

# FUNCTIONAL SERVICE PROVIDER FOR BIOMETRICS

## Client Situation

A young biotechnology company had outsourced its clinical trials, both study management and biometrics, to a full service CRO. The company was focused on the CNS (Central Nervous System) therapeutic area and the CRO had been chosen for its niche expertise in clinical study management for CNS trials and access to global sites. The CRO had the clinical database and staff for data management. But it had difficulty in recruiting and retaining experienced statistics and programming resources. This impacted the quality and timelines for the Biometrics deliverables, though subject recruitment and monitoring was on track. The CRF and database finalization was delayed and the decision criteria and stopping rules for the interim analysis were not finalized.

## Sciformix Solution

Sciformix used a phased approach to help the client move to an FSP model where Sciformix handled all biometrics activities while the CRO handled all study conduct and monitoring activities. The approach was piloted with a Phase 2 study. Sciformix deployed its experienced in-house team of statisticians, statistical programmers, data managers and medical writers for study design, protocol writing, study setup. SOPs of the sponsor and the CRO that would apply were identified, and the activities for which Sciformix SOPs would be used were determined. Sciformix trained its team on the SOPs, system and culture of both companies, CRO and the Client. Interaction was required with both CRO and sponsor, during setup and then the conduct of the trial. Communication requirement and channels were clearly agreed between the 3 companies and documented. Sciformix designated a project manager to coordinate all activities, and also deployed experienced resources for the study close-out activities, including database audit and authoring of the Clinical Study Report (CSR).

## Outcome

The Client was able to successfully implement the FSP model. The Biometrics activities were transitioned seamlessly from the CRO for the pilot Phase 2 study and the CSR was produced on time. The Client was able to get the cost reduction it had hoped to achieve by outsourcing all activities to the CRO which had operations in cost-effective geographies. About 40% cost reduction was achieved by using a global delivery model. Quality and performance standards were at par or better than client's expectations. Sciformix ensured that client oversight effort wasn't increased despite use of multiple vendors. The Client adopted this FSP approach for their future studies.

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

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