

Initiation of a multi-center Phase III clinical study in India within 60 days



Customer Profile

A large MNC pharmaceutical company approached MakroCare to initiate and conduct a multi-center clinical study in India. The study contained a very complex protocol. Earliest initiation of study is the key factor for a successful outcome.

Challenges

Initiation of the study within stated deadline of 60 days, which required accomplishment of challenging tasks like selecting appropriate study sites, recruiting qualified investigators, as well as providing necessary documentation support on time.

Solution

Leveraging from the expertise and experience of Clinical Operations team at MakroCare, we followed very effective strategy to address these challenges.

Our clinical operations team follows a PSSV (Pre-study Site Selection Visit) strategy to identify and evaluate sites. Clinical operations team maintains continuous contact with sites by periodic visits and telephonic calls to sites, interact with site staff, collect and analyze relevant data. Databases of sites and of investigators across different therapeutic areas and geographical regions are developed. MakroCare also conducts high-level scientific campaigns developing good professional

relationships, which give us a privileged access to the investigators.

We prepared list of key attributes from protocol, which helped us for a quick short-listing in selection of investigators and sites utilizing our databases. Communication with respective sites and investigators was done to evaluate their interests, capabilities, and availability to participate in this study. Further, analysis of the data helped us in finalizing prospective sites and investigators for study. Henceforth our clinical operations team successfully accomplished a faster site selection and investigators selection. Simultaneously we obtained IEC approval, regulatory approval, and completed necessary documentation work on stipulated time periods, which helped for successful initiation of the study within 60 days.

About MakroCare

MakroCare, a global clinical services organization, provides clinical research support to pharmaceutical, biotechnology, and medical device industries. The company offers site selection, patient recruitment, clinical monitoring, quality assurance, data management, medical writing, PMS/Pharmacovigilance, biometrics, and regulatory assistance. MakroCare has offices in USA (New Jersey, Illinois, Pennsylvania), India (Hyderabad, Mumbai, New Delhi), Europe (Frankfurt) and Japan (Tokyo).

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