› CASE STUDY

VERISTAT

Guiding an Emerging Biotech's First Phase I Oncology Trial

Comprehensive Expertise Drives On-Time Completion and Seamless Advancement to Phase II

Background

A clinical-stage biopharmaceutical company selected Veristat to conduct their very first clinical trial, a Phase I oncology trial for patients with B-cell malignancies. At the start, the sponsor was a three-person team. Veristat became their project team, providing clinical research associates (CRAs), a medical director, data managers, statisticians and programmers, medical writers, and a project manager to lead the development of their compound.

Challenges and Solutions

Reducing the Cost of Site Contracting

The sponsor had no experience negotiating or executing site contracts. Veristat offered to manage the process; however, the sponsor had not allocated a budget for this activity. Instead, Veristat trained the sponsor on how to create, negotiate, and execute contracts, building confidence, saving costs, and strengthening trust.

Managing Academic/KOL Sites

The sponsor chose to work with leading U.S. academic oncology sites. While these sites bring scientific prestige, they also face challenges, such as high turnover rates among study coordinators. Veristat anticipated this risk and implemented strategies to keep the study on track:

- Built strong relationships with site personnel through multiple touchpoints and backup contacts.
- Developed a focused training program for coordinators that could be rapidly deployed to new staff.
- Supported each transition with direct CRA involvement and hands-on training.

As a result, coordinator changes did not delay the study, and sites remained engaged throughout the project.

STUDY DEMOGRAPHICS

INDICATION
- Relapsed non-Hodgkin's B-cell lymphoma & B-cell Chronic Lymphocytic Leukemia (B-CLL)

SITES
- 5 academic sites in the U.S.

PATIENTS
- 40

DESIGN:
- Phase I dose-escalation trial

SERVICES PROVIDED
- Clinical Monitoring
- Safety Management
- Data Management (EDC)
- Biostatistics & Programming
- Data Monitoring Committee (DMC) Support
- Medical Writing
- Project Management

Maintaining Study Momentum Amid Protocol Adjustments

Over the course of the trial, six protocol amendments were required. Each impacted not only manuals and IRB submissions but also site retraining, database updates, and data validation. Veristat ensured:

- Timely database updates and system testing for each amendment.
- Rapid re-training of site staff with clear documentation.
- Continuous monitoring to confirm all changes were understood and implemented correctly.

This attention to detail kept momentum strong despite frequent protocol changes.

"I have worked on both sides of the clinical trial fence, and I have never been more pleased with a clinical research team than our Veristat team."

— Chief Medical Officer

DMC Preparations

Because the study was dose-escalating, a DMC reviewed each cohort before escalation to the next dose level.
To ensure fast, accurate review:

- CRAs worked with coordinators to prioritize safety data entry in EDC.
- Data management focused reviews on critical safety variables, aligned with monitoring visits.
- Biostatistics/programming pre-built DMC data packages, enabling rapid QC and delivery.

As a result of this preparation and collaboration, six DMC packages were delivered in under five business days each—keeping patient safety and timelines intact.

Impact

- Enrollment for all six dose-escalation cohorts and the expansion phase was completed as planned.
- Despite coordinator turnover and multiple protocol amendments, the study stayed on time with no project delays.
- The product advanced successfully to Phase II, with timelines met and the sponsor positioned for future success.