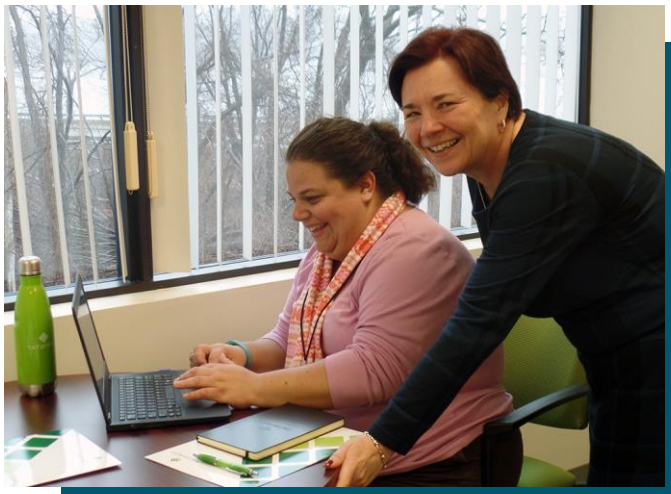
VERISTAT



# GUIDING AN ONCOLOGY PROGRAM TO SUCCESS

***Veristat Leads A Growing Biotech Firm Through Its First Clinical Trial***

## Background

A clinical stage biotech firm engaged Veristat to run their very first ever clinical trial, a phase I US-only oncology trial. When the project started, the client was a three-person team. Veristat was and still is the entire project team and we have and continue to work with this client to guide them and train them through the clinical trial process.

At the beginning of the study, the Chief Medical Officer (CMO)/Medical Monitor was very involved, but has pulled back his involvement as the trial progressed. He has grown to completely trust and rely on the Veristat project team.

## 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**

**5 Academic Sites**

**40 Patients**

# KEY STUDY CHALLENGES

## Site Contracts

The phase I trial started as one project and over time grew into 3 projects. Our client had no experience with negotiating and executing contracts with sites. They did not have the budget for Veristat to manage this entire process for them. Therefore, Veristat's project team trained the client on how to create, negotiate and execute the site contracts. This saved the client budgetary resources, and helped solidify a trusting and transparent relationship.

## KOL/Site Management

For this study, our client wanted to work with very well-known US Oncology Academic sites. Our project team was very candid and transparent about the challenges of working with the chosen sites based on our previous experience with them. We even suggested some alternative sites to add to the site list, but our client really 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 turnover throughout the duration of the project. Since these were planned for, they didn't interfere with the study timelines. Specifically, our Leads (CRA) gave the sites more attention, took the time to train and then re-train site coordinators as they turned over. Our goal was be more accessible to the sites than their other projects were.

*"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, Biotech Firm**

## Protocol Revisions

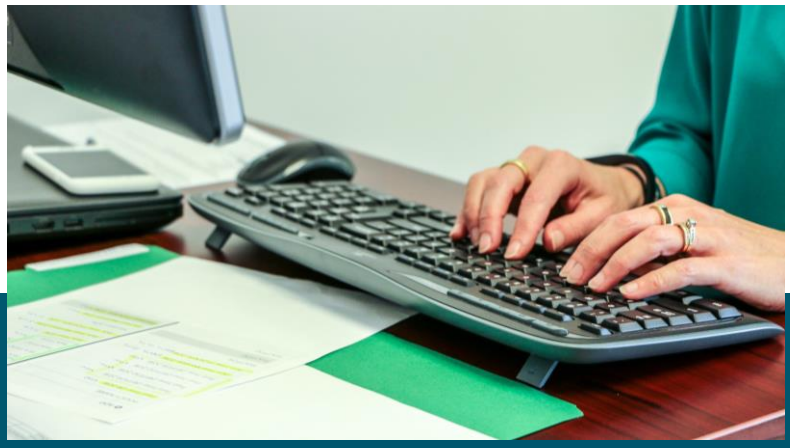
This study went through many changes. The protocol was revised six times resulting in multiple manual revisions to continuously support these changes. The Veristat clinical monitoring team successfully managed to support the sites throughout all the submissions to the IRB to ensure that the momentum 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 little nuisances and attention to details kept the study moving and site staff and sponsor supported.

## KEY STUDY CHALLENGES

### DMC Preparations

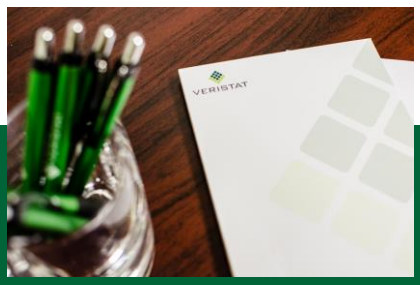
As this is a dose-escalation study, the study was designed to have a DMC review and approve every dose escalation to the next dose cohort. This was a critical trial design element from a business as well as safety perspective in order to proceed through the escalating dose cohorts. The site resourcing was limited, so the Veristat CRA was required to teach the site coordinators how to review medical records and find safety information. Since the goal of the study is 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.

To date, six DMCs have been completed. Most were a very last minute scramble where the DMC package was pulled together in less than a week. Again, Veristat CRAs worked in close collaboration with the sites to get them to enter the data in a timely manner to make this possible.



## RESULT

Currently, enrollment is complete for all six dose escalation cohorts. We are about to begin enrollment into the expansion phase of the study. The study is currently tabled for 'soft lock' of the database. The extract will be used at an upcoming FDA meeting and to determine the next steps for this development program.




## Contact Veristat Today

To learn more about Veristat and how we can help you achieve success with your trial or development program and regulatory submission, reach out to us today.

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