

Setting Up a Statistical Computing Environment

A mid-sized Biotech company contacted PharmaStat to redesign their Statistical Computing Environment (SCE) in preparation for their first NDA. They started by licensing PharmaStat's APT© Software Library (<http://www.pharmastat.com/products/>) to improve productivity. We developed use cases to help Biometrics staff visualize the new SCE. The use cases would become requirements for vendor selection, workforce development, software production, and validation.

PharmaStat installed and validated APT© and helped the Biometrics department integrate it with their business processes to produce reports for the eCTD. Once the NDA was filed, PharmaStat helped the company choose an SCE vendor and provided services to support the installation. These services included validation, training, and the management of upgrades for the SCE software, SAS, and APT©. Later, PharmaStat developed tools to further automate the production and verification of statistical reports

