

A SAS/AF® Application for Organizing the Data Management Activities of the CHIMES Follow Up Study

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ABSTRACT

The CMV & Hearing Multicenter Screening (CHIMES) Study is a multi-center NIDCD funded study to define the contribution of congenital cytomegalovirus (CMV) infection in childhood hearing loss. The CHIMES study consists of two components, the screening study and the follow up study. The follow up study consists of children who test positive for congenital CMV infection. These infants are followed from infancy to 4 years of age to monitor any changes in their hearing status. All data for the CHIMES study are entered by scanning TELEform designed data forms and using the TELEform software to read, process, and verify the data. Once the data are verified they are saved in a comma separated value (CSV) format. SAS® programs are run on the data while in the CSV files for identifying logic and possible data entry errors prior to making the data permanent in SAS datasets. Once the data are converted to SAS data files any changes made to the data are tracked using SAS/FSEDIT screens. Using the data in the SAS data files, a listing of CMV confirmation results received for the enrollment visit of new study participants may be generated. This SAS/AF® application has been developed to help organize the data management tasks of the follow up study. Separate frames with icons are used to list the twenty-four pre-SAS programs and sixteen FSEDIT screens the user may choose to run with a third frame available for generating the list of CMV confirmation results by way of an ODS PDF report form.

INTRODUCTION

The job of a data manager requires multitasking when working on a multicenter longitudinal study spanning over seven years. Entering data, running error checks, querying sites for corrections, updating the data sets with corrected data and many other daily tasks occur repeatedly over the lifespan of the study. To help automate a few of the more common data management tasks we developed this application for the CMV follow up study portion of the CHIMES Study. This paper will discuss three tasks the user may choose in the application along with a description of the objects and SAS Component Language (SCL) used for each frame of the application.

DESCRIPTION OF MAIN MENU OF THE CMV FOLLOW UP STUDY APPLICATION

The opening frame of the CMV Follow Up Study Application presents the user with three choices of how to proceed. The user may choose to run the PreSAS Programs, FSEDIT Correction Programs, or the Confirmation Result Reports (Fig.1) by selecting the appropriate icon on the frame or the user may select the "EXIT" Command Push Button for exiting the application.



Figure 1

The SCL for the Main Menu frame uses the CALL DISPLAY routine for opening the selected frame.

```
PRESAS:  
Call Display('PreSASmenu.frame');  
return;
```

A description of each choice follows.

PRESAS PROGRAMS

The PreSAS program Icon takes the user to a listing of twenty four SAS programs that are organized and labeled by the data form number assigned by the Data Management Unit (DMU) of the CHIMES Study. The data for the CHIMES Follow Up Study are entered using TELEform designed data forms that are scanned, processed and verified using the TELEform system. Once the data are verified by a data manager, the data are exported into comma separated value (CSV) format files. Before the data are imported into the SAS datasets a series of programs are run on the CSV files checking for logic and data entry errors. There are twenty four different forms that are used during the follow up study and each form has its own specific PreSAS program. Forms that were processed on a given day will determine the programs that will be needed. Since there are multiple programs we developed this part of the application as a means to organize and easily call up the specific program as needed (Fig. 2).

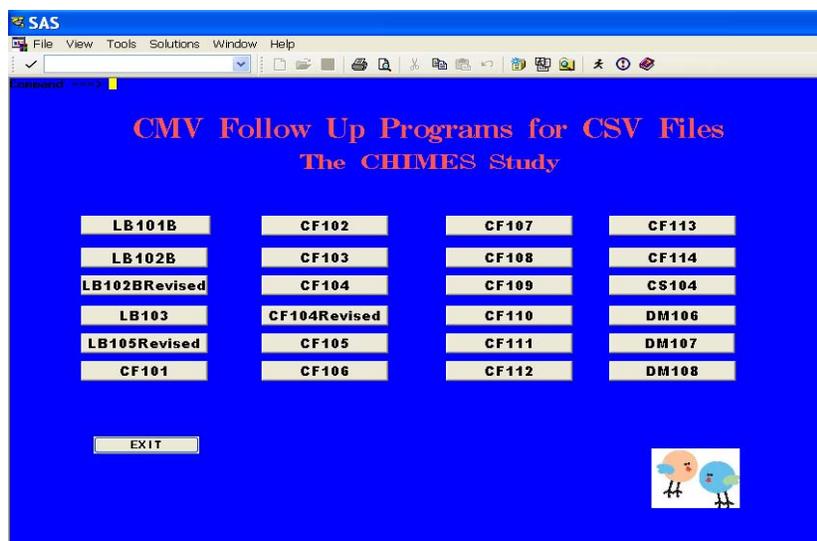


Figure 2

Push Button Controls are used to list the different data form programs with an "EXIT" Command Push Button at the bottom for exiting back to the main menu frame. Once the user selects a button, the SCL behind the button calls up the appropriate base SAS program, submits the program and ends by showing the user the output window with the results. The code needed is within a Submit block using a DM statement with the Submit option.

```
BNLB101B:  
SUBMIT CONTINUE;  
dm 'pgm; include K:\CMVFollowupData\FollowUpDataCorrectionApp\presasprog\PresasformLB101B.sas'  
submit;  
ENDSUBMIT;  
RETURN;
```

To run multiple programs the user clicks back to the application in the Window Bar and selects another program from the list.

