

DATA MANAGEMENT IN CLINICAL TRIALS MADE EASY

Fiona Campbell-Daigle, Loeb Medical Research Institute, Clinical Epidemiology Unit

ABSTRACT

The Ottawa Civic Hospital's Clinical Epidemiology Unit (CEU) is the data management coordinating centre for approximately 13 multicentre clinical trials. Each trial has varying data management needs which trial coordinators may not be trained to perform. Along with these needs come many different time requirements. Many of these requirements entail access to data and the generation of standard monthly reports, tables and graphics. Due to the constant high demand on the data management team and the varying data management experience of the trial coordinators, these requirements could not always be achieved in the desired time periods. This led to the development of a 'user friendly' SAS®, environment to incorporate the ability for trial coordinators to access data and generate a variety of standard reports at their own discretion. Through the use of SAS/AF, FSP, SCL and BASE SAS, an interactive data management and reporting system was developed to perform such routine tasks. This resulted in the ease of use of the SAS system for trial coordinators as well as free up time for data management personnel to concentrate on more complex data management tasks.

INTRODUCTION

Data management plays a key role in the success of clinical trials. The Clinical Epidemiology Unit currently conducts approximately 13 multicentre clinical trials. Each clinical trial has specific data management needs, which in turn place different demands upon the data management team. For clinical trials at the CEU, four points influence the nature and the extent of the demands placed on this team:

1) **The size of the clinical trial:** This includes the number and location of Trial Centres involved, the number of participants and the number of visits per subject (one or multiple follow-up visits).

2) **Specific needs of the trial:** These are determined by the type of clinical trial being conducted. For example, if the trial requires multiple follow-up visits for the patients, patient follow-up schedules may be required for each trial centre. In addition, are there any special reports may need to be generated depending upon the type of treatment the patients will be receiving.

3) **Time constraints:** Is there a timeline which determine when reports or schedules are to be produced.

4) **The skills of the clinical trial personnel:** Experience in computers and in performing data management both influence the magnitude of the data management team's work load.

Due to the number and the nature of the clinical trials being conducted in the unit, the work load for data management was found to be overwhelming. Consequently a system which enables the trial coordinator to be self sufficient was needed. This paper will discuss how SAS® software can assist in producing a 'user friendly' system. The 'Propranolol for Small Abdominal Aortic Aneurysms Trial (PAT)' will be used to demonstrate this system.

OVERVIEW

The data management duties which the PAT trial coordinator is responsible for are:

- 1) accessing data
- 2) generating various standard reports
- 3) generating trial specific scheduling

SAS software attempted to make each of these duties as easy as possible to perform. Through the use of PROC BUILD, SAS/AF: FRAME Software and SAS/Screen Control Language (SCL), a series of screens with icons were created to help perform these various tasks. The PAT coordinator, using the computer mouse, clicks on the desired icons to perform the required tasks. The coordinator, therefore, does not require any prior knowledge of computers or the SAS programming language. All programs accessed by the trial coordinator through this environment are created externally from the AF: Frame system, in batch mode. Having the SAS programs external to the devised system allows the data management personnel to easily update the programs.

PROCEDURES

When SAS is invoked by the trial coordinator, an autoexec.sas file is executed and the main AF Frame is invoked:

```
autoexec.sas program:
libname pat '/diskd/users/paaa/data';
libname frame '/diskd/users/paaa/frame';
```

```
dm 'af c=frame.sample.data.frame' af;
```

A screen with two icons will be invoked (FIGURE 1):

- 1) Data entry
- 2) Reporting/Scheduling

Data Entry

When the data entry icon is chosen, a radio box created with SAS/AF: Frame, appears. The trial coordinator then chooses the type of trial form they would like to view (FIGURE 2). Through SCL call routines and FSP the appropriate data is accessed and displayed.

example SCL program:

```
CHOICE:
/*patient demographic data */
if choice=1 then do;
call
fsedit('pat.demo','pat.demo.scrn1','browse');
end;

/*patient follow-up data*/
if choice=2 then do;
call fsedit('pat.fup','pat.fup.scrn1','browse');
end;

/*patient randomization */
if choice=3 then do;
call fsedit('pat.random','pat.random.scrn1');
return;
```

The trial coordinator, however, has restricted permissions to read and write to the SAS data sets. Data sets which can only be browsed, are invoked in browse mode and data sets where the trial coordinator is required to enter and edit data are invoked in edit mode. The coordinator then uses the pmenus on the FSP screens to maneuver through the SAS data sets.

