Case Study

PHARMACEUTICALS

Phase II and III Clinical Trials – Process Design, Analysis and Support

Pharmaceutical firms invest billions of dollars in successfully introducing a new drug into the market, involving several stages of discovery, validation and testing. These are broadly categorized into Phases I through IV. Once the initial safety of the therapy has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess clinical efficacy of the therapy; as well as to continue Phase I assessments in a larger group of volunteers and patients.

Phase III studies are randomized controlled trials on large patient groups (300–3,000 or more depending upon the condition) and are aimed at being the definitive assessment of the efficacy of the new therapy, in comparison with current 'Gold Standard' treatment. Phase III trials are the most expensive, time-consuming and difficult trials to design and run; especially in therapies for chronic conditions. Phase IV trials involve the post-launch safety surveillance and ongoing technical support of a drug.

The amount of data gathered, organized, examined and analyzed during the four Phases is staggering. Complex systems, tools and analytical methods are critical to success. We assisted one of the industry leaders in Discovery and manufacturing of ophthalmic pharmaceutical, surgical, and vision care products successfully deploy and expand the IT processes and capabilities related to Phase II and Phase III trials of a new drug for Glaucoma, or ocular hypertension. Our work allowed the timely accumulation, organization and analysis of data during the trials.

OUR CLIENT

Our client is a NYSE company, a world leader in development, manufacturing and marketing of ophthalmic pharmaceuticals, ophthalmic surgical equipment and devices, contact lens care products and other consumer eye care products that treat diseases and conditions of the eye. Its broad range of products represents the strongest portfolio in the ophthalmic industry, and has leading market share positions across most major product categories.

OUR CLIENT'S NEED

As our client's earlier work in Phase I demonstrated promise, and the work moved to Phases II and III, there was a need to expand the IT 'infrastructure' to support the ensuing additional volume of people, locations, organizations and data. Also, the client team managing these trials required access to analysis capability. Additionally, consistent with the requirements for submission of results to the Food and Drug Administration (FDA) on a timely and accurate basis, specific analysis 'profiles' were required. Each analysis required reports to be generated, for archival and future analysis as well as for distribution to various internal and external entities involved. All these needed to happen in a manner that did not disrupt the overall flow of the actual trial work itself.

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HOW INFOVISION HELPED

- A cross-disciplinary team composed of InfoVision and our client's IT and clinical trials process specialists defined the processes associated with phases II and III.

- The technology for this was procured from SAS.

- Using our exceptional domain strength in business analytics and SAS tools, InfoVision team, working under the direction of our client's IT leadership, designed and developed analysis techniques and processes.

- InfoVision team also undertook and responsibility of maintaining the clinical database and the specialized task of executing analysis and generating reports on the results during various stages of the trial.

- The team also prepared and stored SAS programs necessary to produce data and summary statistics tables and graphical outputs, using procedures such as PROC REPORT, PROC GLM, PROC REG, PROC NPAR1WAY, PROC ANOVA, PROC TABULATE and PROC SUMMARY.

CLIENT BENEFIT

INFOVISION'S WORK

Ensured appropriate IT infrastructure and its functioning.

Provided timely insights to experts at various points during the trials.

Improved FDA and other third-party interactions.

ABOUT INFOVISION

From a modest beginning 19 years ago, by technology professionals with a vision to provide quality and cost-effective IT solutions worldwide; InfoVision is today, a global IT Services and Solutions company that covers the full range of needs of enterprises, from Staf ng to Solutions. With a primary focus on Strategic Resources, Enterprise Applications and Technology Solutions, Info Vision's core practice areas include Strategic IT Staf ng and B2B Consulting Services, Business Intelligence Development & Big Data Analytics, Enterprise Application Development Systems and Solutions, Technology, Enterprise Mobility Solutions and Web Application Development, Visualization and Collaboration and Wireless & IP Communications.

InfoVision has gained a reputation, demonstrated the ability to meet highly sophisticated technology needs and maintained resources for big and small clients across the telecom, nance/banking, retail, pharmaceutical, energy/utilities, transportation, healthcare/insurance, manufacturing and other industries. Having executed complex and volume projects on time and within budget; InfoVision's clientele includes Fortune 1000 clients all over USA, from various verticals.

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