FSEDIT CORRECTION PROGRAMS

The FSEDIT Correction Programs Icon opens a frame with a listing of sixteen Push Buttons each representing a CMV Follow Up Study data set (Fig. 3). Each data set has FSEDIT screens where a data manager documents the changes being made to the data.

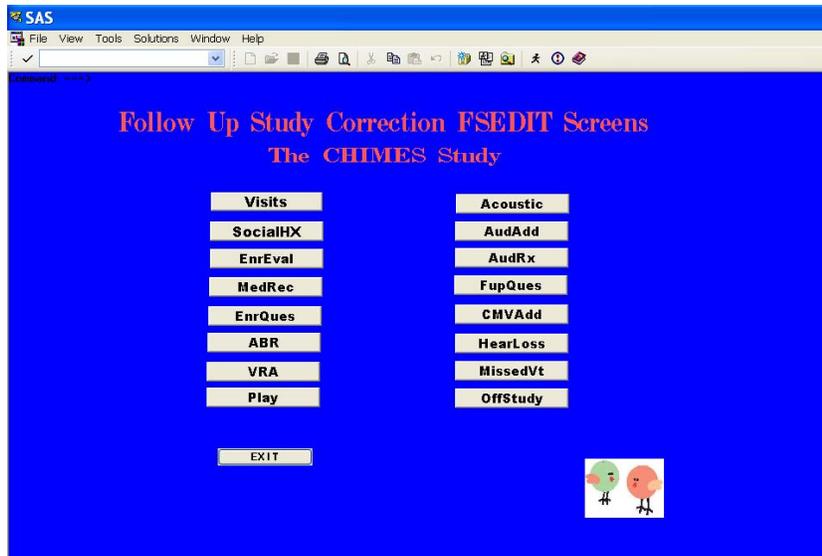


Figure 3

The SCL for the Correction Program frame uses the CALL FSEDIT routine to open the data set and FSEDIT screen selected by the user. Once the FSEDIT screen is closed the user is returned to the application where another data set may be selected or the user may choose to press the “EXIT” Command Push Button returning to the main menu of the application.

```
BNVISITS:
CALL FSEDIT('TEMPVISITSDATA', 'CMVFUP.VISITS.VISITS');
RETURN;
```

Corrections made to the CMV Follow Up Study data are also tracked by adding the date of the correction, the data manager who made the correction and reason the correction was made such as data entry error, site correction, or a query to a correction database in the FSETERM section of the SCL behind the FSEDIT screen (Fig.4).

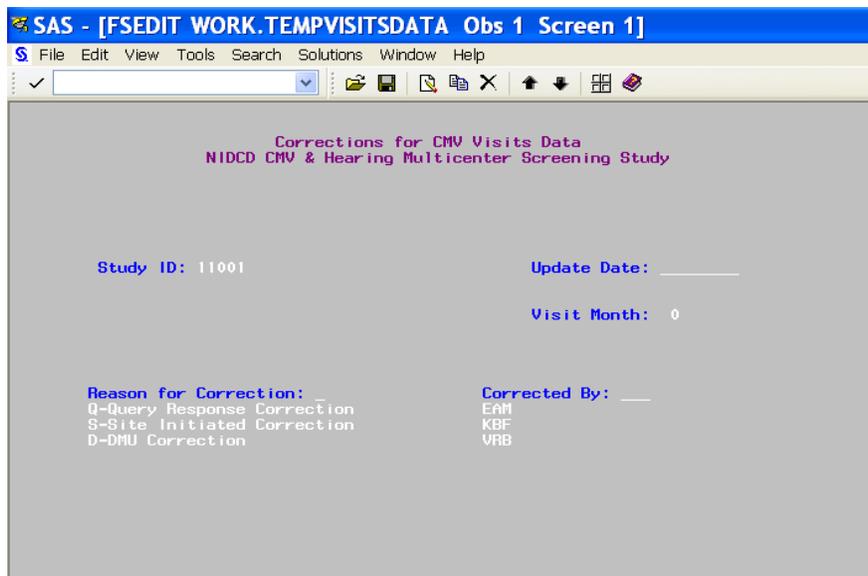


Figure 4

The code for the FSETERM section is as follows:

```
FSETERM:
SUBMIT CONTINUE;
data cmvfup.visitscorrections;
set cmvfup.visitscorrections work.tempvisitsdata
(keep=studyid updatedate reasoncorrection correctby);
where updatedate ne . and reasoncorrection ne ' ';
data work.tempvisitsdata1; set work.tempvisitsdata
(drop=updatedate reasoncorrection correctby);
data cmvfup.visits;
set work.tempvisitsdata1;
by studyid;
run;
ENDSUBMIT;
return;
```

