USING SAS SOFTWARE TO DEVELOP A CLINICAL STUDIES STATUS SYSTEM

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INTRODUCTION

Pharmaceutical companies conduct many clinical studies on a variety of drugs simultaneously. At any point in time, studies at different stages of development and summarization require coordinated staff effort across departments. The tracking of all these activities and staff responsibilities can be confusing and frustrating if there is no mechanism or tool available to organize all pertinent information. Staff may spend needless valuable time and effort trying to determine the status of project activities.

This paper describes TOSS (Technical Operations Status System), a software system developed at the Parke-Davis Research Division to maintain status information on clinical study progress. TOSS executes in SAS 5.18 under TSO in an MVS environment. The system is currently being tested and used by the four departments which make up the Technical Operations Section: Clinical Data Management, Biometrics, Clinical Programming, and Medical Writing.

REQUIREMENTS

The requirements for TOSS were as follows:

Current Information

Information contained in the database would need to reflect up-to-date status information on any given day. The system was not required to track changes from planned study dates as a study progressed.

User-Friendly System

The system would need to have flexibility to interact with users with different levels of computer expertise. The staff actively working on clinical studies would be entering data directly into the TOSS database. These users might be computer literate; however, the information contained in the database might then be manipulated by managers not quite as versed in computer systems. Less experienced users would benefit from a menu-driven system. In addition, an on-line Help facility would be essential since extensive training of all users would not be possible.

On-Line and Hard Copy Reports

 Retrieval of data is an equally important function as that of entering information. On-line reporting as well as the ability to produce hard copy would be needed. Standard reports would be produced on a regular schedule with ad hoc reporting on an as-needed basis.

Security System

It was anticipated that many users would be interested in the information contained in TOSS. However, only a subset of that group from the Technical Operations Section would actually be editing the database. Therefore, it would be necessary to add a security system to monitor the users.

Working Prototype

A driving requirement for the system was that a working prototype was needed as quickly as possible. Therefore, it was necessary to have a software solution that included tools to encourage rapid development.

TOSS 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 develop quickly, test, and put a system into production for department managers to use and review.

The TOSS database consists primarily of three SAS datasets: (1) PROTOCOL - one record per clinical study containing descriptive information for each study, (2) DEVELOP - one record per clinical study for tracking Technical Operations one-time development activities, and (3) SUMMARY - one record per research report per clinical study containing data for all summarization activities involved in producing a report. Browse FSP screens displaying these three datasets are displayed in the Appendix.

Two auxiliary datasets are also used in the system. The ID dataset maintains a record for each user with their user access code. The ACTIVITY dataset ties activities in the DEVELOP and SUMMARY datasets to the appropriate staff member category.

The following flowchart shows the functional design of TOSS.
Users enter TOSS from the TSO Ready state by executing the TOSS clist. The clist allocates the database and menu files, specifies the appropriate autocall file, and calls the first macro to initialize the system and display the following Main Menu program screen. From this menu, the user chooses from the options presented. Basically, the user may choose to edit or browse the database, generate a report, perform a consistency check on the database, enter a TSO command, or exit TOSS.

The Main Menu which drives the system is displayed in the next figure. This is followed by a description of the different menu options and several of the program screens that support the Main Menu.

**Menu Options 1 and 2**

Main Menu Options 1 and 2 allow the user to Edit and Browse the TOSS database. In either case, the next menu is presented to the user.

**Menu Options 3, 4, 5, and 6**

Options 3 through 6 concern production of reports using the TOSS database. A report is generated in the Display Manager output screen so that the user may view the report on-line (Option 3). The user may repeatedly view the report in the Output screen (Option 4) or clear the Output screen (Option 5). If hard copy is desired, then the output screen can be captured in a TSO disk file and/or printed (Option 6).

A selection of Option 3 brings up the Report Generation Menu.

**Report Generation Menu**

There are several different ways of reporting the data. Two reports display study development or summarization activities by study date or staff member responsibility. There are also two reports showing important milestones for each study. The last two reports list all variables collected in the TOSS database. A user may select as many reports as desired and will be presented with all produced reports in the output screen.

Option 4 provides an opportunity for the user to view a report in the output screen at another time. The user will see a screen with instructions to page backwards to view the report.

Option 5 clears the output screen.

Option 6 displayed in the next figure gives the user an opportunity to produce hard copy.

