

eCTD Prep with Biometrics Support

A small pharma company contacted PharmaStat for help in the midst of preparing an eCTD. Two vendors were already engaged in producing CDISC data but their interpretations varied and their databases were different.

PharmaStat consultants wrote specifications and conducted reviews to coordinate the work of the two CROs. New Biometrics tasks were added: we revised the ISS SAP, produced the ISS integrated databases, generated TFLs for the ISS, and documented all the databases. We also advised and supported the client through the filing and the FDA review period.

The company brought PharmaStat back to lead the data submission for a second NDA that year. Both products were approved.

eCTD Rescue

A small pharmaceutical in the throes of preparing a submission for a combination product (drug and device) came to PharmaStat five months before the planned filing date. Their relationship with another vendor had broken down and they needed strategic advice, vendor management, and help in Biometrics.

PharmaStat consultants worked closely with the sponsor to develop a plan and assemble a team that could pull the submission together under extremely aggressive timelines. The eCTD was filed without a major delay and the product was approved.

