

Using SAS/AF® to Create Applications for the Administrative Aspects of Data Management in Clinical Trials

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ABSTRACT

SAS/AF® Frame applications enable the data manager to maintain patient randomizations and case report forms (CRFs). The user is able to create patient calendars, generate monthly expected visit reports, and maintain logs of CRFs received for a patient at any given study visit. These administrative tasks are easily accomplished with the use of a SAS/AF® application. Upon randomization into the clinical trial, the user is able to generate a patient calendar projecting the dates for all the study visits required by the protocol. The information generated by the patient calendar is used by another SAS/AF® Frame entry to generate expected visits for intervals chosen by the user. A SAS/AF® Frame entry for receipt of CRFs for data entry was developed listing CRFs required for a study visit with check boxes for forms received. Using the information from the CRFs receipt frame, missing or delinquent CRF reports may be generated.

INTRODUCTION

As part of the quality management plan for the Southeastern Pediatric AIDS Clinical Trial Unit (PACTU), the data management team is responsible for generating monthly reports of expected study visits and maintaining an ongoing list of the case report forms (CRFs) not in the national data base for study visits at the Southeastern Unit. The PACTU at UAB participates in multiple clinical trials and includes four sites in Alabama and Georgia making it tedious and time consuming to maintain paper records and generate monthly administrative reports for the four different sites. Maintaining the sites' study participant enrollment, clinic visits and receipt of CRFs could easily be accomplished with the development of a SAS/AF® application for these specific PACTU administrative tasks.

We created a SAS/AF® FRAME Application in Version 6.12 of the SAS System on the Windows 95/ Windows NT platform. The user enters the main menu of the application and selects either the Randomization submenu or the Case Report Forms submenu by pressing the appropriate Icon (Fig. 1). The description of the two options, Randomizations or Case Report Forms, are described in more detail in this paper.

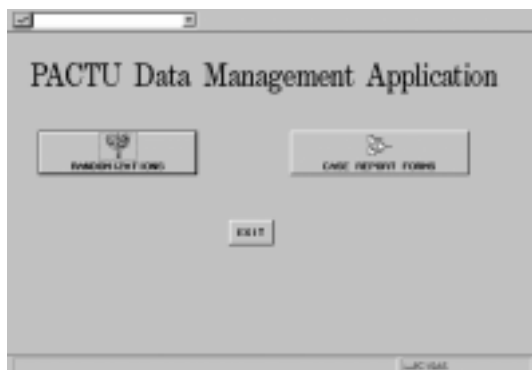


FIGURE 1

RANDOMIZATIONS:

Upon entering the Randomizations frame the user is given four choices of how to proceed (Fig. 2). The user is able to select a new randomization, search and edit previously entered observations, generate patient calendars, or generate an expected visit report. Each choice is described below:

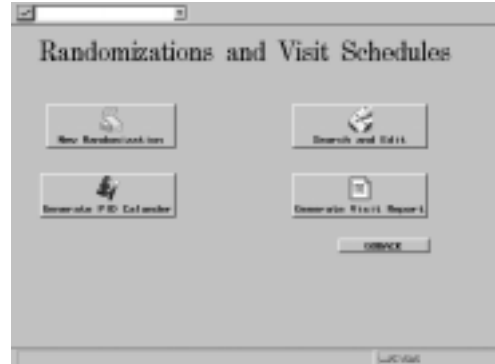


FIGURE 2

New Randomizations:

The purpose of the New Randomization frame is to enter the information necessary for generating a calendar for a new patient enrolled on one of the study protocols (Fig. 3). Once the new study patient is entered into the data set in this frame their next study visit will appear when the expected visits report is generated.



