Clinical Data Abstraction – Case Study

Client Profile:

The client is an international Clinical Data Science company providing clinical insights and decision support solutions around Treatment Efficacy and Tolerability to physicians, pharmaceutical companies and healthcare providers.

Project Brief:

The project entailed extraction of clinical and statistical data related to Clinical Trials and Meta Analysis papers published in international journals across the world.

Business Challenge:

Clinical insights and decision support were to be derived by abstracting data from large repository of Trial and Meta Analysis papers published in international journals for last 20+ years. The abstraction work was initially done at client's end. However, basis the business need, client had to provide trial summaries by abstracting 5000+ papers in a short span of time. With the limited team size at their end, this was a challenge and hence they were looking for an outsourcing partner who can deliver with the required speed and quality.

Project requirement:

The project entailed knowledge and understanding of ICH-GCP guidelines for Clinical trials and Meta Analysis studies, Trial design and Study methodology, Diseases and indications, Inclusion & Exclusion criterion, Treatment categories – Surgical/non-surgical, Delivery mechanism, Demography and Sample collection, Efficacy Outcomes and measures, Tolerability Outcomes and measures, Statistical methods for outcomes comparisons, Risk of Bias, AMSTAR, GRADSTAR scores.

Role of BDS:

A pilot was first awarded to BDS. After successful execution of the pilot, project was carried out in 2 phases. BDS had to quickly ramp up, train the team on domain as well as statistics and go live considering the stringent delivery timelines.

Team comprising Physicians and Life science graduates was assembled. Clinical and statistical data belonging to requisite categories was abstracted and fed into client system for generation of reports. A strong and continuous engagement process with client was established for clarification and query resolution to ensure speed as well as error avoidance. This was followed by review of abstracted data as a part of Quality Control. Emphasis was given in performing error Root cause analysis and future error avoidance.

Success Story:

BDS was able to deliver the project as per schedule with required quality SLA being met. In the course of the project, BDS also facilitated finetuning of client system to enhance outcome coverage. With this association, client was able to attain the required speed and quality to meet their business challenge of launching the offering within timelines. As a result of this successful endeavour, client has awarded similar project for current ongoing papers and are able to completely focus on their core offering of analytics and insight generation.