

Creating Visit Specific CRF Checklists for a Longitudinal Study using a SAS/AF® Application

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ABSTRACT

A longitudinal study recently opened at our Pediatric AIDS Clinical Trials Unit (PACTU) requiring complex study visits, a large number of case report forms (CRFs) and an increased frequency of study visits. To assist both clinical and data management staff in managing and maintaining a visit checklist of CRFs required, we modified a previous SAS/AF® application. Five sites in Alabama, Georgia, and Florida send CRFs for data entry to UAB and we have created a Data Management Application (SAS v.8) that generates the expected visits for new patients randomized and also generates the data for the visit specific CRF checklists for each participant's subsequent study visits. The visit specific CRF checklist includes the Patient Id Number, expected visit date range for the next study visit, the study calculated year, month and visit week of the upcoming visit and a list of all the CRFs required for the visit per protocol. Using the data obtained in the randomization section of the application we are able to calculate the differing follow-up schedules based on the age and infection status of the patients. This information is then exported to WordPerfect where a macro generates the visit specific CRF checklists for the participants.

INTRODUCTION

The data management team for the Southeastern Pediatric AIDS Clinical Trial Unit (PACTU), generates monthly reports of expected study visits, and also an ongoing list of delinquent case report forms (CRFs) not in the national database. With the recent addition of a longitudinal study (protocol 219C), the number of study visits and number of CRFs required has significantly increased. In order to assist the clinical and the data management staff, an older version of the PACTU Data Management Application has been updated to generate visit specific CRF checklists for each participant's study visits. The PACTU Data Management Application has been previously discussed in the SESUG 99 paper entitled "Using SAS/AF® To Create Applications for the Administrative Aspects of Data Management in Clinical Trials" (Mixon, et al. 1999).

We have created a SAS/AF® FRAME

Application in Version 8.0 of the SAS System on the Windows 2000 platform. Upon entering the PACTU Data Management Application, the user enters the main menu for PACTU Randomizations and Visit Schedules and is presented with four choices of how to proceed (Fig. 1). This paper will address each of these options (New Randomizations, Search and Edit, Generate Visit

Reports, and 219C CRF Data Set) in the following respective sections.

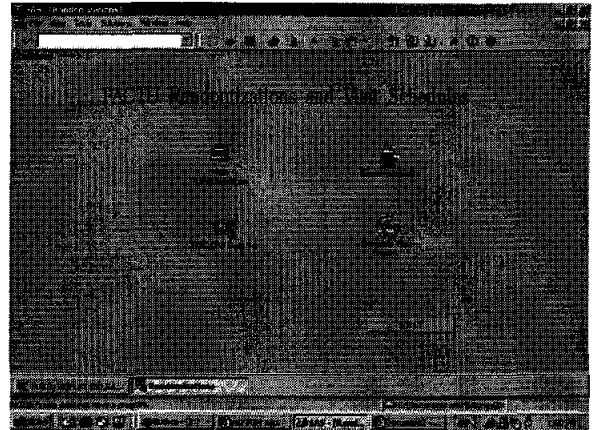


Figure 1

NEW RANDOMIZATIONS

As described in the SESUG 1999 paper, the purpose of the New Randomization frame is to enter the information needed for generating the expected visits report (Fig. 2). We have updated the frame using new SAS/AF® Version 8 features. The randomization frame has a Data Form with Text Entry Control components for entering the data and Text Label Control components for labeling the different fields. Both the heading of the frame using a Graphic Text Control and the Command Push Buttons at the bottom of the frame are objects from SAS/AF® version 6.12.