The code is run within a Submit block with the variables collected for tracking corrections being kept in a separate correction data set. When the code moves on to updating the main data set the tracking variables are dropped. Once the user has made corrections to a data set, exiting the FSEDIT screen will return to the application window where another data set may be selected for making corrections.

CONFIRMATION RESULT REPORTS

Specimens are collected at the enrollment visit of the CMV Follow Up Study to confirm CMV infection identified during the newborn screening process. Confirmation lab results are reported to the CHIMES DMU where the results are added to the SAS permanent data sets and the DMU reports the results to the appropriate site. This is a revised system to automate the reporting of the confirmation results. Previously a data manager would manually search for the hard copy of the result forms and then complete a fillable PDF fax form (Fig. 6) that was then faxed to the appropriate site. With this application a data manager now just clicks on the Confirmation Result Reports Icon opening a frame where upon entering a start date faxable CMV confirmation result reports will be generated (Fig. 5). The start date for running result reports is entered by the user into a Text Entry object. Pressing the Generate Result Reports Icon then submits the date and individual result sheets are generated (Fig. 7).

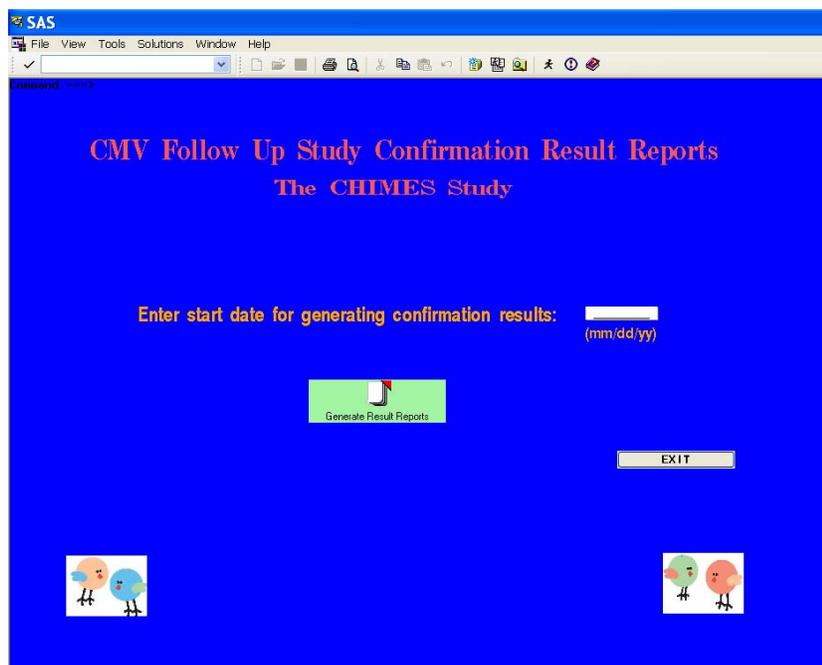


Figure 5

UAB Department of Pediatrics
Division of Infectious Diseases
Offices of Epidemiology and Data Management
1600 7th Ave South
CHB 304
Birmingham, AL 35233
Phone: 205-996-7792

Fax

To: _____ No. of Pages: 1 _____
 Fax Number: _____ Date: _____
 Phone Number: _____ From: The CHIMES Study DMU
 Re: Enrollment Visit CMV Results Fax Number: 205-975-3221

CMV Follow Up Study Laboratory CMV Confirmation Results Report
 NIDCD CMV and Hearing Multicenter Screening Study

Study ID: _____

Specimen Type: Saliva Rapid Culture Urine Rapid Culture

Date of Test: _____

Result: Positive
 Negative
 Unknown / Not Done
 Indeterminate
 Pending

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Figure 6

UAB Department of Pediatrics
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Offices of Epidemiology and Data Management
1600 7th Ave South
CHB 304
Birmingham, AL 35233
Phone: 205-996-7792 Fax: 205-975-3321

CMV Follow Up Study Laboratory CMV Confirmation Results
 NIDCD CMV and Hearing Multicenter Screening Study

Coordinator: Alice Brumbach
 Fax number:
 Phone number:
 Fax date: 06/29/10

Study ID: 11060

Date of Test: 02/25/10
 Specimen Type: Saliva Rapid Culture
 Test Result : Positive

