



case study:

EARLY DATABASE LOCK

Challenge: Accelerate database lock and preliminary results with just 60 days to go in the study. A pharmaceutical company had developed a new formulation for a CNS drug. They needed pivotal study results to decide whether to allocate resources and proceed with an NDA submission. Previous trials had shown promise, but were inconclusive. In order to make budgetary decisions relating to the future of the drug, the client was eager to have results as quickly as possible. Two months prior to the scheduled database lock, the customer asked i3 Statprobe if it would be possible to lock the database and receive top-line statistical results of the decision-making information weeks earlier than planned.

Solution: Use staff experience to create a new schedule while at once adding the necessary resources to meet it. The i3 Statprobe team

worked out a detailed plan using study metrics to forecast the date of the last subject's last visit, CRF collection schedule, query resolution efforts, and database lock. Resources were scheduled and assigned to tasks to execute the expedited data collection part of the plan. At the same time, the i3 team worked closely with the client to define critical parameters to be analyzed in order to write and test data output programs.

Result: The preliminary results are delivered, as requested, two weeks early. According to the new plan, the database was locked on a Friday. The team worked through the weekend to break the treatment blind, execute the statistical programs, perform quality control reviews of the statistical analyses, and deliver the results to the client on the following Monday-weeks early, as requested.