› CASE STUDY

VERISTAT

Leading a Phase I Cancer Trial Through a Full-Service Approach

Veristat Guides a Growing Biotech Through the Planning and Execution of Its First Clinical Program

Background

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

Study Demographics

Indication

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

Primary Services Provided

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

Phase I Dose Escalating Trial
in United States

40 Patients

5 Academic Sites

CHALLENGES AND SOLUTIONS

Reducing the Cost of Site Contracting

The Phase I trial started as a single project and over time grew into three projects. The sponsor had no experience negotiating and executing contracts with the investigational sites. Veristat offered to manage this process on their behalf, though in the end, the sponsor didn't have this in their budget. Veristat's solution was to have the project team train the sponsor how to create, negotiate and execute the site contracts. The training not only kept the sponsor on-budget, but also helped to solidify a trusting and transparent relationship with the Veristat team.

Managing the Academic/KOL Sites

For this study, our client only wanted to work with well-known US Oncology Academic/ Key Opinion Leader (KOL) sites. Our project team was candid and transparent about the challenges of working with the chosen sites based on our previous experience with them. We suggested that they consider adding alternative sites to the site list, but the client wanted to limit the study to their selected sites.

To prevent delays our team spent a great deal of time strengthening our personal relationships with these sites. We anticipated the study coordinator turnover challenges with all the sites, and as expected, all sites did have multiple study coordinators turn over throughout the project. Since we planned on turnover, it didn't affect the study timelines. Specifically, our Leads (CRA) gave the sites more attention, and took the time to train and then re-train site coordinators as they turned over. Our goal was to be more accessible to the sites than their other project support teams were.

Implementing Six Protocol Revisions

This study went through numerous protocol amendments – six protocol revisions in total. Each amendment resulted in edits to the study manuals and retraining of the sites. The Veristat clinical monitoring team successfully managed to support the sites throughout all the submissions to the IRB, ensuring that the momentum of the study remained intact. With each iteration of the study manual, the team followed up with the appropriate site staff to confirm and clarify that they understood the changes. These nuisances and attention to details kept the study moving and site staff and sponsor supported.

DMC Preparations

As this was a dose-escalation study, the study was designed to have a Data Monitoring Committee (DMC) review and approve every dose escalation to the next dose cohort. The DMC review ensured the safety of patients in the current dose prior to escalating the dose cohorts. Resourcing was limited at the sites, so the Veristat CRA was required to teach the site coordinators how to review medical records and find the required safety information. Since the goal of the study was to find the maximum tolerated dose (MTD), Veristat needed clean data from the sites to present to the DMCs to keep the study moving forward.

Throughout the study, the sponsor ran a total of six DMCs. For each committee meeting, our project teams prepared the DMC packages in less than a week. To achieve these timelines, the Veristat CRAs worked in close collaboration with the sites to get them to enter the data in a timely manner to make this possible. Enrollment was completed for all six dose escalation cohorts and we continued enrolling patients into the expansion phase of the study.

IMPACT

The product is currently in Phase II studies where initial results are expected in 2020.

"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

ABOUT VERISTAT

Veristat is a smart, effective and impactful CRO focused on advancing medical therapies through the clinical development and regulatory submission process. Our work delivers meaningful clinical impact and our regulatory submission expertise is unrivaled in our industry. Veristat teams have worked on more than 75 regulatory submission projects that have resulted in more than 50 submission approvals to date from various regulatory agencies around the world. We partner with and guide biopharmaceutical companies from nonclinical planning through to market approval so that new therapies become available to improve and save people's lives.

Contact Veristat Today

Learn more about Veristat and how we can assist you with your oncology trial development and execution.

www.veristat.com