The Use of the SAS Macro Facility in the Development of a Clinical Information System

Thomas R. Hoffman, Lederle Laboratories

INTRODUCTION

This paper discusses the use of the SAS macro facility in the development of THECIS, a system in use at Lederle Laboratories for processing information from clinical studies. Information on THECIS was first published in 1984[1]. Since that time, data from nine drug projects, including 70 studies and more than 5000 patients, have been processed in THECIS.

The original THECIS code contained no macro language. Instead FSEDIT screens were used to display menus and capture user requests. SAS code was first written to a temporary file, and then executed using the %INCLUDE statement.

During the past year, the system has been completely 'macronized', that is, the SAS macro facility has been used throughout the system. Currently, THECIS uses over 600 macros. Forty percent of the SAS statements that are used to control the system contain some reference to the macro language (a word beginning with either an & or %), and 20% of the THECIS program library contains macro code.

WHY MACRO?

The conversion to a macro system required a substantial effort. It not only meant re-writing over 10,000 lines of code, but required learning a new and different language. The question, 'Why macro?' was raised on more than one occasion.

However, now that a working macro system is in place, the reasons for using the SAS macro facility for systems development are quite clear. They can be summarized as follows:

1. Responsive.
   The response time to invoke a macro menu and validate a user's response is less than a second. Also, since macro variables are available anywhere in the session, information required for controlling the system is readily available.

2. Modular design.
   Each macro can be designed to perform a specific task. This organization not only simplifies maintenance, but makes the system easily expandable.

3. Reduced coding.
   The macro facility can be used to build a higher level command language specific to the system. Once these commands are in place, they can be used instead of many lines of code. This feature simplifies coding, documentation, and maintenance.

   The macro facility can be used to send messages to a user, evaluate the user's response, and then conditionally send the user another message. In some situations, this conversational mode of operation is preferred to a menu system. Rather than read an entire menu, the user only sees the necessary information.

5. Menu avoidance.
   Many experienced users prefer to avoid or skip menus. This menu avoidance, or option stacking, feature is relatively easy to implement using the macro facility.

6. On-line help files.
   The SAS HELP command can be used to obtain help for any menu or menu option. Maintaining these help files is simply a matter of entering information into a member of a partitioned dataset.

TYPES OF MACROS

Although the macros in THECIS are used to perform many different tasks, they can be classified into three general types:

1. Control.
   These macros control either an interactive or batch session. They may display menus, converse with the user, or use information in control datasets to determine which task needs to be performed.

2. Program.
   These macro produce a report. The content and layout of the report may differ depending upon the options specified when the macro is invoked.

These macros are tools used by both control and program macros. They may simply write a message to the screen or they may perform a complex data management task.

A THECIS DEMONSTRATION

The remaining sections of the paper will demonstrate the macro facility by stepping through some of the menus and code in THECIS.

The primary menu that appears when a user enters the THECIS command depends on the user's job function. Clinical research associates, statisticians, data coordinators, and system analysts all have different menus. Two additional menus, one for maintenance and the other for entering case report form specifications, are available only to a few users.

When a member of the clinical data coordination group (CDC) enters the THECIS command, the following menu appears:

The first three items on the menu outline the responsibilities of this group: setting up new studies, loading data, and editing data. The lettered options are available on the primary menus of all users groups. These options are useful for tracking, browsing, reporting, and exploring data.

When option 1 is selected, the user is prompted for a protocol or study number. If a valid number is entered, the following menus appear:

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER

---

THECIS DRUG 041

CDC PRIMARY MENU

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RM Report Menu

X EXIT THECIS

Enter option, then press ENTER
The overnight batch processing is an important feature of THECIS. By deferring all updates to after hours, both the CRF (Case Report Form) and drug level databases remain available to all users during the day. Note that only one job is submitted per study, regardless of the number of sessions.

The New Study Setup menu defines all the tasks required for setting up a new study. There are two macros associated with each of the numbered options. One macro controls the interactive session and the other controls the batch processing.

Suppose the user has finished the new study setup activities and next wishes to review the CRF database for protocol 029. Rather than return to the CDC primary menu, the user can go directly to the CRF database menu by entering 'R C' as shown below:

When option S is selected, a directory of all the form datasets is displayed:

The BF option is used to browse a form dataset:
As can be seen from the above screen, the datasets in the CRF database are designed for displaying and editing one page of data at a time. This horizontal dataset structure is ideal for editing data, but is not useful for ad hoc queries or for running standard safety reports. The drug level database has been designed for this purpose.