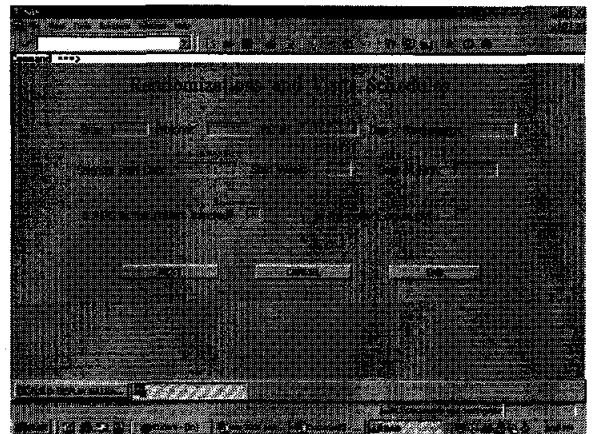


Figure 2

SAS SOLUTIONS AND VERTICAL PRODUCTS

The SCL for the New Randomization frame calls the Data Form allowing a new row to be added when needed. The SCL behind the Data Form sets all the fields to missing, moves the cursor through the fields, and calculates a visit schedule based on the data entered by the user.

SEARCH AND EDIT RANDOMIZATION ENTRIES

The Search and Edit Randomization Entries frame allows the user to sort the randomization data set by either site number (from five study sites in Alabama, Georgia, and Florida) or Patient Identification (PID) number (Fig. 3). The Search and Edit frame is similar to the one described in the SESUG 99 paper except for using Version 8 controls. The Graphic Text Controls for the site numbers subsets the Data Table by the user selected site. Entering a PID number in the Text Entry Control and clicking the "Sort Table" Push Button Control subsets the Data Table for only those entries with the specific PID number. Selecting the row in the Data Table pulls up the New Randomization frame containing the Data Form with the selected observation allowing the user to edit the record (Fig. 4).

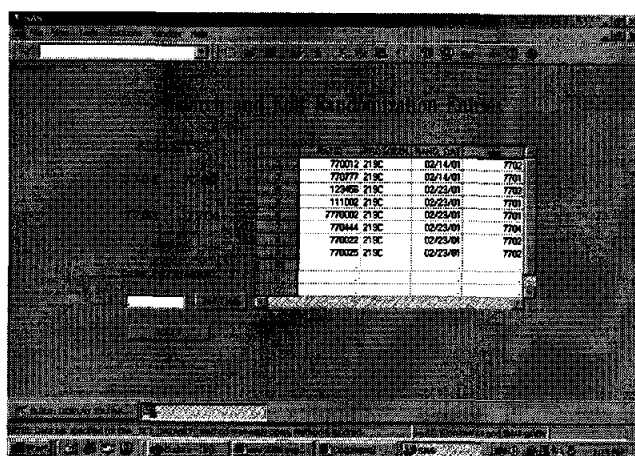


Figure 3

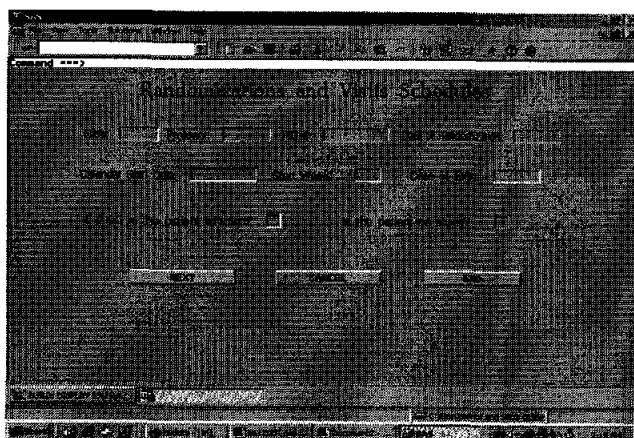


Figure 4

The SCL for the Search and Edit frame begins by declaring an object called ID. The data set is opened by the ID._SETDATASET statement and lists are created using the MAKELIST method. The Graphic Text Controls are coded to change color and to subset the Data Table using the _SET_WHERE_ method. The Data Table is also sorted when a PID number is entered into the Text Entry Control and the Push Button Control is selected. Once the Push Button is pressed, a PUT statement with a CALL PUTLIST routine is used to check the value entered into the Text Entry Control and to verify that the value from the MAKELIST is correct. These events are followed by the Data Table being subset using the ID._SETWHERE method. To view a single observation displayed on the Data Form, the SCL for the Search and Edit frame uses the _SET_INSTANCE_METHOD_ and the _SELECT_ methods as described in the SESUG 99 paper. When the user exits the frame, the data set is closed and the lists are deleted.

