Developing and Managing a SAS® Macro Library

Margaret James, Carolyn Maass, Ginger Redner
Merck Research Laboratories, Blue Bell, PA

ABSTRACT

A SAS® macro library developed in-house is a valuable resource for providing standard tools to support statistical planning, analysis, and presentation of results for work in the pharmaceutical industry. The library ensures quality, minimizes rework and validation efforts, and facilitates preparation of regulatory submissions and responses to agency questions. The maintenance and continued growth of the library requires dedicated efforts from many developers and users. This paper will describe the organization and maintenance of a SAS® macro library that has evolved over the last seven years for use by statisticians and statistical programmers to support the development of drug and vaccine products. The distributed structure of subcommittees designed to handle the communication and processing for continued growth of the library will be described. The roles of each subcommittee and the challenges faced in the management of the macro library will be discussed.

INTRODUCTION

A SAS® macro library developed in-house supporting programming needs in the pharmaceutical industry ensures quality, minimizes rework and validation efforts, and facilitates preparation of regulatory submissions. In this paper we will highlight the development and management of a macro library which serves the needs of a large group of statisticians and statistical programmers supporting multiple therapeutic areas working in drug and vaccine development, medical communications and epidemiology. Each macro that is included in the library must comply with good programming practices, follow the standard operating procedures (SOPs), and be fully validated in the environments in which it will ultimately be used. Development of clear user documentation is essential for the macro to be easily understood and correctly applied by users. Communication of macro revisions and training about new macros may be required as well, particularly for more complex macros. A support system for user questions and issues is key to the continued use and growth of the library. The management and continued growth of the library requires dedicated efforts from many developers and users.

In the environment of a large pharmaceutical company with many potential users, we have adopted a distributed structure of subcommittees to manage the communication and processes for the maintenance and continued growth of the library. In this paper, we present the structure and division of responsibilities in these subcommittees, the managing tools that we have utilized and some challenges experienced in continuing the growth and maintenance of the library.

BACKGROUND AND SCOPE

A committee of statisticians and statistical programmers was formed in July 1997 to develop a macro library with the following purpose:

(1) Provide SOP-validated, user friendly SAS® macros to be used routinely by the statistics and programming groups.
(2) Facilitate programming standardization in order to eliminate duplication of effort within the department.

The macro library was developed at one site of a large global pharmaceutical company for use across multiple sites by approximately 70 statistical programmers and 90 statisticians employed primarily in the work of product development. Currently, the macro library is maintained by a group of 23 individuals (70% statistical programmers and 30% statisticians) who contribute their time on a part-time basis to work on the macro library in addition to their project work. The members represent different work and therapeutic areas, including, for example, clinical pharmacology, vaccines, oncology, standard reporting, and medical communications. Additional individuals may volunteer to be involved intermittently in validation efforts but are not formally included as a member of the committee.
Currently, the macro library consists of 74 fully-validated macros, grouped in 6 categories based on functionality:
- 26 Statistical
- 25 Utility
- 10 Text handling
- 5 Data manipulation
- 4 Graphic
- 4 Document Formatting

The utility macros are frequently used by statistical programmers. An example of a utility macro in the library is one that was developed to check the SAS® log or text files for strings of error, warning, uninitialized or repeats of by values messages.

The statistical macros that are included in the library provide tools for applying common statistical methodologies. An example is a macro which calculates the exact confidence interval for a binomial response. Another example of a statistical macro is one which performs survival analysis using SAS® PROC PHREG and generates report-ready output tables with event counts, hazard ratio/risk reductions, confidence intervals and p-values.

