A SAS® WINDOW APPLICATION FOR GENERATING FOLLOW-UP CLINIC SCHEDULES AND MONITORING ACCRUAL IN A VA COOPERATIVE STUDY

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ABSTRACT

In the Personal Computer environment an interactive data entry WINDOW system was designed using the SAS® System. This application was written to facilitate the generation of schedules for patient follow-up clinic visits and graphically monitor patient accrual in two Veterans Administration Cooperative Studies Program Clinical Trials. The use of customized WINDOWS as data entry screens proved to be a quick and easy way to enter pertinent study data immediately into the system and to trigger the generation of patient accrual plots using SAS/GRAPH®. The DATASETS procedure with the APPEND option aided in updating the databases. This paper discusses this system and displays the data entry screens and output created by it.

INTRODUCTION

The rate of patient accrual and scheduling of patient follow-up clinic visits are two important features of a multi-center clinical trial. A SAS system of interactive data entry WINDOWS was developed as a tool to aid the end user in generating patient follow-up schedules and to generate SAS/GRAPH plots displaying patient accrual. This system was developed for use in a VA Cooperative Studies Program Coordinating Center (CSPCC) multi-center clinical trial of Percutaneous Transluminal Coronary Angioplasty Compared to Optimal Drug Therapy for Myocardial Ischemia (ACME) and expanded to the trial of Secondary Prevention of Coronary Heart Disease in Men with Low HDL-Cholesterol and Desirable LDL-Cholesterol (HIT). The ACME trial is managed solely on an IBM PS/2® Model 80 Personal Computer with 2 Kbyte memory capacity and 70 Kbyte of hard disk space. The HIT trial is managed on the Yale University IBM 3080 mainframe system. Both trials utilize this PC based SAS data entry WINDOW application for patient scheduling and monitoring of patient accrual. Graphics for patient accrual plots were produced on a Hewlett Packard LaserJet® Series III. The ACME trial will be used for discussion in this paper.

OVERVIEW

In the ACME trial patients were screened at eight VA Medical Centers and if found to be eligible for the study were then randomized to either PTCA or Drug Therapy by calling the Coordinating Center. At the Coordinating Center the information was recorded and immediately entered into the system (Fig. 1). As patients were entered into the system a schedule for follow-up clinic visits and two SAS databases were created. These two databases contain the patient's entry criteria and dates for follow-up clinic visits. They become the basis for all monitoring of both patient accrual and patient scheduling.

DATA ENTRY OF PATIENT INFORMATION

Randomization information is keyed into the system by an interactive data entry WINDOW program which prompts the user for key information. For all screens the AUTOSKIP=YES option is set for all variables which eliminates the need to press the ENTER key each time a value is entered. A dummy variable is used at the PRESS ENTER TO CONTINUE command in each screen. The AUTOSKIP option is set to NO for this variable to allow the user to pause, check the screen for entry errors, then press the enter key.
The patient's randomization number is keyed in the first screen (Fig. 2A) which triggers the second screen (Fig. 2B) to appear. The second screen prompts the user for hospital code, sequence number, date of randomization, patient's name, social security number, treatment assignment, and number of study lesions. The next screen (Fig. 2C) will vary depending on the number of index lesions. These three screens are all part of one WINDOW statement. Each screen is a different GROUP. When all new patients are entered, the user will enter nines (9999999) which shuts off the data entry mode allowing the program to process.

The program creates two SAS databases, RAND.SSD and CLINIC.SSD. The RAND.SSD database contains the randomization information that was keyed in during this step. The CLINIC.SSD database contains the date of randomization and generated target visit dates for follow-up clinic visits for the remainder of the trial. The WEEKDAY function identifies Saturday and Sunday visits which are changed to Friday and Monday. The APPEND option of the DATASETS procedure is used to update the database with new patients. The BASE dataset is the existing dataset while the NEW dataset is the data for patients entered during the current session. For this particular trial patients are randomized for three years and are seen every month for six months. After the six month visit, follow-up will occur annually until the end of the study (six months after the end of randomization). This leads to schedules differing in the number of visits per patient varying from 6 months to 3\(\frac{1}{2}\) years. A variable, RSTOP, is created to identify the number of visits per patient. Lower and upper ranges for follow-up clinic visits are also generated and stored in this database. An interval is set which allows some flexibility in case of scheduling problems.

**FOLLOW-UP CLINIC VISIT SCHEDULES**

This data entry WINDOW program generates a schedule of follow-up clinic visits for each new patient which aids the study nurse in scheduling the patient's follow-up clinic visits according to the study protocol. This is accomplished with a DATA NULL report writing data step using PUT statements and the RSTOP variable to control the number of DO loop iterations. The output (Fig. 3) includes the patient's name, randomization number, hospital name, date of randomization, and a schedule of follow-up clinic visit dates for the entire trial. An expected visit date for each follow-up clinic visit and an interval to allow for scheduling problems appears on the output. It is recommended that a patient be seen as close to the target visit date as possible. These dates are stored in the CLINIC.SSD database which is used later for the monthly reminders. The output is sent to the study nurse immediately after randomization.

**MONTHLY REMINDER TO SCHEDULE PATIENT FOR FOLLOW-UP VISIT**

Each month the Statistical Assistant at CSPCC generates a notice to remind the clinical staff at each medical center of the patients to be seen in the upcoming month. A program which reads the CLINIC.SSD database is used to generate these monthly reminders. This allows for contacting the patient and setting up an appointment for his next follow-up clinic visit. A data entry screen (Fig. 4) is displayed prompting the user for the desired month and year of follow-up. This date is used to scan all the patients in the CLINIC.SSD database in search of those who have a scheduled visit during the time period. Once the database is subsetted, a report is generated using a DATA NULL report writing data step and PUT statements. The visit number and special instructions for key visits are included on this report (Fig. 5). This allows for scheduling of special laboratory procedures. Displayed in the title by a macro variable is the month and year that was entered in the data entry screen. This report is a snapshot of the patient's full study schedule that was generated at the time of randomization.

