Abstract

SAS® code has many structured features which lend themselves to fill-in-the-blank menus for the naive user which, when processed, create SAS code for a specific task.

In a work environment where information is continually updated, a flexible system which enables the management and use of such information in a timely and efficient manner enables the user to keep abreast of the implication of such changes. We have found that the SAS full screen editor, available through PROC FSEDIT in SAS/FSP®, provides the capability of a menu-driven system which has the added advantage of placing the user directly into the SAS environment.

In this paper we discuss our system of monitoring pharmaceutical product development using interactive techniques of PROC FSEDIT which apply to both the TSO and CMS environments and make use of both the DATA and PROCEDURES steps of SAS.

Introduction

Pharmaceutical Product Development (PPD) is the multi-faceted process which a pharmaceutical product undergoes in its evolution from a formulation of the dosage form to the ultimate marketing of the final product. The process includes stability studies of the dosage form, scale-up work for production, designing packages and package materials, and preparing documents to be submitted to the Food and Drug Administration.

Several individuals are given specific tasks which must be coordinated and completed in a stepwise fashion before each product can be marketed. Each individual needs access to project information and project status reports which are referred to for dates, expenditures, and the continued progress of the project. Planning meetings are periodically held to discuss the progress of each project and revisions to the time and event schedules are made, if necessary.

Rationale

Information concerning a PPD project is kept in a file consisting of papers, forms, and memos. When information such as a particular date, a dollar amount, a summary for the project, or a completion date for a certain step on the time and event schedule was needed prior to the development of our system, it was necessary to look through the entire file. This was a very time consuming process. We decided that a computerized system would help us handle the information more effectively.

A system which would allow for the editing, updating, and retrieval of data on a daily basis as new information and facts become available was desired. Moreover, the technique used to manage and report this data had to be "user friendly" and allow for quick and easy revisions of the data so that the information would always be current. PPD information could be classified into three general categories: project background information, project status, and project time and event schedules. A system which would allow us to access information for a particular PPD project or for several PPD projects across one, two, or all three categories of information at the same time was also desirable.

Each particular pharmaceutical product development project has several steps which need to progress in a stepwise fashion before the ultimate completion of the project. Completion dates for each step change rapidly and the order of the steps often fluctuate. Many of the steps can not start until the completion of an earlier step, hence time and event schedules require constant changes if early deadlines are not met. Changes such as adding or deleting a step or simply correcting a typographical error need to be done quickly and efficiently without taking the time to retypethe entire schedule.

We have found that a menu-driven SAS system which utilizes the structured features of SAS procedures and the SAS full screen editor, available through PROC FSEDIT in SAS/FSP®, satisfies our needs of managing information and revising time and event schedules quickly, whereby reports can be generated with a minimum of effort.

Methods

SAS code is fairly structured and allows for a specific number of options and alternatives. This is true of the PROCEDURE steps as well as the DATA step. The DATA step also has the very important attribute of being temporary or permanent depending upon the needs of the user. The system which we have developed makes use of temporary SAS data sets which take on user-supplied variable values through PROC FSEDIT to generate SAS code for a particular job. The jobs include the editing of permanent SAS data sets and the creation of reports, all
of which are intimately connected to a menu-driven system by the use of the %INCLUDE statement.

We determined that the information pertinent to the management of pharmaceutical product development could best be classified into three permanent SAS data sets:

Project Background Information

Each project can be uniquely identified by an ID number, a company assigned project number, the name of the product, and a description of the product form.

This data set also includes dates for the initial project request, committee review, time and costs requested, time and costs received, committee approval, and when work can begin. It also includes estimates for date of initiation, date of completion, and total cost of the project (Figure 1).

Project Status

This data set has the unique identifiers, as mentioned above, a date for the time of the update, and a paragraph describing the projects' current status. This data set may be thought of as an audit trail of changes in the projects' status (Figure 2).

Time and Event Schedules for Each Project

This data set also has the unique identifiers, a step number, a description of the work to be done, the person responsible for the work, the date work is to be completed, and a revised date when revisions are made (Figure 3).

