



Case Study Biometrics

STUDY QUALITY MONITORING

Client Situation

A top-20 global pharmaceutical company evaluated all its Biometrics processes, including a root-cause analysis of the inadequacy of data/subjects available for certain types of efficacy analyses. They found that missing or invalid data identified after study completion led to inadequate data being available for certain key analyses, like the evaluable subset analysis for primary efficacy. The Client desired to put in place a plan and a process for monitoring the quality of the study on an ongoing basis, over and above monitoring of the quality of data. This was discussed with Sciformix.

Sciformix Solution

Statisticians and programmers from Sciformix worked closely with the Client's statistics and programming team to determine the type of issues that need ongoing monitoring during study conduct. For example, eligibility criteria and definition of analysis subsets (ITT, per protocol, completers) were carefully reviewed to identify data inadequacies that may cause some data or subjects to be excluded from certain analyses. As another example, if certain subgroup analyses are specified in the SAP (statistical analysis plan), the number of subjects in the subgroups would have to be regularly monitored in order to have meaningful subgroup analyses at the end of the study. A template of a Study Quality Monitoring Plan was agreed jointly with the Client, and the type and timing of checks was specified. The specifications for monitoring study quality were proposed by Sciformix and signed off by the Client.

A 2-member core statistics and programming team from Sciformix has been dedicated to this Client's projects for the past year. This team has an in-depth understanding of the analysis and population subset specifications commonly used by the client for each therapeutic area. They write the Study Quality Monitoring Plan for each clinical trial after reviewing the protocol, CRF and analysis plan. The specifications in the monitoring plan are then coded and executed on the data at regular intervals.

Outcome

Sciformix conducts periodic checks to monitor study quality, against plan and specifications agreed with the Client at study initiation. The output is reviewed and Sciformix alerts the Client about data issues and trends that may have an adverse impact on the reliability and credibility of the analysis conducted at the end of the study. The Client provides feedback to investigators and data management personnel as required. The Client's clinical team decides if any changes are required to the study design and conduct. Thus the study quality is not compromised and there are no data-related surprises at the end of the study that may adversely affect the validity of the results. The Client found a marked difference in the timeliness and quality of analysis for a recently completed Ph 2 Pain study.

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

URL : www.sciformix.com