The transformation from CRF to drug level is simplified by %VFORM, a very powerful utility macro. The command %VFORM(BR06) returns 14 records for the patient’s data shown in the previous screen. Another utility, %LABNORM, adds the appropriate normal ranges to each laboratory test value.

The results of these transformations can set HEMA as shown below:
The following menus demonstrate a useful tool for a member of the systems group. By entering the option string R R SPF 2, the user can temporarily leave THECIS, and make changes to one of the macros controlling the session. (Note that the SAS display manager cannot be used with macro menus).

```
DRUG LEVEL DATABASE
```

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S Database Directory and Status</td>
<td></td>
</tr>
<tr>
<td>B BROWSE dataset</td>
<td></td>
</tr>
<tr>
<td>G DS/GL Query Language</td>
<td></td>
</tr>
<tr>
<td>R Return to primary menu</td>
<td></td>
</tr>
<tr>
<td>X Exit THECIS</td>
<td></td>
</tr>
</tbody>
</table>

Enter option, then press ENTER

```
RRSPF2
```

After selecting menu C, the CDC primary menu is once again displayed.

The next screens demonstrate how THECIS handles an invalid protocol selection:

```
THECIS DRUG 041
```

```
CDC PRIMARY MENU
```

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RN Report Menu

X Exit THECIS

Enter option, then press ENTER

```
C
```

Enter protocol number, then press ENTER

```
99
```

```
Protocol number 99 is not recognized by THECIS
Try again, enter R to return to menu, or enter L for protocol list.
```

Enter protocol number, then press ENTER

```
L
```

```
002 009 010 018 019 021 022 023 025 026 027 029 030 031 032 033 035 040 041 043 046 048 054 055 056 059 062 063 064 068 069
```

Enter protocol number, then press ENTER

```
A
```

```
Option A can be used to review the current status of any study in the system.
```

```
THECIS DRUG 041
```

```
CDC PRIMARY MENU
```

Option

1 New Study Setup / Study Maintenance
2 Card Image Data - Status / Browse / Load / Print
3 EDIT

A Study Activity Status - all protocols
C CRF Database - Status / Browse / Print
D Drug Level Database - Status / Browse / Query
RN Report Menu

X Exit THECIS

Enter option, then press ENTER

```
A
```

```
Option A can be used to review the current status of any study in the system.
```

547
The drug level dataset DPSETUP provides a good example of the 'control dataset' concept. Information in this dataset is used by THECIS to determine which menu items can be accessed for the selected study.

HOW IT WORKS

Refer to the sample code included at the end of the paper. Macro CC illustrates both how to build a macro menu and control an interactive session. First note that the positional parameters OPT and OPT2 are used for stacking options. After the menu is written to the screen and the options have been input, the utility macro OPTHELP branches to a help file if the user enters HELP or an option number followed by HELP.

The macro ENTERP first prompts the user for a protocol number. It next uses information in the DPSETUP dataset, both to validate the selected protocol and to create the macro variables required for controlling the session.

If the selected protocol is valid and if the selected option is valid for that protocol, then the ALLOC macro is used to allocate the appropriate datasets.

For options 1 and 2, the CSUB macro is called. This macro (not shown) conditionally submits an overnight batch job. Finally, the macro appropriate to the selected option is invoked. OPT2 is used to avoid the secondary menu and go directly to an option.

SUMMARY

Only a small part of THECIS has been shown in this paper. However, hopefully, enough information has been given to illustrate the power of the SAS macro facility in the development of an online system.

Unfortunately, one of the most important uses of the macro facility has not been demonstrated - generic application programming. The THECIS program library contains many 'turn key' programs. All programs have the ability to select a subset of patients, to combine data from several studies, and to blind or unblind the results.

In addition, an entire macro library of tools has been developed for managing data in the drug level database. For example, the macro VISITFL flags any visit outside the day range specified in the study design. The macro DOSEVAR adds dosing information to any specified dataset.

THECIS continues to grow. As more users gain familiarity with the system, new ideas are incorporated. Because of the modular design of the system, additions and enhancements are easily implemented.

