



## Case Study

# Statistics Support

# STATISTICS SUPPORT

## Client Situation

A large top-3 global pharmaceutical company, like all its peers, had all statisticians in-house at their major R&D locations around the world, and when studies were outsourced in a full-service model, statistics support was also provided by the CRO. A few years ago, they set up statistics teams as part of their captive development units in cost-effective locations. A couple of years back they decided to add small, niche providers as statistics FSPs (Functional Service Providers). Sciformix is one of these companies and has been providing statistics support to this company for over a year.

## Sciformix Solution

Sciformix deployed a six member team of statisticians, with each statistician having 4+ years of relevant experience. The team included 3 statisticians with PhDs from reputed Universities in the US, one of which was a senior statistician with 15+ years of clinical research experience. The solution was customized based on the requirement of each project. Different models are used to provide the required support.

- Offshore Sciformix statistician who functions as a protocol statistician (across any phase of trials, phase I through 4) is involved in study design, randomization, development of SAP and efficacy analysis & reporting. The Client statistician continues to be the project or the program statistician, and is available locally to participate in project team meetings and for any face-to-face interaction that is required.
- In some assignments, Sciformix statisticians are involved in discrete pieces like simulation for sample size calculation, exploratory analysis, meta analysis, pharmacogenomics analysis, outcomes research etc.
- A senior statistician is based at or near the client site for assignments that require more real-time interaction with project teams and more interfacing with the statisticians who function as protocol statisticians.

## Outcome

The client is benefited by the flexible resource augmentation model, especially in view of large swings in resource requirements with the acquisitions and subsequent rationalization of the development portfolio. Client's statisticians are able to focus more on working with the clinical teams to optimize the clinical development programs, while receiving additional statistical support of the required quality, in a cost-effective manner.

Sciformix is knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.

For more information on how Sciformix Biometrics service can benefit your enterprise contact us at

## Sciformix Corporation

1500 West Park Drive, Suite 250, Westborough , MA 01581

Phone : 1(877) 576 - 5005

Fax : 1(508) 302 - 6520

Mail : [ask@sciformix.com](mailto:ask@sciformix.com)

URL : [www.sciformix.com](http://www.sciformix.com)