VERISTAT

RUNNING SUCCESSFUL CLINICAL PROGRAMS WITH AN EXTERNAL BIOSTATISTICS TEAM

How This Worked Successfully For A Growing Biotech Firm

Background

A biotechnology company specializing in rare and ultra-rare disease research started working with Veristat over 7 years ago as a small venture funded start-up company. Our initial engagement began with strategic statistical consulting by our Chief Statistician to help them analyze their data from a previous natural history study to be used for planning a new clinical program. Our biostatistics team has supported this company as they have grown from a four person to a 300+ person team, and today we are helping them with the regulatory submission for the product that we originally started working with them on.

2010
Relationship begins with statistical consulting

Provided biostatistics & programming support for over
15 Studies

2017
Established preferred provider status and began work on an MAA Submission

The Initial Engagement

In 2010, a four person biotechnology company came to Veristat for statistical consulting. Veristat co-founder and Chief Biostatistician helped the client's medical team explore and analyze the data from a natural history study, that would be used to plan the future trials. The program was for a childhood degenerative neurological disease. We helped design the study, and proceeded to provide an integrated biostatistics team to work on the phase II and comparative studies.

ROAD TO A SUCCESSFUL PARTNERSHIP

The Biostatistics Relationship Matures

During the past 7 years, 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 that they are working on. We even assisted with publication support, data safety management boards and safety data analyses.

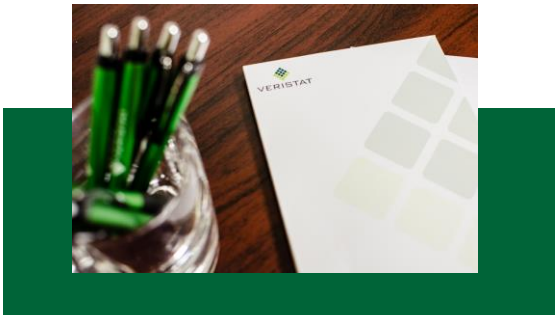
Building a Collaborative Internal Biostats Team

In 2016, the client experienced an overall growth spurt to handle the increasing numbers of studies they were running and decided to begin building their own internal biostatistics team. Not because they were unhappy with our work, but rather it just 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 our 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 of their clinical trials and their current regulatory submission. Through 7 years of evolution, our relationship with this company is stronger than ever and continues to grow through collaboration and a one-team approach, regardless of how complex or simple the current challenge is.

RESULT

We are 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. We are currently helping with a Marketing Authorization Application (MAA) which is slated to be submitted to the EMA in 2018, and we have two separate biostatistics teams supporting their two other ongoing clinical development programs.



Contact Veristat Today

To learn more about Veristat can partner with you to reach your goals with your clinical trial or development program and regulatory submissions, reach out to us today.

+1 508.429.7340
marketing@veristat.com