**PATIENT ACCRUAL**

Another important aspect of a clinical trial is the rate of patient accrual. Accrual is monitored monthly during the randomization period to assess the performance of the participating medical centers. In a clinical trial it is necessary to achieve the target number of patients in a study in order to make decisions with statistical significance. This system allows for a quick and easy
way to evaluate patient accrual using a data entry WINDOW and SAS/GRAPH. The end user need only to enter the cutoff date in the screen (Fig. 6) for the requested evaluation period. A patient accrual plot is then produced displaying accrual from the start of the study to the cutoff date. The date entered in the data entry screen is displayed via macros in the title on the plot. The projected target intake line is also displayed. The plot is produced using PROC GPLOT and an ANNOTATE dataset. The ACME trial was stratified into single and double vessel disease treatment arms so two intake plots were produced each month. The single vessel accrual plot will be displayed (Fig. 7).

DISCUSSION

The system described in this paper is successfully being used for the VA Cooperative Studies Program's ACME and HIT Clinical Trials. It is operated on an IBM PS/2 model 80 and a DELL® 325D. Previous studies have utilized the mainframe for schedule generation in batch mode. The use of interactive data entry WINDOW screens has allowed for faster production of pertinent study material. The ease of producing patient schedules has allowed for speedy scheduling of patients at the time of randomization. As the study database accumulates and problems arise with missed visits, these schedules are utilized to check visit numbers and dates.

The monthly reminders have aided the clinical staff in scheduling the patients for follow-up clinic visits. This job often becomes burdensome as the number of patients at the site increases over time. Patient accrual is monitored monthly and when problems arise at a particular site, attention is promptly given to that site. These accrual plots are also utilized in reports to the Participating Investigators and Data Monitoring Board when they meet annually. The use of a Personal Computer combined with the SAS System for generating schedules and monitoring accrual have been very effective in the management of these clinical trials. These programs are easily adaptable to other studies and will be utilized for future studies at the West Haven Coordinating Center.

REFERENCES


* SAS and SAS/GRAPH are registered trademarks of SAS Institute Inc., Cary, NC, USA.

* DELL is a registered trademark of Dell Computer Corporation, Austin, TX., USA.

* IBM is a registered trademark of International Business Machines Corporation, Armonk, NY, USA.

* LaserJet Series III is a registered trademark of Hewlett-Packard Co., Palo Alto, CA, USA.

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1032
ENTERING NEW PATIENTS TO RAND FILE

** TYPE IN PATIENT'S ID NUMBER **
(IF FINISHED, TYPE IN 9999999)

ENTER PATIENT ID: _______ ==> PRESS ENTER TO CONTINUE ==>

** ENTER VALUES AS DIRECTED **

Hospital Code:___ Strata:__ Seq#:________
Date of Randomization: _____________ (MONTH,DAY,YEAR)
Patient's Name:____________________ (LAST, FIRST, MIDDLE INIT)
Social Security Number:___________ (NO DASHES)
Treatment Assigned:______________(1=PTCA, 2=MEDICAL)
Number of Study Index Lesions:____(1-4)

==> PRESS ENTER TO CONTINUE ==>

** ENTER STUDY INDEX LESION(S) **

LESION #1: _____ (01-17) ==> PRESS ENTER TO CONTINUE ==>

FOLLOW-UP SCHEDULE

CSP #267 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)
COMPARED TO OPTIMAL DRUG THERAPY FOR MYOCARDIAL ISCHEMIA

PATIENTS NAME: Smith, Roger
PATIENT NUMBER: 888-1111
HOSPITAL NAME: West Haven, CT
DATE OF RANDOMIZATION: 12JAN1990

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<th>EXAM NUMBER</th>
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Fig. 2A-C: Data Entry Screen for Entering Patient Information

Fig. 3: Sample Output of Patient Follow-up Clinic Visit Schedule
DATES
Command ===> 

******************************************************************************
* MONTHLY FOLLOW-UP SCHEDULES BY HOSPITAL  *
******************************************************************************

ENTER MONTH: ___ 
ENTER YEAR: _____ --- PRESS ENTER AFTER EACH ENTRY ---

Fig. 4: Data Entry Screen for the Date of the Monthly Reminder

CSP #267 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) 
COMPARSED TO OPTIMAL DRUG THERAPY FOR MYOCARDIAL ISCHEMIA
PATIENTS TO BE SEEN DURING THE MONTH OF JANUARY 1991
HOSPITAL: 888 WEST HAVEN, CT

<table>
<thead>
<tr>
<th>PATIENT NUMBER</th>
<th>PATIENT NAME</th>
<th>DATE OF EXAM</th>
<th>FOLL-UP NO.</th>
<th>EXPECTED DATE OF EVALUATION</th>
<th>INTERVAL BEFORE</th>
<th>ACTUAL DATE OF EVAL</th>
</tr>
</thead>
</table>

* 6 Mon follow-up visit - Schedule readmission & follow-up catheterization & ETT
REMINDER: Ship Blood Samples to Lipid Lab in Lexington this month.

Fig. 5: Sample Output of the Monthly Reminder List
**Fig. 6:** Data Entry Screen for the Cutoff Date for Accrual Plots

**Fig. 7:** Sample Output of Patient Accrual Plot