› CASE STUDY

VERISTAT

Initiating a Successful Clinical Development Collaboration

Preparing an Investigational New Drug Application (IND)

THE SITUATION

An emerging biotechnology company with a focus on innovative medicines for women's health asked Veristat initially to provide statistical consulting support as they were preparing for their pre-IND meeting. They specifically asked for the statistical review of the Statistical Analysis sections of their Phase I synopsis, study protocol, and pre-IND meeting Briefing Book.

As a result of our suggestions to update these documents, the client asked Veristat to attend the pre-IND meeting, which was less than a month away. After the pre-IND meeting, the client realized they needed additional support in order to complete their IND submission. A Veristat IND project team was quickly pulled together to manage, prepare, and publish the IND.

THERAPY FOR HOT FLASHES

- Statistical Consulting Review
- IND Management and Publishing

- Provided project management, medical writing, and biostatistical support
- Managed the nonclinical and publishing vendors

- Veristat is still working on this compound, which is near completion of two Phase I studies

THE SOLUTION

We began in mid-November, with the client wanting their IND filed in January. Our team included a project manager, medical writers, and biostatisticians, and we added a nonclinical vendor and a publishing firm to round out the team. The client had their own regulatory and clinical experts as well.

The IND timeline was tight, but not unrealistic; we had nearly six weeks to get the IND written, reviewed, and published to the US Food & Drug Administration (FDA). The client ran into some Chemistry Manufacturing and Controls (CMC) issues, which slowed their timeline slightly, but we kept to our timeline.

Another challenge that arose involved the client's regulatory expert, who was only available one day a week. We identified and brought onboard a new expert to assist with the regulatory support when the client's expert was not available.

As the mid-point of the project approached, the short timelines became challenging, so we added additional medical writers to the team in order to stay on track. This improved our efficiency, but put a strain on the review cycle times. To resolve this, we transferred the IND modules to the publishing partner on a rolling basis so that they could finalize the modules for upload, one by one.

"Our partnership with this emerging biotech company began with a simple request for statistical review and we have continued to support the IND and first two Phase I studies."

– Martha Plaza, MBA, Project Director of Submissions at Veristat

IMPACT

An Early Submission

Due to our quick-response solutions, the IND was submitted early, ahead of the original timeline. The original target for final publishing was scheduled for Close of Business (COB) on a Friday and we completed the upload to the FDA early.

A Continued Collaboration

The IND was approved and we are now supporting all the IND updates moving forward including safety updates. Our client was so happy with their Investigator Brochure (IB) that they have requested that same writer do any and all IB updates moving forward.

The Veristat project manager, biostatisticians, and medical writers have continued to work on two Phase I studies in men and women for this compound.

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 over 75 regulatory submission projects that have resulted in nearly 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 strategic consulting, data analysis, clinical trial management, or regulatory submission support.

www.veristat.com