GENERATE MONTHLY EXPECTED VISITS

The Monthly Expected Visits frame generates a report of expected visits by site and time interval specified by the user (Fig. 5). The site number is selected from a list in a Radio Box and the date range is entered into Input Fields. Once the user has selected the values for the fields, the "Print" Icon is pressed generating the expected visits report.

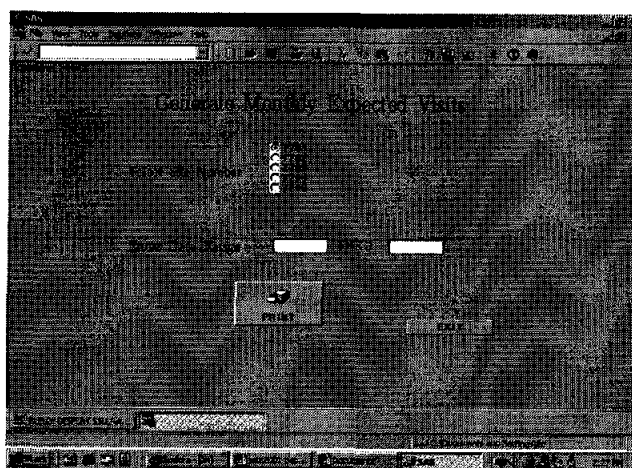


Figure 5

The SCL for the Monthly Expected Visits frame begins when the "Print" Icon is pressed. The data are subset based on the site and date range specified by the user. A macro is then executed to check all of the date variables in the

data set to determine if they fall within the date range specified. If the dates within the specified range are identified, the dataset is subset using an OUTPUT statement and labels are assigned for the variables appearing on the report. Multiple reports may be generated while in this frame with the user exiting from the frame upon completion.

219C CRF CHECKLISTS

The 219C CRF Checklist frame saves the data set that will be imported into WordPerfect® for generating the visit specific CRF checklist for each individual participant (Fig. 6). The frame consists of Graphic Text Controls, an Input field for specifying the PID number needing the checklists, a "Generate Checklist" Icon, and a Command Push Button. The SCL behind the frame is initiated within a SUBMIT CONTINUE routine when the "Generate Checklist" Icon is pressed. The data set is subset by both on the PID number entered by the user and protocol equal to 219C. Visit specific variables (PID number, expected visit date, study calculated year, month and visit week) are kept and saved as a DBF file. The user then exits the application and opens WordPerfect®. A WordPerfect® macro imports the DBF file, creates a WordPerfect® data file and then merges the data file with the 219C CRF Checklist forms (Fig. 7). The 219C Checklist forms may be printed and distributed to the clinical personnel.

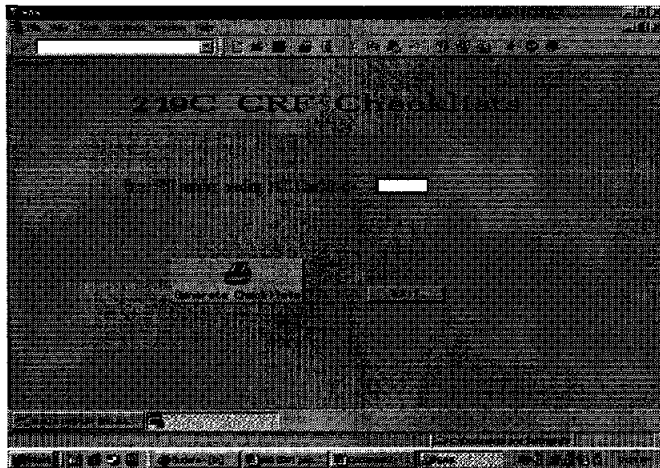


Figure 6

CONCLUSION

Modifications made to a previous SAS/AF data management application enables the generation of CRF checklists for a longitudinal study recently opened at our PACTU sites in Alabama, Georgia, and Florida. These checklists aid the clinical and data management staff in managing the large number of CRFs required at the specific study visits. This application could easily be

revised for use in the data management of other research studies.

Figure 7

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