INTRODUCTION

Pharmaceutical companies conduct many clinical studies on a given drug over a period of time. The reporting and summarization process of such studies may be complicated by the necessity of dealing with data from many different databases that have been developed over time, with different variable names and dataset organizations.

This paper describes the Summary System, a menu-driven software system developed at the Parke-Davis Research Division to provide standardized reports for many different clinical studies on a single drug. The Summary System executes in base SAS® software Version 5.18 in an MVS environment. The system is currently being used by the Clinical Programming, Clinical Communications and Biometrics Departments in the Technical Operations Section of the company.

REQUIREMENTS

The requirements for the Summary System were as follows:

Multiple Sources of Information

The Summary System would need to produce summarized reports from at least nine different SAS® databases, each of which may contain data from multiple clinical trials. Dataset organization, variable names, and format libraries differ between datasets.

User-Friendly System

The system would need to have flexibility to interact with users with different levels of computer expertise and exposure to the clinical trial summarization process. The anticipated end users of the Summary System were statisticians and medical writers as well as clinical applications programmers, not all of whom would have equal familiarity with the computer system. Such users would benefit from a menu-driven system with an on-line help facility.

Hard Copy Reports

The ultimate purpose of the system would be to provide hard copy summary reports for use in official summary documents for clinical trials. These reports would need to be numbered, labeled and printed according to the specifications of Clinical Communications. Interim reports might be requested on different subsets of the data.

SUMMARY SYSTEM DESIGN

Based on the requirements described above, SAS 5.18 was chosen as the software package to use for this application. The combination of SAS/AF®, SAS/FSP®, and SAS macros would provide the tools to quickly develop an application with the necessary flexibility.

The format and contents of the summary reports was determined by Clinical Research, Biometrics, Clinical Communications, and Clinical Programming. Generic SAS code was written based on these specifications. Control tables were created to contain information about the specific datasets and variables that the generic code would use to produce reports. This information was organized as a series of SAS datasets, and linked to the program code with macro calls and macro variable names associated with the symbolic fields on the AF application screens. The control tables datasets are as follows:

DBA - Database names and associated format libraries. Each database is assigned a number.

STOVAR - Macro variable names and format defaults used by the Summary System code. Each variable is assigned a unique number.

TRANSVAR - Database-specific variable names and formats, associated with the variable number (from STOVAR) with which it corresponds.

SUBSCRPT - Subscripted variable names found within each database.

SYMPTOM - Clinical signs and symptoms for each clinical trial. (This information is used in a specific summary report.)

Figure 1
WUPROT - Protocol and trial numbers of clinical trials and the number of the database (from DBA) in which they are found.

The flowchart in Figure 1 shows the functional design of the Summary System.

Users enter the Summary System from the TSO ready state by executing the SUMM CLIST. The CLIST allocates the control tables database and AF application files, specifies the autocall file, allocates external files in the user's TSO area, and calls PROC DISPLAY to display the Main Menu screen. From this menu, the user chooses from the three options presented. Basically, the user may choose to edit or browse the control tables, generate summary reports, or exit the Summary System.

Figure 2 displays the Main Menu of the Summary System. Descriptions of the options follow.

Main Menu Option 1

Main Menu Option 1 allows the user to produce summary tables. The next screen (Figure 3) is presented to the user.

From this Report Section Selection Menu, the user selects the type of data to be summarized and the type of analysis to be performed. Each option on the screen brings up a different series of selection screens. A sample selection screen series is shown beginning in Figure 4.

On this screen the user enters the identifying information of the clinical trial to be summarized, the parameters of the analysis, and the summary reports desired. Additional reports that are available for certain subsets of the data can be selected on Page 2 (Figure 5). The user is given the option of entering title and footnote information. Entries made from this screen will override the titles and footnotes generated by the program itself.

Figure 4 and footnotes generated by the program itself.