Reporting and Scheduling

Reporting

For the PAT trial, numerous reports are essential. These include tables reporting the number of patients enrolled in the trial, graphs displaying the cumulative patient enrollment, basic frequency reports for the various SAS data sets, and a case report form tracking report. The reporting icon invokes an AF Frame which displays icons which in turn, generate the required reports. In order to generate the desired report the time period to

Posters

generate the report for and also, if applicable, the centre to generate the report for is required. When a report icon is chosen, a frame is displayed with text entries where the trial coordinator is prompted to enter the requirements of the report (FIGURE 3). The MACRO language and SCL access and submit the specified report. The results are then displayed in the output window.

example SCL program:

```
DATE:
submit continue;
%let date=&date;
%include
'diskd/users/paaa/report/accrual-tables';
endsubmit;
return;
```

'accrual-tables' program:

```
PROC TABULATE; where date le &date;
  class hospital ethics num;
  var total monmean discont random;
table hospital= 'ethics= ' all='Monthly Totals',
  ((num= ' *random=')*f=5.
  monmean='Monthly Ave.'*sum=' *=7.2
  discont='Trial Drug Stop'*sum=' ) /
  misstext='0' rts=30
  box='Randomization Centre';
```

In this program, the date specified in the frame entry is submitted into the 'accrual-tables' program into the &date variable. This allows the accrual tables to be generated for the appropriate time period. The output for this report will be displayed in the output window. The report can then be printed through the use of the pmenus. In order to print the report in the correct format (portrait/landscape, margins) a permanent print set-up form is created using PROC FORMS. The specific commands for printing are stored in this form. The form is then set in the options statement of the external SAS program:

example:
options forms=pat.land.print;

Each required report is generated in the same manner.

Scheduling

The PAT trial requires more than one follow-up exam per patient. In order to inform trial centres of upcoming patient exams a scheduling system is generated. Patients with follow-up visits to be completed within the next 2 months, have their trial number, examination date and 'time window' that the exam is to be completed within, listed for the specific centres. The follow-up exam schedule program accesses the appropriate data set and generates the patient list based upon the information the coordinator selected. This list is automatically printed on a standard form. This standard form is designed through the PROC FSLETTER. (FIGURE 4) One form is generated for each patient listing the patient's upcoming examinations:

example SCL program:

```
DATE:
submit continue;
%let date=&date;
%let hospital=&hosp;
%include
'diskd/users/paaa/reports/followup-sched';
endsubmit;
return;
```

All schedules for patient follow-up visits and ultrasound visits are generated in the same manner.

CONCLUSION

According to the trial coordinator and data management personnel, this data management system has proven to be both efficient and easy to use. In addition to Pat, other clinical trials in the CEU have adapted this system. The advantage of this is that instead of recreating the system for each trial, the components can be copied to other trials with only slight modifications to be performed (i.e. libname statements and data set name modifications). Consequently data management personnel can implement the system in a shorter time period. Furthermore, trial coordinators become more self sufficient from the onset of the trial. In conclusion, one

can see that SAS software can be utilized in a clinical research setting. It also quite feasible that SAS can be adapted/modified to suit the needs of other types of work environments.

SAS, SAS/AF, SAS/FSP, and SAS/SCL are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries.
 ® indicates USA registration.

Fiona Campbell-Daigle
 Loeb Medical Research Institute,
 Clinical Epidemiology Unit
 Ottawa Civic Hospital
 1053 Carling Ave
 Ottawa, Ontario
 Canada
 K1Y 4E9

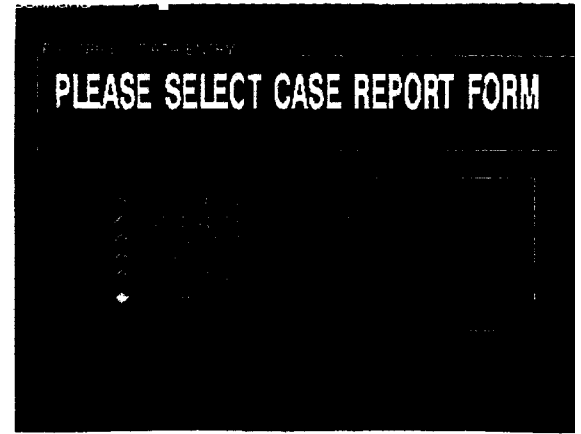


FIGURE 2

FOLLOW-UP SCHEDULE

PLEASE ENTER BEGINNING DATE AND CENTR

DATE

CENTRE #

FIGURE 3

P.A.T. DUTIES

PAT TRIAL COORDINATOR

FIGURE 1

CLINICAL EPIDEMIOLOGY UNIT
 OTTAWA CIVIC HOSPITAL

PROPRANDLOL FOR SMALL ABDOMINAL
 AORTIC ANEURYSMS TRIAL

GUIDELINES FOR PATIENT FOLLOWUP

Hospital:

Randomization Number:

Date of Randomization: \$DRAN

FOLLOWUP DATES:	TIME FRAME:	
2 week phone followup:	\$phone1	\$phone1a -- \$phone1b
1 Month Clinic visit:	\$fup_1	\$fup_1a -- \$fup_1b
3 Month Phone Followup:	\$phone2	\$phone2a -- \$phone2b
6 Month Clinic visit:	\$fup_2	\$fup_2a -- \$fup_2b
9 Month Phone Followup:	\$phone3	\$phone3a -- \$phone3b
12 Month Clinic Followup:	\$fup_3	\$fup_3a -- \$fup_3b

IF YOU HAVE ANY QUESTIONS CONCERNING THIS TIME FRAME OR HAVE ANY PROBLEMS WITH MEETING THESE DATES PLEASE CONTACT THE STUDY COORDINATOR LYNDIA HOEY AT (613) 796-5555 EXT 8687.

FIGURE 4