FIGURE 3

The New Randomization frame has a Data Form with Input Field and Radio Box widgets for entering the data. The user is able to choose the site number based on the choices given in the Radio Box. The date of randomization, start date of visits, and identification numbers are always entered. However, depending on the protocol selected certain fields may be skipped. For example, the user is allowed to enter the patient's date of birth only when protocol 219 is selected, otherwise the date of birth field is skipped. If the user selects protocol 316 the cursor continues to the Radio Box for denoting whether the patient is the mother or the infant. When other protocols are selected this Radio Box is skipped. The user is able to add another entry by pressing the "Next" Command Push Button. If the "Cancel" Command Push Button is pressed the current entry is not saved, whereas if the "End" Command Push Button is pressed the data will be saved and the user will be returned to the previous frame.

The SCL for the New Randomization frame simply

calls the Data Form and enables a row to be added when indicated. The SCL behind the Data Form is more complex. In the INIT section, all of the fields are set to missing and the cursor is set to appear at the first field which in this case is site. Continuing to the MAIN section, the cursor progresses through the different widgets after the current widget is filled in and the enter key is pressed. Based on the protocol selected by the user, a visit schedule is created in the MAIN section of the SCL establishing the data necessary for a calendar to be printed and an expected visit report to be generated.

Search and Edit Randomization Entries:

The purpose of the Search and Edit frame is to allow the user to look up a particular patient identification number by searching the data set sorted by either site or protocol number (Fig. 4). By double clicking on a row in the Data Table, the New Randomization frame appears with the Data Form filled in with the observation selected and the user is able to edit the observation.

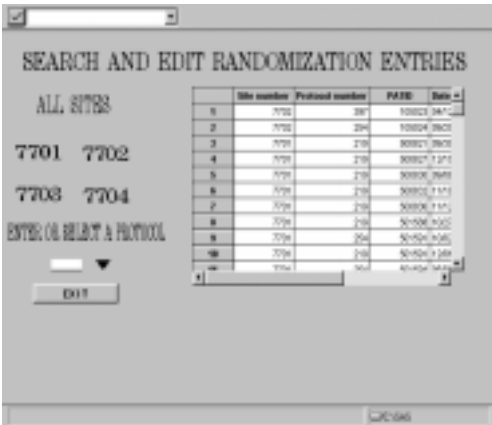


FIGURE 4

The Search and Edit frame is set up so that the user is able to sort by site simply by selecting the site number Graphic Text Object. Once the site number is chosen, the color changes of the selected Graphic Text Object and the Data Table observations are sorted accordingly. Should the user want to sort the data set by protocol, the protocol number can be typed in on the Text Entry Object or retrieved by selecting the Control Object Arrow listing all active protocols.

The SCL for the Search and Edit frame begins with specifying the columns shown in the Data Table before any sort has been requested. The data set is opened and lists are created. The protocol list for the Control Object is created by using the LVARLEVEL function to compile a list of all the unique values for the protocol variable. The Graphic Text Objects are then coded to change color when selected by the user and the data to be displayed in the Data Table sorted by the _SET_WHERE_ method.

The code for the protocol Control Object calls up a Popmenu displaying the list of active protocol numbers. Once the selection is made, the _SET_WHERE_ method is used to sort and display only the observations of the selected protocol number. When the user exits the data set is closed and the lists are deleted in the TERM section.

In order for a single observation to be displayed on the Data Form, the _SET_INSTANCE_METHOD_ and the _SELECT_ method are needed in the SCL for the Search and Edit frame. The _SET_INSTANCE_METHOD_ and the _SELECT_ methods identify the row selected from a list and then displays the Post frame with the Data Form from the New Randomization frame. The SCL for the Post frame controls the display of the observation if a row was identified by the Select Method. The user is able to make edits to the data on this frame. The SCL behind the Data Form on the Post frame is the same SCL code that is behind the Data Form on the New Randomization frame. Once the user presses the "End" Command Push Button on the Post frame the edits are saved to the data set and the user is returned to the Search and Edit frame where another search may be made or the user may exit from

the frame returning to the main Randomization frame.