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Figure 7

The SCL behind the Confirmation Result Reports frame subsets the data set within a Submit block using a WHERE statement. The date entered by the user in the text entry field on the frame is pulled into the WHERE statement using the macro variable reference with the SCL variable name assigned to the text entry field.

```
SUBMIT CONTINUE;
LIBNAME CMVFUP 'K:\CMVFollowupData';
data one; set cmvfup.visits;
where (visitdate gt &tevtdate and visitmonth=0) and
(cmvrresultsaliva ne . or cmvrresulturine ne .);
data conresults;
set one(keep=studyid visitmonth visitdate cmvrresultsaliva testdatesaliva cmvrresulturine
testdateurine);

length specimentype $20.;
length result 8.;
length studycor $30.;
length faxnum $13.;
length phonenum $13.;

if 11001 le studyid le 11200 then do;
studycor = 'Jane Doe';
end;

if 33001 le studyid le 33200 then do;
studycor = 'Mary Doe';
faxnum = '(601)999-9999';
phonenum = '(601)888-8888';
end;
```

A temporary working data set is created using variables that are kept from the visits data set along with creating other temporary variables for study coordinator, fax number, phone number to be used in the header of the faxable result

form being generated. Once values are assigned to the temporary variables the SCL continues to the section for outputting the report as described below:

Proc Template

ODS is used to deliver the output to a PDF file. The goal is to make the SAS output look as close to the original fillable PDF report as possible. A new style was defined in PROC TEMPLATE to accomplish this task. Modifications were made to the fonts, color, borders, and justification.

```
PROC TEMPLATE;
DEFINE STYLE Faxlayout1;
PARENT=STYLES.PRINTER;
Replace Fonts /
  'TITLEFONT2' = ("Times", 15pt, BOLD)
  'TITLEFONT' = ("Times", 15pt, BOLD)
  'DOCFONT' = ("Times", 13pt);
Replace Color_List/
  'BGA' = CXFFFFFFF;
Replace Table from Output/
  frame = void
  rules = groups
  cellspacing = 0.25pt
  cellpadding = 4pt;
style header from header /
  just=c;
END;
RUN;
```

Proc Report

We decided to use PROC REPORT to deliver the output. This procedure is powerful, yet fairly easy to understand. Since the output was going to be a PDF file, the ODS LISTING CLOSE option was used in order to suppress the output in the output window. Each observation in the temporary working data set will become a separate report. This was accomplished by creating the COMPUTE variable alldata. The ESCAPCHAR method was used within this compute block in order to place the variables on different lines. We defined our escape character as a tilde (~). A pagebreak was placed after a unique identifier variable in order to print each observation on separate pages. The title and footnote found on the original PDF fax form was then added to the TITLE and FOOTNOTE statements within the code.

```
ods listing close;
ods pdf file = "K:\CMVFollowupData\Confirmation results.pdf" style = faxlayout1;
options nodate;
ods escapechar='~';
run;

proc report data=conresults nowd center split = '~';

column newstudyid studycor faxnum phonenum studyid testdate specimentype result rundate
alldata;
define newstudyid /order noprint;
define studycor /display noprint;
define faxnum /display noprint;
define phonenum /display noprint;
define studyid /display noprint ;
define testdate /display noprint;
define specimentype /display noprint;
define result /display noprint;
define rundate /display noprint;
define alldata /computed ' ' flow width = 35;

compute alldata / char length = 400;
```

```

alldata ="~n ~n ~n ~n ~n ~n ~n"
  || "Coordinator: " || put(studycor, $20.)
  || "~n Fax number: " || put(faxnum, $15.)
  || "~n Phone number: " || put(phonenum, $15.)
  || "~n Fax date: " || put(rundate, mmdyy8.)
  || "~n ~n"
  || "~n Study ID: " || put(studyid, 8.)
  || "~n ~n"
  || "~n Date of Test: " || put(testdate, mmdyy8.)
  || "~n"
  || "~n Specimen Type: " || put(specimentype, $20.)
  || "~n"
  || "~n Test Result : " || put(result, resultfmt.)
  || "~n ~n";
  endcomp;

break after newstudyid / page;
Title1 'UAB Department of Pediatrics';

footnote1 j=c font='Arial' h=6.1pt 'This document transmission may contain CONFIDENTIAL
information belonging to the';
run;
ods pdf close;

```

CONCLUSION

The CMV Follow Up Study Application provides an efficient method for accessing the many logic check programs and FSEDIT screens used by the data management staff of the CHIMES study. The ability to generate CMV Confirmation Result Reports makes the reporting process to the sites more efficient since the output can be faxed to the appropriate site. The simplicity of the application makes it potentially usable in the data management tasks of other research studies.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

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