Time & Cost Effective Management of Voluminous Clinical Data is Easier Than You Think!

MakroCare is the right partner for Pharmaceutical companies performing clinical trials with its expertise and available resources for managing paper based, voluminous clinical data running into tens of thousands of pages.

In a large number of clinical trials conducted for pharmaceutical drugs, the clinical data collected is entered in paper Case Report Forms (CRFs). CRFs typically run into hundreds of pages, and Phase II and III trials would typically have anywhere between 100-300 and 1000-3000 patients respectively, bringing the total to tens of thousands of CRF pages. This information has to be entered and validated in a Clinical Data Management System (CDMS) for maintaining a repository of validated clinical data and for retrieval for further analysis, mainly biostatistical analysis.

Since the clinical data contained in these CRFs put together are so humongous, it is a grueling task to enter and validate them in a CDMS. Also, time required is huge and cost involved runs into millions of dollars. This requires well-trained resources of adequate size who can start the Clinical Data Management (CDM) on the fly. To handle such transitory, voluminous data pharmaceutical companies prefer to take assistance from reputed CROs who have expert personnel readily available.
MakroCare has a strong CDM team in USA, India and Germany, who have years of experience in clinical data management using Oracle Clinical (OC) CDMS, thereby providing cost and time effective data management solution to pharmaceutical companies. This was a key feature that our pharmaceutical client in Germany was looking for from a CRO.

The pharmaceutical client was conducting Phase II clinical trial in cardiovascular therapeutic area. The trial was conducted in three sites with 270 patients in all. The paper CRFs ran into approximately 140 pages for each patient, totaling the number of CRF pages to almost 38,000. The clients were looking at a cost-effective service from MakroCare; hence we offered the CDM services from our offshore site in India. MakroCare designed eCRFs in OC and performed data entry, validation and coding of the clinical data before sending it to the clients.

Our experience in managing paper based clinical data using a standard CDMS, Oracle Clinical, helped the client to complete the trial in a simpler, cheaper and faster manner. MakroCare delivered CDM services that met our clients expectations for a cost and time-effective clinical data management with the best quality standards maintained in the pharmaceutical industry.

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, PMS/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).