Generate a Patient Calendar:

The purpose of the Calendar frame is for the user to print out a calendar of expected study visits that a patient will have on a particular protocol (Fig. 5). The user is asked to enter both the identification number of the patient (PID) and the protocol the patient is enrolled on. Pressing the "Print Calendar" Icon generates a print out of the calendar for the specified patient automatically. There are Control Objects for both the PID number Input field and the protocol number Input field. The SCL INIT section opens the needed data set and creates lists. The lists needed for the Control Objects are created by using the LVARLEVEL function to return the values of all the unique protocol numbers and PID numbers and populate the list for the Control Objects. Once the user has entered the PID and protocol numbers needed for the calendar the "Print" Icon may be pressed and the SCL continues providing a title for the printout by filling in the appropriate PID number and protocol number in the title. Due to the way the data set was initially created for use in a SAS/FSP® (PROC FSEDIT) environment, PROC TRANSPOSE is needed for the layout of the calendar so the list of visit weeks and dates line up vertically instead of horizontally. The data set is closed and the lists are deleted in the TERM section once the user exits from the frame and returns to the main Randomization frame.

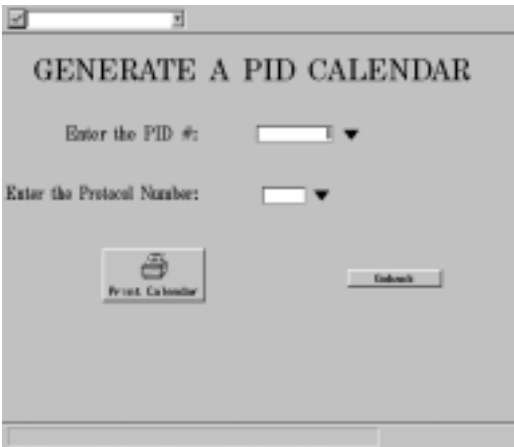


FIGURE 5

Generate Monthly Expected Visits:

The purpose of the Report frame is to generate a report of expected visits for a user-specified time interval (Fig. 6). The user is asked to select the appropriate site number from a Radio Box Widget and then enter the date range for the expected visits. Once these fields have been completed, pressing the "Print" Icon will automatically generate the report. The Report SCL begins with the activation of the "Print" Icon. The INIT section of SCL subsets the data set with only those observations for the specific site number selected. The site number and date range entered on the frame are included in the title for the report. A macro has been written that goes through all of the date variables in the data set checking to see if the value for these variables falls between the date range requested by the user. If the values are within the specified time frame they are subsetted using an OUTPUT statement. The final steps in the SCL generate the labels for the variables that will appear on the report. Should the user want to print out a listing of the expected visits for all of the sites, then the macro is run again for all of the observations in the data set instead of only selected sites. The user may continue to generate other reports or exit from the frame.

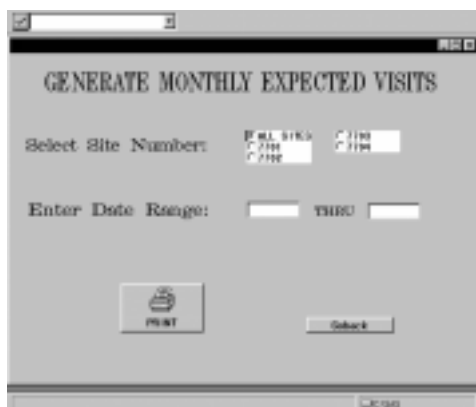


FIGURE 6

CASE REPORT FORMS:

Upon entering the Data Management of CRF's menu, the user is given three choices of how to proceed (Fig. 7). The user is able to enter case report forms received for a new study visit, edit the forms received for a previously entered visit, or generate a missing forms report. Each choice is described in the sections below.