Accordingly, the reports which utilize this information fall under four categories:

1. All Steps for Time and Event Schedules to be Completed by a Specific Date,
2. Project Background Information,
3. Project Status, and
4. All Steps From Any Time and Event Schedule.

Figure 4 outlines the system we presently use.

As this system is completely menu-driven, there is one program that may be thought of as the "driver" program which defines all of the SAS code using Filedefs (Figure 5). This program takes us into FSEDIT and supplies the user with a PRIMARY OPTION MENU (Figure 6) which allows the user to select which direction he/she would like to take, i.e., update or change a data set, browse a data set, create a report or end the session. Each of the first three options take the user to a second OPTION MENU by constructing a temporary file that is created by the use of a PUT statement and a %INCLUDE statement. In this way, text substitution can take place in a predictable fashion so that this temporary file may be utilized by means of another %INCLUDE statement (Figures 7-9). If the user selects to create a report, another data set is created which allows the user to input through FSEDIT a particular date or a particular ID number which is then used to subset the data and create a very specific report (Figure 10). The system is flexible enough so that additional variables may be added to the permanent data sets or alterations can be made in the reports which utilize the data without developing a new system.

Discussion

Our generalized full screen system used to monitor Pharmaceutical Product Development enables us to overcome the problems of looking for information among many papers and searching through files for miscellaneous facts by making current information available on a moments notice. Moreover, the information can be utilized anywhere in the company through a CRT terminal and is not dependent upon the location of a particular file cabinet.

PROC FSEDIT is a very flexible SAS procedure that allows full screen data entry as well as the capability for a menu-driven SAS system when used with the %INCLUDE statement and PUT statement. The system is based on a few basic concepts of the SAS structure and is easy enough for the beginning SAS user to understand.

The flexibility of the system is enhanced by the ability to add or update the information as it becomes available, retrieve the data quickly, and create reports of the information selectively. Indeed, the ability to update time and event schedules has proven to be the most useful aspect of the system. Reports from any data set can be retrieved for all projects or individual projects and the time and event schedules can be created to include steps completed by a given date or all steps for a specific project.

Our system was designed to guide the user through the program in a step-by-step fashion. By defining the program function keys and prompting the user to select which program function key should be used to continue, the user with little SAS experience can work the system in a quick and efficient manner to provide management with up-to-the-minute information of pharmaceutical product development progress.

References


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Figure 4

SAS code used to generate the Primary Option Menu.

PROC PSEDIT DATA=MAINMENU SCREEN=SCREEN.MAINMENU OPTION=1; RUN;
DATA MAINMENU; SET MAINMENU; FILE TEMP;
IF OPTION GE 0 THEN DO;
  PUT 'INCLUDE MAINMENU;';
END;
ELSE IF OPTION=1 THEN PUT 'INCLUDE OPTION1;';
ELSE IF OPTION=2 THEN PUT 'INCLUDE OPTION2;';
ELSE IF OPTION=3 THEN PUT 'INCLUDE OPTION3;';
RUN;
INCLUDE TEMP;

Figure 6

SAS code used to generate the Primary Option Menu.

PROC PSEDIT DATA=MAINMENU SCREEN=SCREEN.MAINMENU OPTION=1; RUN;
DATA MAINMENU; SET MAINMENU; FILE TEMP;
IF OPTION GE 0 THEN DO;
  PUT 'INCLUDE MAINMENU;';
END;
ELSE IF OPTION=1 THEN PUT 'INCLUDE OPTION1;';
ELSE IF OPTION=2 THEN PUT 'INCLUDE OPTION2;';
ELSE IF OPTION=3 THEN PUT 'INCLUDE OPTION3;';
RUN;
INCLUDE TEMP;

Command ---
PSEDIT Screen Modification

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>pps project monitoring system</td>
</tr>
<tr>
<td>2</td>
<td>primary option menu</td>
</tr>
</tbody>
</table>

Please select an option from the list below... (Hit p2 key after making your selection)

