› CASE STUDY

VERISTAT

Running Successful Clinical Programs with an External Biostatistics Team

How Our Long-term Collaboration Worked Successfully for a Growing Biotech Firm

Background

A biotechnology company, specializing in rare and ultra-rare disease research, started working with Veristat nearly 10 years ago as a small venture-funded start-up company. Our initial engagement began with strategic statistical consulting by our Chief Statistician to help the company analyze their data from a previous natural history study to be used for planning a new clinical program. The relationship grew from there. Our biostatistics team, along with many other functional groups, has supported this company as they have grown from a four-person to a 300+ person team. Today, that relationship continues to evolve to meet the dynamic, growing business needs of our client.

The Beginning

In 2010, a four-person biotechnology company came to Veristat for statistical consulting work. Veristat's co-founder and Chief Biostatistician helped the client's medical team explore and analyze the data from a natural history study, which would be used to plan the future clinical trials. The clinical program aimed to successfully treat a childhood degenerative neurological disease, for which there were limited treatment options. We helped our client design the study and proceeded to provide an integrated biostatistics team to work on the Phase II and comparative studies.

The Relationship Matures

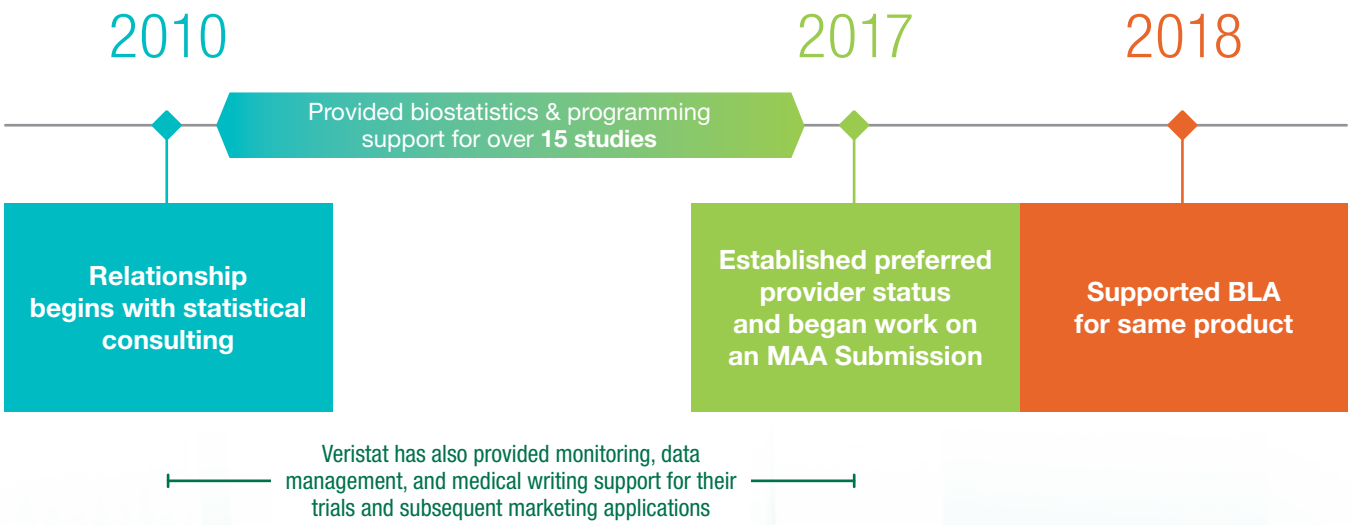
Over the past decade, Veristat has been this biotechnology company's biostatistics team. We helped take a successful European study and developed the strategy to bring the clinical trials into the United States. We've attended numerous US Food & Drug Administration (FDA) and European Medicines Agency (EMA) meetings, designed countless statistical strategies, and worked with their medical teams to support the many clinical programs on which they have worked. We also assisted with publication support, data safety management boards, and safety data analyses.

Building a Collaborative Internal Biostats Team

In 2016, the client experienced an overall growth spurt to handle the increasing numbers of studies they were running, and decided to begin building out their own internal biostatistics team. They were happy with our work, but it made sense at this point in their corporate growth to create a biostatistics and programming department.

Near the end of 2016, a Biostatistics Director joined the client's company. Our team worked collaboratively with the new Director and shared our historical knowledge of past and ongoing studies. To date, the Biostatistics Director has hired a Director of Programming, a few support Programmers, and an independent consulting Biostatistician. The company still relies on the Veristat biostatistics team to support all their clinical trials and their current regulatory submissions. Through our client's growth and evolution, our relationship is stronger than ever and continues to grow through collaboration and a one-team approach, regardless of a program's complexity.

A Growing Collaboration



IMPACT

Veristat is currently the “Preferred Provider” and the only biostatistics team that this client uses. The collaboration between both of our biostatistics teams has accelerated the progress that our client is making in their ongoing studies. In the last two years, we prepared a Marketing Authorization Application (MAA) that was submitted to the EMA in 2018 and recently received a Conditional Marketing Approval (CMA). We are also preparing a Biologics License Application for the same product. Additionally, we have two separate biostatistics teams supporting two other ongoing clinical development programs.

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 clinical trial development, execution, and regulatory submission preparation.

www.veristat.com