ABSTRACT

In the pharmaceutical research industry, it is essential to monitor each study site for all ongoing drug studies to .0Ditor each study site for all ongoing drug studies that are adhering to protocol with relative ease or sites that seem to be problematic. Questions can be asked early and problems may be resolved in a timely fashion. The Clinical Data Management (CDM) system was designed and developed as a tool to meet the needs of the Clinical Data Management Department at Parke-Davis to track the status of all CRFs received in-house.

RATIONALE

The Clinical Data Management (CDM) department needs to maintain clinical study status in terms of tracking CRFs. Computerized systems contain a great deal of information regarding patients who are enrolled in clinical studies. The group of personnel in ensuring that the study sites are operating smoothly. For example, if a site is not gathering data as outlined in the protocol, the data cannot be entered into the computer until the problems are resolved.

Prior to CDMSSTAT, the department produced monthly status reports by either of the following methods: 1) A hand-generated monthly report form or 2) A spreadsheet produced using Lotus 1-2-3. The Lotus 1-2-3 spreadsheet system overcame the problem associated with this by allowing the reports to be performed on a monthly basis. However, several obstacles still remained. One monthly status spreadsheet was generated as soon as the data entered into the spreadsheet. Therefore, a system was needed that met the following requirements:

User-Friendly
Database
Accessibility
Low Maintenance

For these reasons the SAS software was chosen as the primary software tool for CDMSSTAT.

THE SYSTEM

CDMSSTAT is a menu-driven Case Report Forms Tracking System using the SAS/AF and SAS/PDF software. The menu system provides a means for data entry and report generation.

The following two CLIST is used to allocate files, call SAS, and to initialize the system:

```sas
PROC DSREAD
CONTROL RUNSTOP;
IF IREAD = 0 THEN CONTROL NO LIST CONTINUE;
ALLOC (FILENAME)'AAS.KSS999AL.CBS_STAT.SAS'DR;
SAS OPTIONS(RUN)
SAS OPTIONS(RESOURCE) 372 532 TEL=123 TYP=60 FS=55 -
SAS OPTIONS(RESOURCES) 372 532 TEL=123 TYP=60 FS=55 -
PROC DDISPLAY C-KEY.STATUS.DBA.PROGRAM;
RUN;
Figure 1: CDMSSTAT CLIST

AAS.KSS999AL.CBS_STATUS.DATA' is where the system macros are stored and 'AAS.KSS999AL.CBS_STATUS.SAS' is the system's SAS/AF library. The INIT macro (see Figure 2) initializes SAS Display Manager system variables, declares some global variables, executes the DISPLAY MACRO which displays current data and time, and finally, displays the database selection screen.

```sas
MACRO INIT;
OPTIONS TLS=132;
GLOBAL TTEXT DATE FILE DBASE;
LIST FILE = ;
RUNSCHD(OUTPUT ON, WID=O);
RUNSCHD(OUTPUT, WID=O);
RUNSCHD(OUTPUT PAGE, WID=O);
RUNSCHD(OUTPUT PAGE, WID=O);
RUNSCHD(VSCROLL PAGE, WID=P);
RUNSCHD(VSCROLL PAGE, WID=P);
DAYSINES;
PROC DDISPLAY C-KEY.STATUS.DBA.PROGRAM;
RUN;
Figure 2: INITIALIZATION MACRO

THE TRACKING FACILITY

SAS/AF software was used to build a front-end to the system. The first menu that appears allows the user to choose any of the eight databases (see Figure 3).

```sas
Command ---
--- Enter Choice of Database: 1  ---  09/04/21
  1. Cardiovascular Database  - CI-945 / CKS
  2. Cardiovascular Database  - CI-945 / CKS
  3. Antilinfensive Database  - CI-945 / CKS
  4. Oncology Database  - CI-945 / CKS
  5. CKS database  - Glatanretin etc.
  6. Phase IV Database  - CI-945 / CKS
  7. Allergy / Clin Pharma / Misc Database  - CI-945 / CKS
  8. CKS/Torres Database  - CI-945 / CKS
Figure 3: Change Database Screen

After pressing PF2, a main menu (see Figure 4) is displayed that allows the user many choices pertaining to editing, copying, reporting, etc. If options 1, 2, 3, 4, or 5, is chosen, the selection criteria screen is

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The ability to edit the databases is accomplished through the SAS/PS procedure FSEDIT. Entering options 1, 2, or 3 from the main menu will display the FSEDIT screen for either the Protocol, Site, or, Monthly Site dataset (see Figures 6, 7, and 8).

The reports generated from the system provide answers to questions concerning the status of CRFs received from all investigators participating in a particular protocol or participating in a particular set of protocols associated with a particular drug.

By entering option 5 from the main menu, the Selection Criteria screen is first displayed (see Figure 5). Here the reporting period date field must be entered. The Report Generation screen is then displayed as illustrated in Figure 9. The user may either select 1 report or both reports. After pressing the PF3 key, the report(s) he/are displayed on the user's display terminal using the SAS/PS procedure, FSLIST. This procedure displays external files onto a terminal screen. It was used in this system to display the external sequential data set, userid:CONVAY.PREPOSITION. To exit display mode, the user presses the PF3 key to return to the main menu screen.
The user would print the current report by selecting option 8 from the main menu. The print report screen will then be displayed as illustrated below in figure 10.

To create additional reports, option 5 would be selected from the main menu. If the user would like to generate more reports, she may want to clear the report file by choosing option 7 from the main menu.

CONCLUSION

The development of a menu-driven system for case report forms tracking achieved all of the objectives needed in such a facility. SAS/AF and SAS/FSP software provided all the tools needed to develop this system. This facility provides a means for tracking, while at the same time linking together a report generation and an on-line status system.

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