The last page of the report selection screen (Figure 6) displays the JCL parameters under which the summary report job will run. A macro initializes these parameters with the user's TSO ID and values provided by the Applications Programmer, but the user can change any values. Similar report selection screens are presented for each of the options on the Summary Report Section Selection Menu.

Upon submission of a report selection screen, the SAS code generated by AF resolution is written to an external file; JCL is written to a second file which references the first. The user exits automatically from the application and the CLIST gives the user a choice of submitting the job immediately or exiting to TSO.
The JCL files and SAS code files created by the resolution of the AF application can be edited directly by the user, adding another level of flexibility to the Summary System. A user can change the JCL, change table titles, or subset the data requested.

**Menu Option 2**

This option allows the user to perform utility functions on the control tables. The Utilities Menu (Figure 7) is presented to the user.

A user may select Browse or Edit from the Utilities Menu. In either case, a list of the available members of the dataset is presented (Figure 8). If the user is browsing the data, the next screen presented is the FSP screen displaying all variables in the selected dataset. However, if the user is editing the selected dataset, the user's TSO ID will be checked against a list of users authorized to edit. An error screen is presented if the user's TSO ID is not found, and the user will be returned to the Utilities Menu.

The Utilities Menu was designed to give the users an easy way to check to see if a particular clinical study was "known" to the Summary System before attempting to obtain summary tables, and to allow the Applications Programmer to add clinical studies, with the appropriate variable names, protocol numbers, titles, etc., to the System.

**PROGRAM FEATURES**

There are other features of the Summary System not apparent in the preceding discussion of the screens. Many of the intricacies of the system are in the following macros contained in the autocall file (many of these macros interact with the control tables to "read" study-specific values):

- **SCRN** - Selects the appropriate trial and macro variables based on values entered on the screen.
- **DBA** - Names the appropriate database and format library.
- **KEEPVAR** - Loads the Summary System macro variables with correct SAS variable names for the database selected.
- **MIF** - Used in DATA steps to generate subsetting IF statements based on values entered on the screen.
- **GENCOD2** - Contains study-specific information for titles, footnotes, treatment groups, and report numbers.
- **MJCL** - Writes the JCL necessary to produce the summary job to an external file, using the parameters the user has entered on the screen.

Many of the advanced features of version 5 SAS/AF were used to develop the Summary System. All of the AF screens following the Main Menu are Program screens as opposed to Menu screens. Therefore, it is possible to use the ### Macros to initialize and validate user responses. Macro variables are associated with symbolic fields. Help screens tied to all program screens and parameters are consistently accessed by a function key. Color and reverse video are used on all AF and FSP screens.

Additional features are described below:

The NEXT SCREEN option, present on all report selection Program screens, allows the user to jump directly to another report selection screen without returning to the report selection menu.

If the user selects the WHOLE PACKAGE option on the report selection screens, hitting enter will put an 'X' beside all of the reports relevant to the clinical trial identified by the PROTOCOL, WU/TRIAL, and CUBE parameters. The user does not have to remember which reports are pertinent to which studies.

The APPENDIX/TABLE option on the report selection Program screens automatically enters the word 'APPENDIX' or 'TITLE' in the Appendix Selection columns of the screen, depending on whether the user enters 'A' or 'T'. These fields then appear as the first titles on the reports selected. The user can add appendix numbers, or enter a different first title if so desired.

**FUTURE ENHANCEMENTS**

Conversion of the Summary System to Release 6.06 should greatly expand capabilities for field validation and automatic field entry. In addition, the windowing facility of Release 6.06 will allow the Applications Programmer to simplify the Report Selection Screens and thus make them easier to use.

**CONCLUSIONS**

A SAS-based menu-driven system has been developed at the
Parke-Davis Research Division to provide standardized summary reports on clinical trials whose underlying data may differ in structure. It utilizes auxiliary control tables organized as SAS datasets and the macro facility to load study-specific variable names and other values into macro variables for use in generic summarization programs.

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