FIGURE 7

CRF's Received:

The purpose of the CRF's Received frame is to record the forms received for a study visit (Fig. 8). Once the forms are recorded in the data set, a report of all the forms not received may be generated. The CRFs frames are a bit more complicated than those described in the Randomization frames. When the frame first appears, a list of Input Fields and a Radio Box are present for the user to enter the requested information (Fig. 8). A Control Object is available for the visit week Input field. The user can either enter the visit week on the Input Field or use the Control Object to call up a Popmenu displaying a list of all the available study visits. A Radio Box Widget records if all the forms for the study visit were received. By pressing the "Show Forms" Graphic Text Object, a Data Table appears (Fig. 9). Based on the visit week requested by the user, the Data Table will list only the forms needed for that visit and a column for the user to mark with an "X" if the form was received. The subsetting of the data set is accomplished using the `_SET_WHERE_` method and `_SET_DISPLAYED_COLUMNS_` method. The user can then press the "Update Table" Graphic Text Object and the values entered into the Input fields and the Radio Box will be added to all of the rows displayed in the Data Table using the `_GET_VALUE_`, `_GET_TEXT_`, `_SET_COLUMN_VALUE_`, and `_SET_COLUMN_TEXT_` methods.



FIGURE 8

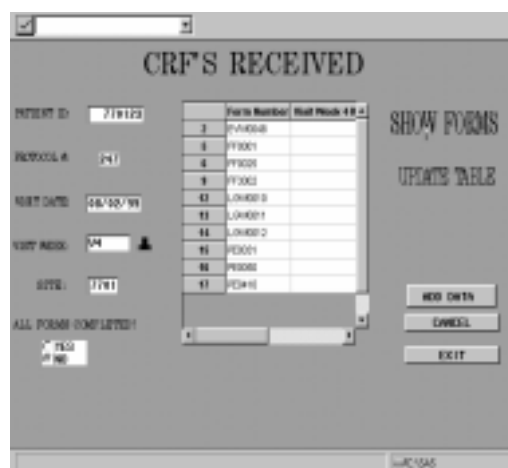


FIGURE 9

There are three different data sets used in this frame. In the INIT section of the SCL for the CRF's Received frame, the permanent data set FORMS247.SD2 is copied to a temporary data set called WORK.SD2. The temporary data set is then opened and used to populate the Data Table. The updates made to the Data Table and the amending of the values from the Input Fields to the rows in the Data Table all take place on the temporary data set. However, when the user presses the "Add Data" Push Button, the edited WORK.SD2 is appended to FORMSREC.SD2 using the PROC APPEND procedure. Once the data has been appended to the FORMSREC.SD2, the WORK.SD2 is deleted. The data sets are closed and the lists are deleted in the TERM section of the SCL.

Search and Edit Visits:

The purpose of this frame is to allow the user to go back to a study visit previously entered and update the forms received (Fig. 10). The user is asked to enter a PID number and a visit week. The values can be entered onto the Input Fields or the user can use the Control Objects to retrieve a listing of the possible PID numbers and study visits. By pressing the "Show Table" Graphic Text Object, a Data Table is displayed listing only the forms for the PID number and study visit selected (Fig. 11). This is accomplished with the `_SET_WHERE_` and `_SET_DISPLAYED_COLUMNS_` methods. Once the user exits the frame, the changes made to the Data Table are saved to the FORMSREC.SD2 data set.



FIGURE 10



FIGURE 11

Generate Missing Forms Report:

The purpose of the Missing Forms frame is to generate a report by site of the CRFs missing for study visits that have taken place (Fig. 12). The user simply selects the site number from a Radio Box and by pressing the "Print Report" Icon, a report is automatically printed listing the PID number, protocol, visit date, visit week and missing forms. The INIT section of the SCL includes the site number and the date the report is generated in the title of the report. The data is then subsetted based on the site number selected by the user. Through a series of data steps the data needed for the report is gathered and the PROC PRINT procedure is executed. The report is printed and the user can either generate another report or exit from the frame.



FIGURE 12

CONCLUSION

The use of SAS/AF® FRAME entries makes it easy to accomplish the administrative aspects of data management in the Southeastern PACTU. This application could easily be revised for use in data management of other clinical trials ongoing at the University. The SCL code for the application will be available at the SESUG 1999 annual conference or by email from the authors.

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