Design Features of a Clinical Information System
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Abstract

At Pharmaceutical Product Development (PPD), we needed a flexible system to facilitate data management and biostatistics activities. The task was to develop a common interface to access multiple and fluctuating numbers of clients and studies per client. PPD Clinical Information System (PPDCIS) is developing as a data driven application that uses a central database to: control access to data across clients and studies and adjust immediately to an addition or deletion of a client or study.

This paper will give a general overview of the application features of PPDCIS and describe the design and advantages of the application's central database, PPD Project Access and Security System (PPD-PASS).

Background - Flow of information

The Data Management and Biostatistics Division receives case report forms (CRF) for each patient enrolled in the clinical trial. These forms contain information such as demographic information, medical history, physical exam reports, therapy logs, and adverse event documentation. This information will be entered into a project database, validated, and presented to the biostatisticians for analysis.

Project setup includes creating a database to store the CRF information. SAS/FSP software is used to create customized screens used for data entry, review and modification.

As CRFs are received, each page is logged into the CRF tracking database. Each form is reviewed for discrepancies and readied for data entry. Dual data entry is performed on small batches of 10 - 15 patients. After each batch is completed, the data are moved to a dated subdirectory in a post entry directory. New entry databases are created and data entry resumes. The post-entry databases are compared to report data entry discrepancies. The databases are corrected and uploaded to the master database.

Concurrently, SAS programs are written and run to validate the master database. These programs include single field checks, cross-field comparisons, and value checks across datasets. The programs are run periodically and inconsistencies are researched and corrected.

After the databases are complete and validated, the biostatistics department creates statistical databases for analyses.

General Application Features

PPDCIS is being developed with Release 6.06 of SAS/AF® software, SAS/FSP® software, and Screen Control Language(SCL) under the VMS® operating system on a Digital VAX® 4000 machine.

The basic application areas are:

- **CRF TRACKING SYSTEM**: a database and reporting system that logs the activities and location of each CRF page
- **PROJECT DATA MANAGEMENT**: facility to access project specific CRF tracking information, data entry system and utilities, master databases, and project management tools
- **BIOSTATISTICS**: on-line review system for biostatistics databases including, generating reports, submitting programs and other utilities
- **UTILITIES**: general application utilities, such as access to the PPD-PASS database.

PPD-PASS - the Application's Central Dataset

The PPD Project Access and Security (PPD-PASS) database interactively defines the scope of the application. PPDCIS reads this dataset to determine the list of clients and studies, the location of the data, autocall macros, and format catalog.
Some advantages to the design philosophy are:

**IMMEDIATE** any changes in this dataset, such as a client being added or deleted, is automatically reflected in the client and project menus.

**APPLICATION IS MORE SYSTEM INDEPENDENT** all system dependent references, like directory paths, are external to the application code. This reduces application maintenance and makes the application portable to other operating systems.

**RESPONSIVE TO SYSTEM CHANGES** when project data are moved to another disk, a new macro directory is needed, or a format catalog moves to another directory, one dataset modification updates the application.

**REDUCES REDUNDANT CODE** the application code uses information such as client and study names and titles to customize menus and screens with study specific information. This reduces the number of study specific programs.

**PPD-PASS Dataset**

A partial view of the PPD-PASS dataset is shown in Figure 1. The dataset contains:

- **Client** a client nickname used to group all of a client's studies.
- **Client Description** the full name of the client.
- **Drug** full name of the drug.
- **Title1 - Title3** long description of the study.
- **Study directory path** the base directory of the study information.
- **Autocall macro directories** the paths to the macro programs used by the study.
- **Format Catalog** the location of the study specific format catalog.

**PPD-PASS Solutions**

Following are a few situations where using the central database philosophy has shown positive results.

**Situation:**

A new client, Company D, has chosen PPD for biostatistics and data management work. The project setup work is complete. How do we update the clinical information system?

**Solution:**

Currently, there are three companies, with multiple studies, in the system. The client/study selection menu is shown in Figure 2. To add company D:

1. Add Company D information to PPD-PASS dataset (Figure 3).
2. Access the client/study selection (Figure 4). Notice that the menus have been updated to reflect the changes.

**Situation:**

The disk that holds the data from Company B is full. How long will the information system be down after the data are moved?

**Solution:**

Five minutes or less. Simply update the PPD-PASS dataset with the new data location and the system will access Company B data from the new location.

**Situation:**

How can the information system have screens that look customized for each study without creating separate screens?

**Solution:**

Pass parameters into menu and screen templates.

**Example 1: Client Data Access Menu**

Figure 5 shows the basic client data access menu. The title information "Company B/STUDY B2" is passed in as a Screen.
Control Language entry parameter. The client and study values are from the PPD-PASS dataset. When this screen is accessed for another client or study, the appropriate title is displayed.

Example 2: Data Management Screen Menu

The data entry menu and screen illustrated in figure 6 are the same menu and screen used for data modification and review. The first title on the menu, "STUDY B2", comes from PPD-PASS. The second title is the result of the user requesting the first data entry session. Also, these user selections determine which database to access, data entry or data management, and whether the database is opened in edit or browse mode.

Conclusion

A central database, like PPD-PASS, has made PPDCIS a flexible and dynamic system that responds easily to change. System maintenance time has been reduced by storing all key project information in one dataset. Programming time is minimized by passing parameters into common program templates to create customized menus.

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Client: COMPANYB
Client Description: Company B
Drug Name: Wonder Drug II
Study Number: STUDY B1
Title: The Drug to Out Sell all Drugs

Study Directory Path: COMPANYB$DISK:[000000]
Autocall Macro Directories:
  COMPANYB$MACS_B1
  COMPANYB$MACS
  PPD$MACS_STAT
  PPD$MACS_DH
  SASAmos
Format Catalog Directory:
  COMPANYB$DISK:[COMPANY_B1.FORMAT.LIBRARY]

Figure 1: PPD Project Access & Security Dataset.

Figure 2: The Client/Study Selection Menu.
Figure 3: Adding New Information to PPD-PASS Dataset.

Figure 4: Update Client/Study Selection Menu.
Place cursor on your selection and press the enter key.

**Figure 5**: Client Data Access Menu.

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**Figure 6**: Data Management Menu and Screen.