to shorten the traditional dose escalation timeline without compromising patient safety or trial integrity. Conventional 3+3 design posed limitations due to fixed cohort sizes, enrollment pauses, and inability to factor in real-time safety data across multiple treatment cycles.

Veristat Solution

Veristat designed a dose escalation strategy using the Bayesian continual reassessment method (CRM), allowing for flexible cohort sizes, dynamic modeling of posterior toxicity probabilities, and the ability to escalate, de-escalate, and re-escalate at dose levels when allowed by the predicted posterior probabilities and underlying decision criteria. This design incorporated data from all DLT-evaluable cycles and provided safety review committees with real-time model updates to guide escalation decisions more efficiently. The approach enabled faster progression through dose levels with low risk of toxicity and reduced enrollment delays, even when faced with non-evaluable participants and the occurrence of adverse health events, otherwise unrelated to the protocol, treatment, and study procedures.

STUDY DEMOGRAPHICS

STUDY PHASE
- Phase 1/2, multicenter, open-label

INDICATION
- Advanced solid tumors

THERAPY TYPE
- Novel oncology compound

PRIMARY ENDPOINT
- Recommended Phase 2 Dose (RP2D)

SECONDARY ENDPOINTS
- Safety, Dose-Limiting Toxicities (DLTs), Preliminary Efficacy

SERVICES PROVIDED
- Protocol Design and Statistical Modeling
- Bayesian Model Operational Planning and Real-Time Decision Support
- Safety Review Committee Participation
- Strategic Consultative Planning and Support

Sponsor Challenge

Operational Complexity of Bayesian Methods

Despite its advantages, the Bayesian CRM approach introduced complexity in both trial design and execution. The sponsor required statistical support to translate model-based insights into operational decisions while ensuring adherence to protocol specifications and regulatory expectations.

Veristat Solution

Veristat provided a comprehensive technical operational plan and training for the sponsor's internal team and investigators. Real-time safety data interpretation was supported through adaptive decision rules integrated into the safety review processes. When multiple interim cohorts were evaluated, Veristat helped navigate dose adjustments and interim dose levels without disrupting trial momentum.

Impact

- Enabled real-time, data-driven dose escalation decisions
- Reduced trial duration and increased flexibility by avoiding rigid cohort size constraints
- Integrated multi-cycle DLT data for a more accurate safety profile
- Successfully managed operational complexity through expert planning and modeling
- Advanced the study toward identifying an optimal RP2D for expansion with minimal delays

Veristat continues to support the sponsor as the trial progresses into the dose expansion phase and prepares for further regulatory engagement.

THE ADAPTIVE ADVANTAGE

Adaptive designs powered by Bayesian modeling can offer:

- Reduced time and cost
- Improved patient safety
- Minimized exposure to ineffective treatments
- Enable faster, data-driven decisions

Meet Veristat

Full-Service CRO and Consultancy That Accelerates Success

If you've struggled with missed deadlines and slow progress, talk to Veristat. We have a proven track record of starting—and accelerating—clinical development programs with the expertise to navigate the challenging path to regulatory submission and approval efficiently. Collaborate with experts who understand the value of speed without compromising quality.

It's not just business for Veristat, it's personal.

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