**MANAGEMENT STRUCTURE**

In order to distribute the maintenance and development of the system across many users in the department, we have distributed the management of responsibilities among a set of subcommittees who assume separate responsibilities in the maintenance of the library (see FIGURE 1). These subcommittees are: Research Effort Committee, Support and Documentation Committee, Macro Approval Committee, Training and Promotion Committee, and Programming and Validation Committee, and special Statistical Macro Development Committees. Both statisticians and statistical programmers participate on these subcommittees, and the coordination of the activities of these 6 subcommittees is co-managed by a statistician and a statistical programmer. A chairperson from each of these subcommittees is responsible for overseeing the work of their subcommittee and reporting on issues at a monthly meeting. Each committee consists of 3 to 6 members. The responsibilities of each subcommittee are described below:

**Research Effort Committee**

This committee evaluates and prioritizes ideas for new macros and existing macro updates. The members assist in developing programming specifications for modifications to existing macros and coordinate needs of all therapeutic areas. They also review and evaluate existing code and tools (Utilities, Electronic Submission Tools, Standard Reports, Etc.).

**Support and Documentation Committee**

This committee develops and implements processes for supporting macros. The members serve as first-line support responding to and tracking all problems, questions and answers concerning the macros. They provide input to enhance macros based on user questions and assist in developing and maintaining macro documentation.

**Macro Approval Committee**

This committee assures all validation documentation is complete. The members prepare additional required documents and serve as gatekeepers of the actual macro shared drive area. They are also responsible for moving the final (validated) version of the macro to production and sending announcements to the user community.

**Training and Promotion Committee**

This committee is responsible for determining macro training needs. Members of this committee assist in the development of training materials and courses for new or existing macros. They maintain the macro library web site by posting macro code and documentation and other useful information. Additionally, they track metrics of macro usage, publicize macro library tools and periodically distribute a newsletter.

**Programming and Validation Committee**

This committee completes programming, developer validation, independent validation and statistical peer review. They also assist in developing macro documentation and training materials and courses. Additionally, this committee educates the Support & Documentation team about the macros.
Statistical Macro Development Committees

These are temporary committees which are formed specifically to develop a new statistical macro for the library. The committee is typically composed of both statisticians and statistical programmers who collaborate to develop the programming requirement specifications for the macro, and to decide on the statistical procedure to be used and the precise format of the output. The committee is responsible for the programming and creation of user documentation.

FIGURE 1
Macro Library Committee Structure
MANAGEMENT TOOLS

To manage the combined efforts of the subcommittees, monthly meetings were established with a representative from each committee providing a summary of the progress and status of the work of his/her committee. Meeting agendas and meeting minutes provide a guideline for tracking progress with macros or resolution of issues.

Tools we have found useful for communication include:

(1) A web site for users to see macro descriptions, and access user documentation for each macro. Also included on the web site are:
- Instructions on how to access the macros with the SAS® autocall facility
- Guidelines for developing new macros
- A flowchart describing the activities required for a new macro to move from initial concept to a final validated and approved macro in the library. (See FIGURE 2)

(2) A public email folder with automatic message forwarding to support personnel. A support person is identified for each macro in the library so that this person can be responsible for investigating or guiding issues identified by users.

(3) A spreadsheet tracking the development of a macro and the completion of activities associated with the macro by the subcommittees

Tools we have found helpful to ensure the quality and standardization of macros include:

(1) A template for developing the User Documentation. It includes the sections and details that should be included with every macro, e.g., required parameters, and specific examples.

(2) A validation guide and checklist, and full validation of new or revised macros.

(3) An approval checklist listing required validation and documentation items.

Tools we have found useful in tracking usage of the macros are:

(1) A metrics tool to measure the use of library macros. This tool searches hierarchical nesting of programs and macros in specified directories, counts the number of times each library macro is called and produces a variety of usage reports, listed by year and overall, including:
- The number and percentage of times each macro was called, by macro category.
- Number and percentage of projects, submissions, protocols and programs using each macro.
- The number and percentage of tables in a submission that were generated using each macro.

Our text handling macros are the most widely used, called over 124,000 times in a six year period, followed by our document formatting macros, called approximately 26,000 times over six years.