Additional information on THECIS can be obtained by contacting

Thomas R. Hoffman
Lederle Labs
Pearl River, NY 10965

Reference

***; %MACRO CC(OPT,OPT2);
*-------------------------------------------------------------------
CDC PRIMARY MENU

%LET CM::CC:
%IF %LENGTH(&OPT»O %THEN %GOTO COPT;
%START:
CLEAR:
%PUT%STR( THECIS
%PUT %STR( CDC PRIMARY MENU
%PUT %STR( Option
%PUT %STR( New Study Setup
%PUT %STR( Card Image Data - Status
%PUT %STR( Study Activity Status - all protocols
%PUT %STR( CRF Database - Status
%PUT %STR( Drug level Database
%PUT %STR( Report Menu
%PUT %STR( X Exit THECIS
%PUT Enter option, then press ENTER;
%INPUT OPT OPT2;
%COPT:
%OPTHELP
%IF &CISRC::HELP %THEN %GOTO START:
%ELSE %IF &OPT=1 %THEN %DO;
%ENTERP
%IF &CISRC:INIT %THEN %eA01IP:
%ELSE %IF &CISRC>O %THEN %GOTO START;
%ElSE %IF "&DESIGN"="." %THEN %DO:
CLEAR;
%PUT The design for protocol &P has not been entered:
%PUT %STRe );
%PUT You will receive output describing the design and visit;
%PUT schedule when completed by statistics:
%RMENU
%GOTO START:
%END;
%ELSE %1
%IF &QPT=2 %THEN %DO;
%ENTERP
%IF &CISRC>O %THEN %GOTO START:
%ElSE %DO:
%ALlOC(TEMP,OLD)
%IF &CISRC>D %THEN %GOTO START:
%CSUB
%IF &CISRC>O %THEN %GOTO START:
%ELSE %CC01 e&OPT2):
%END:
%END:
%ElSE %1
%F &OPT=3 %THEN
%ENTERP
%IF &CISRC>O %THEN %GOTO START:
%ElSE %IF II&SETUPCRFII=""II %THEN %DO;
CLEAR;
%PUT The CRF database for protocol &P does not exist:
%PUT %STR( );
%PUT Use the Option A to determine available protocols;
%RMENU
%GOTO START:
%END:
%ELSE %IF "&LOADDATA"="." %THEN
%PUT The CRF database for protocol &P has no data:
%PUT %STR( );
%PUT Use the Option A to determine available protocols;
%RMENU
%GOTO START:
%END:
%ELSE %DO:
%ALlOC(CRF,SHR)
%IF &CISRC>O XTHEN %DO:
%XCOC(&oPT2)
%END:
%END:
%ElSE %IF &OPT=RM %THEN %XCRM(&OPT2);
%ElSE %IF &OPT=R %THEN %MENU(&OPT2,&SYSBUFFR):
%ElSE %IF &OPT=X %THEN
%00:
ENDSAS %END:
%ELSE %DO;
%PUT Option &OPT not recognized;
%PUT %STRe );
%GOTO START;
%END;
%**; %MEND CC:

XIF ACISRC=HELP XTHEN %GOTO START;
XELSE XIF OPT=1 XTHEN %DO;
XENTERP
XIF ACISRC=INIT XTHEN %G010IP:
XELSE XIF ACISRC=O XTHEN %GOTO START:
XELSE XIF "DESIGN="." XTHEN %DO:
CLEAR;
XPUT The design for protocol &P has not been entered;
XPUT You will receive output describing the design and visit;
XPUT schedule when completed by statistics:
XRMENU
XGOTO START:
XEND:
XELSE %DO:
XALLOC(CR7,SHR)
XIF ACISRC=O XTHEN %GOTO START:
XELSE XIF "LOADDATA="." XTHEN %DO:
XPUT The CRF database for protocol &P has no data;
XPUT Use the Option A to determine available protocols;
XRMENU
XGOTO START:
XEND:
XELSE %DO:
XALLOC(TEMP,OLD)
XIF ACISRC=O XTHEN %GOTO START:
ELSE XIF ACISRC=I XTHEN %DO:
XALLOC(TEMP,OLD)
XIF ACISRC=O XTHEN %GOTO START:
XALLOC(CARD,SHR)
XIF ACISRC=O XTHEN X FREE F(TEMP):
XGOTO START:
XEND:
XELSE XIF "OPT=2" XTHEN %DO:
XENTERP
XIF ACISRC=O XTHEN %GOTO START:
XELSE XIF ACISRC=O XTHEN %DO:
XALLOC(TEMP,OLD)
XIF ACISRC=O XTHEN %GOTO START:
XALLOC(CARD,SHR)
XIF ACISRC=O XTHEN %G010IP:
XELSE XIF OPT=V XTHEN %DO:
ENDSAS %END:
XELSE %DO:
XPUT Option OPT not recognized;
XPUT XSTR( %GOTO START:
XEND:
X")% XMENU CC;
 Validate protocol selection - define control variables