1. Update or change data set
2. Browse a data set
3. Create a report
4. End
Figure 7
SAS code used to generate the Project Update Menu.

```sas
DATA UPDATE;
LENGTH OPTION 2;
PROC PFSEDIT DATA=UPDATE SCREEN=SCREEN.UPDATE OPTION=1; RUN;
DATA UPDATE; SET UPDATE; FILE TEMP;
IF OPTION GE 5 THEN DO;
   PUT '_INCLUDE OPTION1;';
END;
ELSE IF OPTION=1 THEN PUT 'INCLUDE OPTION11;';
ELSE IF OPTION=2 THEN PUT 'INCLUDE OPTION12;';
ELSE IF OPTION=3 THEN PUT 'INCLUDE OPTION13;';
ELSE IF OPTION=4 THEN PUT 'INCLUDE MAINMENU;';
RUN;
INCLUDE TEMP;
INCLUDE MAINMENU;
```

Please select a dataset from the list below which you wish to update: _ (hit pf2 key after making your selection)

1. Project background information
2. Project status
3. Time and event schedules
4. Return to the primary option menu

Figure 8
SAS code used to generate the Project Browse Menu.

```sas
DATA BROWSE;
LENGTH OPTION 2;
PROC PFSEDIT DATA=BROWSE SCREEN=SCREEN.BROWSE OPTION=1; RUN;
DATA BROWSE; SET BROWSE; FILE TEMP;
IF OPTION GE 5 THEN DO;
   PUT '_INCLUDE OPTION2;';
END;
ELSE IF OPTION=1 THEN PUT 'INCLUDE OPTION21;';
ELSE IF OPTION=2 THEN PUT 'INCLUDE OPTION22;';
ELSE IF OPTION=3 THEN PUT 'INCLUDE OPTION23;';
ELSE IF OPTION=4 THEN PUT 'INCLUDE MAINMENU;';
RUN;
INCLUDE TEMP;
INCLUDE MAINMENU;
```

Please select a dataset from the list below which you would like to browse: _ (hit pf2 key after making your selection)

1. Project background information
2. Project status
3. Critical step planning schedules
4. Return to the primary option menu
Figure 9

SAS code used to generate the Report Generation Menu.

```sas
DATA CREATE;
LENGTH OPTION 2;
PROC PREDICT DATA=CREATE SCREEN=SCREEN.CREATE OPTION=1;
RUN;
DATA CREATE; SET CREATE; PILE TEMP;
IF OPTION GE 7 THEN DO;
   PUT 'INCLUDE OPTIONS;';
   END;
ELSE IF OPTION=1 THEN PUT 'INCLUDE OPTIONS1;';
ELSE IF OPTION=2 THEN PUT 'INCLUDE OPTIONS2;';
ELSE IF OPTION=3 THEN PUT 'INCLUDE OPTIONS3;';
ELSE IF OPTION=4 THEN PUT 'INCLUDE OPTIONS4;';
ELSE IF OPTION=5 THEN PUT 'INCLUDE OPTIONS5;';
ELSE IF OPTION=6 THEN PUT 'INCLUDE MAINMENU;';
RUN;
INCLUDE TEMP;
INCLUDE MAINMENU;
```

---

please select the report from the list below which you wish to create: _ (hit pf2 after making your selection)

1. steps from any planning schedule that will be completed before a specified date.
2. background information for any project.
3. status of any project.
4. all steps from any time and event schedule.
5. reports 1-4 together.
6. return to the primary option menu.

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Figure 10

SAS code used to generate the screen below.

```sas
DATA TARGET;
LENGTH DATE 6; LENGTH SPEC_ID 4; INFORMAT DATE MMDDYY.;
PROC PREDICT DATA=TARGET SCREEN=SCREEN_Target OPTION=1;
RUN;
DATA TARGET; SET TARGET; FILE TEMP;
IF SPEC_ID EQ . THEN DO; PUT 'INCLUDE ALLPROJ;'; END;
ELSE IF SPEC_ID NE . THEN PUT 'INCLUDE SOMPROJ;';
RUN;
INCLUDE TEMP;
```

---

please enter the date for which you want a listing of the steps completed by and also the id number for the specific project.

**date:** ______

**id number:** ______

(if you want all projects, leave id blank)

hit pf2 key after entering the date and id number

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