



SAS Pharmaceuticals Case Study

Summary

Client Challenge:

To overcome lack of personnel needed to perform internal clinical programming support.

To control the quality of outsourced clinical programming support.

COMSYS Solution:

Customize validation standard operating procedure for each project. Create independent validation programs and refine through multiple trials. Complete and thoroughly document validation.

Client Benefits:

Improved turnaround time.
Better quality clinical reports.
Project completed without adding to full-time staff or interrupting other projects.
Use of independent team added further credibility to validation process.

Industry:

Pharmaceutical Company

Project Name:

Statistical Program Validation

Client Description:

Our client is an international Fortune 500 pharmaceutical company that discovers, develops, manufactures and markets prescription drugs for therapeutic areas such as oncology, cardiology, diabetes and respiratory/allergy. The company's therapeutic innovations include treatments for lung and breast cancer, thrombosis, seasonal allergies, diabetes and hypertension. The company also offers a range of human vaccine products.

COMSYS Solution:

The client faced two challenges: working with limited internal clinical programming support and controlling the quality of outsourced clinical programming support. The objective of the statistical and programming validation support provided by COMSYS' Consultant Resource Center was to provide the client with an independently validated clinical programming output.

Continued



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COMSYS Solution continued

COMSYS carefully customized its validation standard operating procedure (SOP) for each project, so that validations could be performed effectively and efficiently. Using the protocol and statistical analysis plan provided by the client, the COMSYS team - a master-level statistician and two to four clinical SAS programmers, depending on the project scope - created validation programs independent of the client's version. Following the validation SOP approved by the client, validation findings were submitted to the client regularly for review and correction. The iterative process continued until all programs were 100% validated. Regular discussions with the client helped resolve differences in specification interpretations. The validation process was documented with checklists, program logs and results, and all validation documentation was archived on compact disk(s) and delivered to the client at the project's completion.

Client Benefits:

Our client has been able to complete many aggressive deadlines and enhance the quality of its clinical reports with the aid of COMSYS' clinical programming validation support team. Outsourcing allowed the client to add resources without affecting other mission-critical projects or the need for hiring permanent staff. The use of an independent validation team improved the effectiveness and credibility of the validation process.

Consulting Services Provided:

- Validation SOP development
- Validation via parallel programming
- Validation documentation

Technologies Used:

- PC Base SAS
- SAS Graph
- MS Word



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