CASE STUDY

Improving clinical trial site selection for a large pharma company

Mu Sigma

What We Did: Developed an exception based visualization tool in order to identify sites for future clinical trials for one of the largest pharmaceutical company in the world. Also, helped the client to identify significant drivers that influence the performance of clinical trial sites.

The Impact We Made: The time for selection of clinical trial sites reduced by 1/3rd in comparison to the old process. Along with the time reduction, there was significant improvement in terms of the quality of the sites selected.

Summary: Site selection based on data driven process

The global operations team of the pharmaceutical company uses descriptive analytics to provide decision support to study who are involved in site selection. Only 25% of the sites recruit the required number of patients for clinical trials, owing to gut-based decision making mechanism. This makes the process of selecting the correct site even more critical. In order to generate data driven insights, internal data of drugs' clinical trial needs and external data of site characteristics need to come together in one easy to use source. The client wants a tool based on the centralized data mart to make a data driven decision of site selection.

About The Client - Large Pharmaceutical Company

The client is one of the leading pharmaceutical company in the US which manufactures prescription drugs across several therapeutic areas. For the R&D operations of the firm, there is a constant need to identify clinical trial sites where the drug efficacy studies can be conducted. Since this is one of the most important process in drug development cycle prior to FDA approval, we were approached by the global operations team to optimize it.

The Challenge - Data acquisition issues drove inefficiencies

The current site selection process is riddled with inefficiencies in terms of patient unavailability, quality of medical facilities available at the sites. These issues hamper the process of clinical trials by making the trial process longer. Primary reason for this inefficiency is the unavailability of information in an easily consumable format. Also, the reasons for inconsistency in site performance across different kinds of studies are not available to the global operations team.

The Approach - Site selection dashboard for improved efficiency

Mu Sigma built a visualization dashboard which improved efficiency, reduced time and effort required for site selection:

- Identifying the key metrics and data source by gaining a complete understanding of the current site selection process. Mu Sigma team participated in the discussions with clients to identify all possible metrics. The team identified the key metrics for site selection such as patient pool, past site performance, investigator availability, presence of site monitors, etc.
- Collecting and curating the datasets. The team approached sources within and beyond client environment in order to collect the datasets. These datasets were curated and made analytics ready. Mu Sigma stitched together all individual datasets and created a single platform for site selection.
- Ranking and scoring of sites based on past clinical trial experience was done in order to generate site score.
- Also, deep dive analysis was done to find the effect of each criteria on site performance. Correlation analysis of each criterion on the overall site score was done. Effect of one criteria over the other was analyzed so that potential low performing sites can be detected early and corrective action can be taken
- Driver analysis was conducted to identify the characteristics of high performing sites. Detailed issues tree and hypothesis matrix were created to identify the characteristics impacting site performance. It was noticed that:
    - Site performance gets significantly affected if a site takes more than 14 weeks for completing clinical trial procedure
    - Patient recruitment rate drops significantly once time taken for first person-first visit goes beyond 8 weeks.
- An exception based visualization tool was created on the results of driver analysis along with site score to identify sites for future clinical trials

The Outcome - One-third reduction in time required for optimal site selection

The time for selection of clinical trial sites reduced by 1/3rd compared to old process. Along with the time reduction, there was significant improvement in terms of the quality of the sites selected. The global operations analytics team is able to make better decisions in country planning and site identification through the new visualization tool, which led to the identification of key gaps in current processes and further improvements in site selection processes.

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