
VERISTAT

# Comprehensive Planning for a First-in-Human Cancer Antibody Trial

How Veristat's Strategic Consulting and Data-Driven Approach Positioned a Sponsor for Early Success

## Background

A clinical-stage biotech company developing an immuno-oncology antibody approached Veristat to design and write its first Phase I protocol. The therapy targeted patients with advanced solid malignancies who had exhausted all available standard treatments.

While initially engaged for protocol writing, the scope quickly expanded to encompass comprehensive strategic consulting—integrating clinical development program planning, trial conduct strategy, and regulatory pathway assessment. The sponsor needed an actionable plan to guide not only this first-in-human study but also the long-term development of the asset.

## Sponsor Challenge: First-Time Sponsor, Complex Early-Stage Planning

As a first-time sponsor entering the clinic, the company needed more than a Phase I study design. They faced critical early questions:

- Which potential indications should be prioritized?
- What dose escalation and expansion strategies would optimize safety, speed, and data value?
- Could an expedited regulatory pathway be viable, and what would it require?
- How could risk be mitigated through statistical and operational planning?
- Without in-house experience in early oncology development, they sought a partner who could combine clinical insight, regulatory expertise, and biostatistical rigor.

## STUDY DEMOGRAPHICS

**STUDY PHASE**
- First-in-Human Phase I Study

**INDICATION**
- Advanced solid tumor malignancies

**SERVICES PROVIDED**
- Strategic Consulting
- Regulatory Strategy & Planning
- Biostatistics & Programming
- Data Management
- Quality Assurance
- Project Management

## Veristat Solution

From the outset, Veristat worked as an extension of the sponsor's team, embedding strategic consulting into every stage of planning. Our multidisciplinary experts:

- Evaluated multiple potential indications by reviewing literature, prior trials, comparators, and competitive landscapes.
- Developed clinical development program plans aligned with the target product profile and regulatory goals.
- Advised on trial conduct with risk mitigation strategies for dose escalation and expansion, considering Bayesian, adaptive, and classical designs.
- Assessed expedited versus standard regulatory pathways, outlining requirements, timelines, and trade-offs for each.
- Performed statistical scenario planning, including endpoint selection, confidence intervals, p-values, and minimum detectable differences.

The result was a detailed, adaptable "living" roadmap—integrating indication strategy, statistical design, and regulatory considerations into a cohesive plan that could evolve with emerging data.

## Impact

By combining scientific insight, regulatory foresight, and operational planning, Veristat positioned the sponsor for both immediate and long-term success. The sponsor gained clarity on next steps, flexibility to adjust as data emerged, and the confidence to move forward.

Following the initial engagement, the sponsor expanded Veristat's role to include regulatory planning and IND preparation for their next trial.

## Key Outcomes

- Defined feasible indications supported by competitive analyses
- Developed adaptable dose escalation and expansion criteria
- Outlined accelerated approval pathway options
- Delivered statistical frameworks to support decision-making
- Strengthened readiness for regulatory engagement

# Meet Veristat

From first-in-human studies to global submissions, Veristat helps sponsors navigate complex development landscapes with integrated expertise in clinical, statistical, and regulatory disciplines.

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