

Vendor Support and Data Review

A small pharmaceutical company operating with out-sourced Biometrics found themselves in trouble nine months before their NDA filing was due. The company had engaged seven data management and biostatistics vendors and they were producing data in all flavors of SDTM. The company was referred to PharmaStat late — just as decisions were needed on the package of data that would be delivered with the eCTD.

PharmaStat worked with the sponsor to develop a submission strategy, which included identifying the studies that needed to be submitted with data, the studies that needed to be submitted in SDTM format, and the studies that could be submitted in Item 11 format. The submission would include 23 study databases and PharmaStat worked with the sponsor and vendors to prepare them for submission.

This company had a second product in the pipeline hard on the heels of the first, and they engaged PharmaStat for an even larger scope of work. Both products were approved.

