

Application developed for Pharmaceutical Industry that was easy to maintain and execute and could generate reports for the Clinical Data Management department to investigate each data query.

By identifying DQ issues during the early stages of the data processing, the time and resources of the biostatistics department were greatly saved.

Benefits Achieved

1. Increased productivity in creating data acceptance testing programs

- Focus on *generating output* instead of *writing SAS code*
- Easier to read SAS code that would traditionally be lengthy
- Easier to copy macro calls for creating new data checks

2. Useful to address selected tests on the department validation requirements checklist

Macros are task-oriented to meet specific analysis data set validation requirements

- Check non-derived variables
- Check for duplicate records
- Check for missing values

Some macros are individually associated with selected SAS Procedures

- PROC MEANS with typical descriptive statistics

Data Check macros are useful to check data quality issues

- Cross check logic between variables and dates

3. Practical, simple and easy to maintain macros

Macros provide informative feedback in titles

- Input data set name
- Variables checked
- Any subset condition applied

Macros provide reference information in footnotes

- Program name
- Output file name
- Date executed

Macros use basic macro programming techniques that are easy to understand

- Quick development of new macros
- Quick enhancement additions to existing macros

What Controls Implemented to Sustain the Benefits

The data acceptance testing programs are automatically executed after each monthly data download. Review of these test results is expected by each team member.

Lessons Learned (Barriers Encountered and How They Were Overcome)

System needed to be flexible to drop selected data checks, modify data queries and add new data checks. In addition, displaying the message 'No records found' was important to confirm data quality checks and assumptions were met. Finally, feedback from the clinical data management department needed to be incorporated with the reporting process for each data issue identified. This was important to prevent 're-inventing the wheel'.