(2) A web-based survey that is periodically distributed to all departmental statisticians, statistical programmers and managers asking respondents to subjectively rate the quality, user friendliness, robustness and reliability of the macros on a five point scale. Usage frequency of each category of macro is also requested. The survey results are then loaded into SAS® data sets and graphics are produced to show the quality, effectiveness, frequency of usage and estimates of validation and development time savings gained.
FIGURE 2

Flow of New Macros or Macro Updates

- Progr. or Stat. submits new macro idea or idea for update
- Research team comes up with idea for macro
- Support team suggests update to macro

Research team approves or denies

- Approved idea

Research Team & co-chairs
Determine large Effort

Yes

Special development team formed
Specs (reviewed by research)
Validated program code
 Developer validation doc
 Independent validation doc
 Stat peer review Documentation (reviewed by support + documentation team)
Training material
Training presentation

- No

Developer writes specs, research team reviews or research team writes specs

- Approved specs

Developer or Programming & Val team codes program or update

- Progr. creates doc, Support & Doc team reviews, or Support & Doc team creates doc

- User Documentation

Programming & Validation team validates program or updates

- Independently validated program, Independent validation doc, Logs/Lists/etc.

Promotion & Training team evaluates training need

- Training Required?

Training recommendation

Promotion or Promotion & training develop training + present

Training

Promotion & training team puts doc + training presentation on web + sets up feedback link

Web update

Approval Committee finalizes, adds to library + announces

BENEFITS AND CHALLENGES

Benefits of our macro library have been reported previously (Gillespie, 2005). In short, these benefits include greater productivity and higher quality results. The library minimizes rework and validation efforts, and facilitates preparation of regulatory submissions and responses to agency questions. Our organization has benefitted in having a distributed management structure of subcommittees so that many individuals can share the workload. Individuals can personally develop themselves by being involved in a subcommittee that allows them to enhance their programming or leadership skills. The subcommittees also foster collaboration and sharing of ideas and best practices across therapeutic areas.
Some of the challenges faced in the management of the library include:

(1) Changes to operating systems in work environment (e.g. Window NT to XP)

(2) Revalidation of macros in the library with updated versions of SAS® (e.g. 6.12 to 8.2 to 9.1)

(3) Meeting needs of projects that have immediate requests for slight modifications (addition of new feature, etc.) to existing macros in the library.

(4) Resources (acquiring time from statistical programmers and statisticians who have competing responsibility to project work.)

(5) Ensuring macros will work in multiple platforms (PC and Unix).

(6) Communication of status of various macros in different stages of development across committees.

(7) Globalizing efforts across geographic sites in a large pharmaceutical company.

(8) Promotion of the macros in the library so that people are aware of them, have relevant training on them and actually use them.

CONCLUSIONS

The success of the macro library depends upon the management of communication between each of the 6 subcommittees. Our macro library committee is structured to ensure that each macro will be fully supported throughout the macro's development cycle. Whether a new macro is developed or an existing macro is updated, the macro library committees are responsible to ensure that the macro meets our business needs, provide quality programming, perform independent validation and ultimately approve the macro for the user community. Users benefit by the support provided for each macro through training and documentation.

REFERENCES


ACKNOWLEDGEMENTS

The authors would like to express their appreciation to Amy Gillespie for her assistance in this paper.

TRADEMARK CITATION

SAS and all other SAS Institute Inc. product or service names are registered trademarks of trademarks of SAS Institute Inc. in the USA and other countries. ® indicates US registration.
CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Margaret James
Merck & Co., Inc.
BL3-7
10 Sentry Parkway
Blue Bell, PA 19422
Work Phone: 484-344-7037
Fax: 484-344-4028
Email: margaret_james@merck.com

Carolyn Maass
Merck & Co., Inc.
BL3-7
10 Sentry Parkway
Blue Bell, PA 19422
Work Phone: 484-344-7037
Fax: 484-344-4028
Email: carolyn_maass@merck.com

Ginger Redner
Merck & Co., Inc.
UN-A102
785 Jolly Road
Blue Bell, PA 19422
Work Phone: 484-344-4621
Fax: 484-344-7105
Email: virginia_redner@merck.com