**Print Report Menu**

This option allows the user to save and/or print the contents of the output screen. The user may select to print the report on the mainframe or on a local printer. The report may also be saved in a TSO file. More than one selection may be made.

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Menu Option 7

This option is used to determine if there are any apparent inconsistencies in the TOSS database. A comparison is made of the PROTOCOL, DEVELOP, and SUMMARY datasets to determine if studies with the same -key fields are contained in all three. Any inconsistencies are reported back to the user as shown in the next figure.

Menu Option 8

Option 8 allows the user to enter a TSO command.

Menu Option 9

With the selection of Option 9, the user leaves TOSS and SAS and returns to TSO.

PROGRAM FEATURES

There are other features of the system not apparent from the preceding discussion of the screens. Many of the intricacies of the system are in the following macros contained in the autocall file:

INIT - Called upon entering SAS. INIT sets up system defaults and calls up the Main Menu.

DATETIME - Calculates the current date and time to display on all menus.

BROWSE - Calls FSBROWSE with the appropriate screen for the selected dataset.

SETUP - Sets up macro variables containing dataset and screen names used while editing.

EDITIT - Allows the user with a verified access code to edit the selected dataset.

REPORTx - Produces all the reports. (Currently 'x' has a value from 1 to 4.)

FORMAT - Sets up the decodes needed for producing the reports.

PRINTTO - Sets up a temporary TSO file to which the output is first written in order to process later.

NUMIT - Post-processes the output for reformating.

GETFILE - Allocates and creates TSO files, as needed, with varying formats.

CONSIST - Checks the database for inconsistencies and displays them to the user.

Many of the advanced features of version 5 SAS/AF and SAS/FSP were used to develop TOSS. All the AF screens used are Program screens as opposed to Menu screens. Therefore, it is possible to use the # # # Macros in all screens to initialize and validate user responses. Help screens tied to all program screens or parameters are consistently accessed by a function key. Color and reverse video are used on all AF and FSP screens. There are often many variables to present on the screens, so it is necessary to organize the screens in a clear and efficient manner. Lastly, all FSP screens are password-protected to prevent users from accidently modifying them while editing.

Additional features are described below:

- Whenever a new study record is added to the PROTOCOL dataset, the system propagates records in the other two datasets with appropriate key variables. This helps to maintain data integrity.

- A backup copy of a dataset is made prior to any editing. If the user has any problems while editing, the backup dataset can be retrieved to replace the problem dataset.

- A hidden option on the Main Menu allows the System Developer maintaining TOSS to run PROC BUILD on the menu catalog. This option is protected from the general user by the use of the TSO ID as well as knowing the option number to select. This is very convenient for system maintenance and debugging.

- Another hidden option allows the System Developer to update the User Access dataset. This dataset tracks all users known to TOSS and their assigned access level. A record must be entered in this dataset to allow a user to perform any editing. This is the core of the security system. Not only can users be denied the ability to edit within TOSS, the level of access for a user may also be changed as needed.

- Every screen presented to the user displays the current time and date. It was not possible to use the system macro variables containing the time and date as these values are set at the point of executing SAS and do not change throughout the interactive session. The macro, DATETIME, listed above, retrieves the current date and time.
values every time it is called and presents them on all AF screens.

FUTURE ENHANCEMENTS

Enhancements of TOSS will primarily revolve around reporting capabilities. Although there are currently several different types of standard reports in the system, there are requests for more. Eventually, there will be a series of reports produced regularly and automatically. Also, there is a desire to have additional on-line displays which pull together data across either different datasets or the same dataset across different studies.

One goal of TOSS was to replace the individual status reports maintained by each department since they duplicate TOSS. However, departments still need to maintain some sort of system to monitor their own activities on a clinical study basis. In the future, it may be possible to link the individual systems to TOSS. Not only would this allow for increased reporting across departments, it would also help to maintain referential integrity of the data.

CONCLUSIONS

A SAS-based menu-driven system has been developed at the Parke-Davis Research Division to track clinical studies as they progress. It is user friendly and meets the needs of managers of the Technical Operations Section for tracking clinical projects that have constantly changing priorities. An initial response to the system has been very favorable.

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APPENDIX
FSP SCREENS DISPLAYING TOSS DATASETS

PROTOCOL DATASET

SCREEN 1

SCREEN 2

DEVELOP DATASET

SCREEN 1

SCREEN 2

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SUMMARY DATASET

Screen 1

Screen 2

Screen 3