

## Experience of performing statistical analysis unleashes the power to provide expert opinion and make critical decisions!

Determining the right methodology and appropriate design for any particular trial is only possible with statistical experience, such as the decade long experience we have in clinical trials.

To yield best results from clinical trials, proper protocol design is very crucial since that lays down the plan of how to carry out the trial and get the final output. Consequently, any error made in the design can jeopardize the entire trial, causing wastage of millions of dollars, time and resources. This makes it a top priority for Pharmaceutical companies to have experienced Clinicians and Statisticians work on designing the protocol. Pharma companies, sometimes look for CROs with good previous experience, to either design protocols or to provide consultation by rendering an expert opinion on the study protocol designed by them.

One of the pharma companies, based in USA, was conducting Phase II Diabetes studies in India. They developed protocol for the trial but since their statistics division was established recently and had handled only a couple of projects, they wanted to make sure that the protocol was accurately designed. MakroCare was consulted to review the protocol from a statistics perspective. MakroCare assigned two well-experienced Biostatisticians and a Clinician to support this service. All Statistical aspects of protocol - study design, sampling, randomization, blinding and statistical analysis plan were reviewed. We performed appropriate statistical analysis based on experience of similar studies done previously and taking into consideration the protocol objectives,



hypothesis and all aspects that could affect the outcome of the trial. It was found by MakroCare team that sampling was not done properly. This was because the appropriate power was not considered for the sample size calculation. Higher power is absolutely essential so that crucial information on the efficacy of the drug product in trial is not lost. Ultimately, this will prevent failure of the entire trial and subsequently avoid loss of money, time and resources.

Our Biostatisticians determined the appropriate sample size so that the power of the test becomes greater than 0.8. Initially, the sample size was 210, with an associated power of only 65%. We used the required parameters such as mean and standard deviation from a similar study to calculate the sample size with 90% power, as the study required high precision. It was found that a sample size of 265 was required for the study. Consequently, the sample size for the protocol was altered and trial was conducted. At the end of trial, the

sponsors found that they had sufficient information to prove the efficacy of the drug product. The trial got approved and progressed to Phase III trial stage.

Our client was really happy with the results and had the confidence to come back to us to consult on another trial. MakroCare's extensive statistics experience in various therapeutic segments and drug molecules was used to make such highly effective decision in trial design and statistical analysis planning. Our experienced statisticians and SAS programmers are committed to serve the clients with utmost sincerity and believe in doing justice to work they perform, so as to benefit the society.

## About MakroCare

MakroCare, a global clinical services firm, provides clinical research support to pharmaceutical, biotechnology, and medical device industries. The company offers site selection, patient recruitment, clinical monitoring, quality assurance, medical writing, MS/Pharmacovigilance, clinical data management, biostatistics and regulatory assistance.

MakroCare has offices in USA (New Jersey, Illinois, Pennsylvania, California), India (Hyderabad, New Delhi, Mumbai, Bengaluru), Europe (Germany - Frankfurt) and Japan (Tokyo).

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