› CASE STUDY

VERISTAT

Early Achievement of Patient Enrollment Timelines

Veristat Completes Early Patient Enrollment for a Phase II Study Allowing Sponsor to Start Up Two Additional Studies

Background

A clinical-stage biotechnology start-up asked Veristat to run their Phase II study for a topical spray to treat hypertension. Veristat had already completed a study for this product in another indication which showed evidence that the product reduced elevated blood pressure. Our sponsor was eager to get a second study up and running quickly to see if this product worked for the treatment of hypertension.

Study Demographics

Indication

- Hypertension

Primary Services Provided

- **Project Management:** Vendor oversight of ambulatory blood pressure vendor, central laboratory & drug distribution
- **Clinical Monitoring:** Feasibility, site qualification visits, site initiation visits, monitoring and close out
- **Data Management:** EDC build
- **Biostatistics & Programming**
- **Medical Writing:** Clinical Study Report (CSR)
- **Safety Management**

10
USA Sites Selected

165
Screened Subjects
(132 Randomized)

SETTING UP THE STUDY FOR SUCCESS

Planning, Planning, Planning

Veristat accelerated the proposal to kick-off meeting timeline, completing it in under six weeks. We assembled a strong clinical operations team, consisting of the project manager, lead clinical research associate (CRA), regional CRAs and clinical trial associates, as well as a lead statistician, data manager, medical writer and safety manager. The team started work immediately on feasibility & study setup requirements and prepared timelines to quickly open the 10 sites participating in the study.

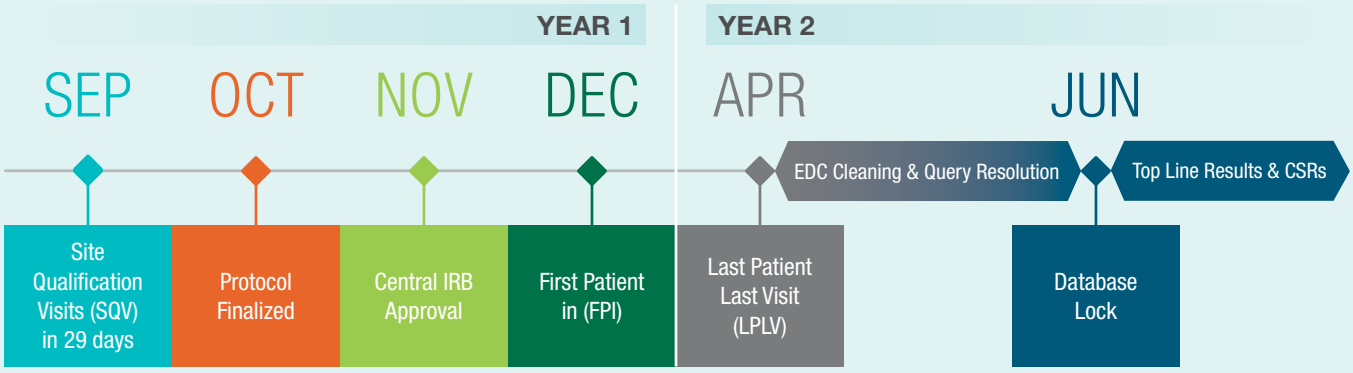
Tools for Success

Our project team employed several tools to establish communication and obtain early agreement on site requirements. Specifically, who was responsible for what task(s) and the setting of realistic target dates for milestones. The project manager set up the project timelines in collaboration with the sponsor, outlining the key milestones (see figure). A Central Independent Research Board (IRB) was confirmed with dates and requirements for submission ascertained immediately. A project management plan was developed with a submission strategy to meet the critical sponsor milestone of first site open.

Milestones Achieved

- **Feasibility** – The feasibility study identified 10 sites out of the 40 initially contacted that would be capable of recruiting quickly due to a high level of patient interest in the study. Therefore, we didn't waste time or resources on opening 40 sites, but focused on just the 10.
- **Site Contracts** – Average time to site contract approval took only four to six weeks because the site contracts and budgets were discussed and defined at the kick-off meeting. The sponsor wanted to use their contract template. We advised and planned for many sites wanting changes, which our project manager anticipated and negotiated quickly.
- **EDC Build/User Acceptance Testing (UAT)** – The Veristat data management team was responsible for setting up the database in the EDC system and completing the UAT, both of which were accomplished in under 60 days.
- **First Patient In (FPI)** – The first patient entered the study in early December, a full two months earlier than anticipated.
- **Top Line Results & CSRs** – Site close and preparation of the clinical study reports (CSRs) was achieved by end of the second year.

Timeline of Milestones Achieved



IMPACT

Due to the success of this project, the client decided to accelerate the start-up of two additional studies for the same product in different therapeutic areas with Veristat, the first of which is now underway.

For the two new studies, we are using the same lead CRA and CRA teams, and after collaborative discussions with the client, we are using different project managers for each study. We felt it was important to have project managers with matching therapeutic experience to lead and be dedicated to each study. Having the same lead CRAs and CRA teams will afford efficiencies of being able to utilize lessons learned to improve processes and to run all three studies with consistent forms, templates and standard operating procedures (SOPs).

> *"We are very happy with the progress that the Veristat team has made on our phase II study in hypertension, having met the enrollment timelines earlier than planned. I continue to be impressed with the strength and breadth of therapeutic experience of my team and value their dedication to our success, transparent communications, and expert management of my studies."*
>
> **President, Biotech Firm**

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

To learn more about Veristat or how we can assist you with the strategy, design or execution of your clinical program, reach out to us today.

www.veristat.com