%GLOBAL DESIGN LPRT FORMS CONSTANT SETUPCRF LOADDATA;
%START:
%LET CISRC=O;
%PUT Enter protocol number, then press ENTER;
%INPUT P;
%PUT working;
%LET P=%UPCASE(%NRBQUOTE(&P»;
%IF %LENGTH(&P}=0 OR &P=R OR &P=Q %THEN %STOP;
%LET CISRC='; %GOTO QUIT;
%END;
%ELSE %IF &P=L %THEN %DO;
%PUT %STR( );
DATA _NULL_;
RUN;
MPUT XSTR( );
QUIT;
%END;
%LET CISRC=NEW:
DATA _NULL_;:
SET DRUG.DPSETUP END:EOF:
IF P==&P THEN DO;
CALL SYMPUT( 'CISRC','O');
CALL SYMPUT( 'DESIGN' • LEFT(PUT(DESIGN,DATE. »;)
CALL SYMPUT( 'LPRT' ,LEFT(PUT(LPRT ,DATE. »):
CALL SYMPUT( 'FORMS' ,LEFT(PUT(FORMS,DATE. }D:
CALL SYMPUT( 'CONSTANT' ,LEFT(PUT (CONSTANT ,DATE _»;
CALL SYMPUT( 'SETUPCRF' ,LEFT(PUT(SETUPCRF ,DATE _»;
CALL SYMPUT( 'LOADDATA' ,LEFT(PUT(LOADDATA,DATE. »);
CALL SYMPUT( 'ALLPTS' ,LEFT(PUT(ALLPTS,DATE. »);
STOP;
END;
IF EOF THEN CALL SYMPUT( 'CISRC','NEW');
RUN;
%IF &CISRC=NEW OR &CISRC=NOOP %THEN %DO;
CLEAR:
%IF &CISRC=NOOP %THEN
%PUT Protocol number &P is not recognized by THECIS;
%ElSE %If &CISRC=NEW %THEN
%PUT No protocols available for Drug &P;
%LET &D_&P:
%GLOBAL &D_&P;
%QUIT:
%END:
%ELSE %If &CISRC=NEW %THEN %DO;
%LET CISRC=1;
RMENU
%GOTO QUIT:
%END:
%END:
%IF %LENGTH(&P)=1 %THEN %LET P=0&P;
%ELSE %If %LENGTH(&P)=2 %THEN %LET P=0&P;
%LET OP:&D_&P:
%QUIT:
%**; %MEND ENTERP:

***; %MACRO ALLOC(FILE,DISP):
%T$O ALLOC F(&FILE) OAC%STR(%'&PR __ CIS_O&O_P •&FILE%'» &DISP:
%IF &SYSRC NE 0 %THEN %DO;
%LET CISRC:'
CLEAR:
%PUT DP &Of&P
is currently in use - try again later;
RMENU
%END;
%**; %MEND ALLOC;

***; %MACRO RMENU;
%PUT %STR( );
%PUT Press ENTER to return to menu;
%INPUT;
%**; %MEND RMENU;

***; %MACRO OPTHELP;
%*------------------------------------------------------------------
Returns CISRC=HELP if OPT or OPTZ equal H or HELP
Calls help file
%LET CISRC=O;
%LET OPT=UPCASE(%NRBQUOTE(ADOPT));
%IF ADOP-H OR ADOPHELP XTHEN XDO;
%LET CISRCHELP;
HELP ADOP;
%END;
%ELSE %IF &ADOP=H OR &ADOPHELP XTHEN XDO;
%LET CISRCHELP;
HELP &ADOP,xADO;
%END;
%ELSE %IF &CISRC=HELP XTHEN XDO;
%LET CISRCHELP;
HELP &CISRC,HELP;
%END;
%**; %MEND OPTHELP;

550