VERISTAT

Advancing Oncology Innovation with Adaptive Trial Designs

How Veristat's Strategic and Regulatory Expertise Helped Guide a Complex, Multi-Regional Phase 3 Oncology Study

Background

A biopharmaceutical company developing therapies for solid tumor cancers partnered with Veristat to design and support the execution of a Phase 3, open-label, randomized, multi-regional clinical trial. The goal: to compare a novel therapy to standard of care for the treatment of oncology patients in a multi-regional clinical trial.

1 Sponsor Challenge

Balancing Global Enrollment in a Multi-Regional Study

The sponsor sought to conduct a multi-regional trial with broad geographic representation to support future regulatory applications in the US, EU, and Asia. A key concern was preventing rapid over-enrollment from within a single region where there are fewer competing trials and access to care. Over-representation from a single region could bias outcomes or limit generalizability, particularly if there are known or unknown differences in underlying characteristics, disease severity, standard or prior treatment options, or likelihood to respond to treatments.

Veristat Solution

Veristat supported geographic enrollment planning aligned with the latest FDA Multi-Regional Clinical Trial (MRCT) guidance. The team provided strategic advice to ensure a representative population by:

- Advising the sponsor to monitor regional enrollment trends in real time
- Recommending site activation and recruitment pacing by region
- Advising on diversity targets to support generalizability for US and EU submissions

STUDY DEMOGRAPHICS

STUDY PHASE
- Phase 3, multi-regional, open-label, randomized study

INDICATION
- Locally advanced or metastatic solid tumor

THERAPY TYPE
- Novel oncology therapy

PRIMARY ENDPOINT
- Progression-Free Survival (PFS)

SECONDARY ENDPOINTS
- Overall Survival (OS)

SERVICES PROVIDED
- Regulatory Strategy, FDA Communication and Meeting Support
- Protocol Design and Development
- Statistical Analysis Planning

2 Sponsor Challenge

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3 Sponsor Challenge

Mitigating Bias in an Open-Label Design

Because the study was open-label, there was a risk that patients randomized to the control arm might withdraw early to seek other treatment options. This posed a threat to data integrity—particularly for PFS, the primary endpoint, which requires sufficient follow-up and recorded disease progression or death event collection.

Veristat Solution

To preserve the integrity of the study's PFS analysis, Veristat recommended several measures:

- An increased sample size to account for potential early dropouts
- Robust participant and site engagement strategies to promote retention
- Planning multiple data handling and missing data considerations to align with the trial's underlying scientific questions within the estimand framework to assess the robustness of the study findings

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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