VERISTAT

EXCEEDING EXPECTATIONS FOR PATIENT ENROLLMENT

Veristat Completes Early Patient Enrollment for a Phase II Study Which Allows Sponsor to Focus On Starting Up Two Additional Studies

Background

A clinical stage US-based biotechnology firm 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. The sponsor was eager to get a second study up and running quickly to see if this product worked for the treatment of hypertension.

10 USA Sites Selected

165 Screened Subjects (132 Randomized)

Study Demographics

INDICATION:

Hypertension

PRIMARY SERVICES PROVIDED:

- **Project Management** to include Vendor Oversight of Ambulatory Blood Pressure Vendor, Central Laboratory & Drug distribution
- **Clinical Monitoring** to include feasibility, Site Qualification Visits, Site initiation visits, monitoring and close out
- **Data Management** including EDC build
- **Biostatistics & Programming**
- **Medical Writing** to include the Clinical Study Report (CSR)
- **Safety Management**

THE GOAL

The goal of the study was to quickly set up the multi-center, open label, Phase II, safety & efficacy study to see if our current client's product worked in a new therapeutic area to treat hypertension.

HOW WE SET UP THE STUDY FOR SUCCESS

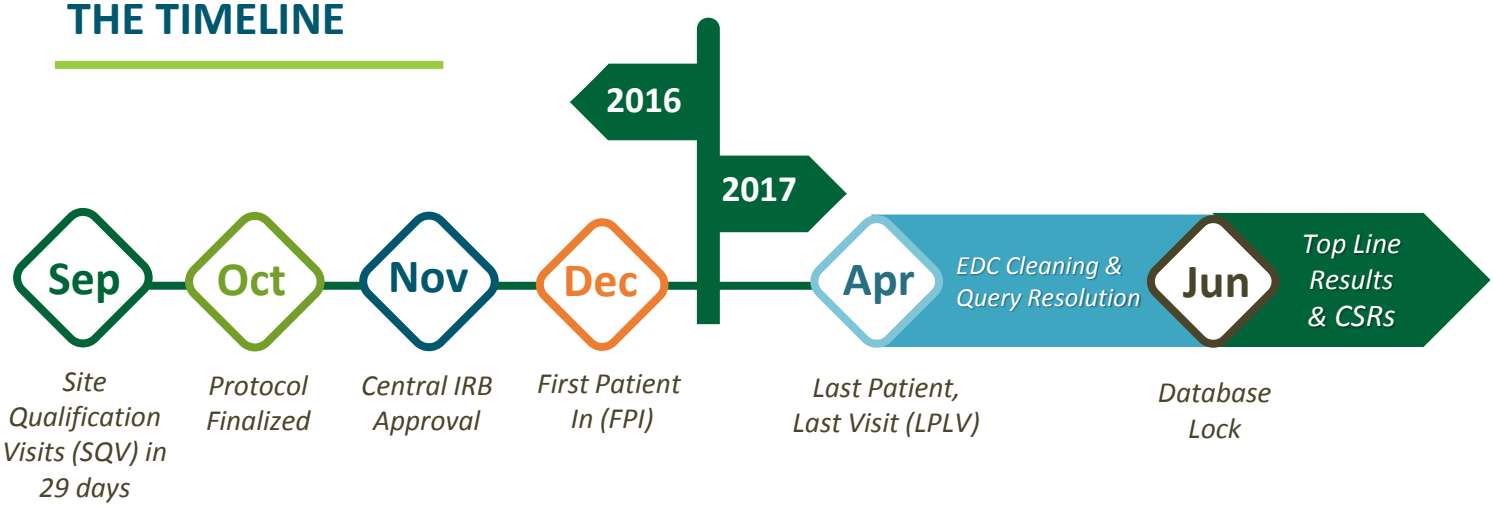
Planning, Planning, Planning

Veristat accelerated the proposal to kick-off meeting timeline, completing it in under 6 weeks. We pulled together 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 set up requirements, and prepared timelines to open the 10 sites participating in the study.

Tools for Success

Several tools were used to ensure that there was early agreement and communication on what exactly was required at each site, which party was responsible for which element and realistic target dates were set for each of these critical steps. The project manager set up project timelines in collaboration with the sponsor with many key milestones including a first patient in (FPI) goal of February 3, 2017. 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 in September of 2016.

THE TIMELINE



*"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**".*

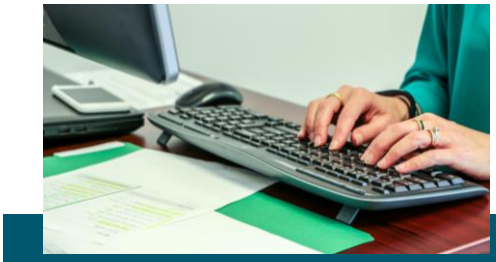
-President, Biotech Firm

MILESTONES

- **Feasibility |** The feasibility study determined that 10 sites out of the 40 that were initially contacted, would be capable of recruiting quickly due to a high level of patient interest in the study.
- **Site Contracts** | Average time to site contract approval was 4-6 weeks because the site contracts and budgets were discussed and defined at the kick-off meeting. The sponsor wanted to use their contract template, however 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 |** We are currently closing out the sites and preparing the CSRs for the end of 2017.

RESULTS SO FAR

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



- **Atopic Dermatitis Study |** Feasibility is underway for 10 sites.
- **Migraine Study |** Will be starting in Q4 2017.

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 that it was important to have project managers with matching therapeutic experience to lead each study 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).

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.

+1 508.429.7340
marketing@veristat.com