

CROMSOURCE Biometrics Team Helped Client Streamline Costs By Adjusting Protocol Design

Background

CROMSOURCE was engaged by a mid-size US biotech company to provide biostatistical consultancy services for their pivotal phase III study. The trial involved a highly advanced and very specific stem cell therapy for the treatment of metastatic melanoma and was highly anticipated by the medical community. The client had been working on the protocol design for more than a year but was unable to start the study without securing additional funding to cover the cost of the project.

The Challenge



Without the funds to complete their complex project from start to finish, a successful FDA IND submission would be meaningless. Initiation of this important study was therefore already behind schedule.

Our Solution



In less than 30 hours of consultancy services, our biostatistics team redesigned the study and updated the protocol to make it more efficient, while still meeting all of the objectives. Our experienced team managed to reduce the cost of the study by 44% (\$13 million to \$9 million).

As a result of the improved efficiencies and reduced cost of the new protocol the Client was able to move the project along with the funding they already had available to them.

Once the protocol was updated and submitted to the FDA, the CROMSOURCE Biostatistics team met and interacted with the FDA to ensure that the protocol was understood, agreed upon and eventually approved. The Client was then able to start the study two months after the meeting with the FDA.



The Result



With the help of our team the Client was able to save a significant amount of money (\$4 million) and start the project. We were excited about the outcome of this consultancy and providing the Client with the guidance they needed to help the patients that were in need of this treatment.

As a result we have been this company's go-to biometrics consultants for many years.



Client Quote

"If it wasn't for CROMSOURCE Stats, we would not have gotten this study off the ground."

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, more than 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.