

Implementing APT© for CDISC Data

A mid-sized Biotech client acquired PharmaStat's APT© Software Library (<http://www.pharmastat.com/products/>) in preparation for an FDA filing. The submission consisted of two Phase III studies and a Phase II study — which were included as individual study reports — and an integrated efficacy analysis. An outside vendor conducted integrated safety analysis and early-phase study reports. Several specialized sub-analyses were done in-house.

When APT© was licensed, the Biometrics department was defining its programming standards and procedures. Analysis was done by deriving ADaM datasets from the data management vendor's SDTM data. APT© was used for 98% of the tables and graphs. APT© programs produced tables as RTF files, which were incorporated directly into the study reports. Graphs were produced by generating the statistical results with APT©, and using S-Plus code for presentation.

Programming was carried out over five-months. The analysis involved more than 1500 tables and figures. The programmer time required was less than 2 hours per table or graph. The managers estimate that this represented an efficiency gain in table and graph production of approximately 50% compared to their previous methods.

In preparation for the NDA the company sent the FDA review division a pilot version of APT's 'generated-code' technique (simple, executable analysis code derived from the macro library) for submitting analysis programs. The FDA approved this methodology for submission. This technique was used for packaging the key efficacy and safety analysis programs.

The company prepared their second submission using APT© and now uses it as their default analysis tool. The managers characterize the impact of APT© in the department as "a huge improvement". Producing tables and graphs was significantly faster, taking roughly half the time previously required. The company felt that the consistent programming approach — made possible by APT© — made verifying the analysis much easier. They also noted that their confidence in the analysis was dramatically increased by using a validated library.



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