Features of SAS/PH-Clinical™ Software
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Abstract
Although SAS software has been used extensively in the pharmaceutical industry, our most familiar users have been statisticians and clinical data processors. This paper discusses features of a new SAS® product designed to meet the needs of these users as well as other important users, including physicians, CRAs, and managers.

The new product, SAS/PH-Clinical software, enables you to quickly create patient groups for special populations, query to find out how many patients meet given criteria, combine across studies, and view summaries for studies. The product provides descriptive statistics including percentage change and confidence intervals, basic inference, a wide variety of graphs, an ad-hoc tables facility, and interfaces to SAS/ASSIST® software and SAS/INSIGHT™ software. The product's core feature, the Resource Manager, handles a variety of data structures; and allows you to use the product without requiring you to know the location of data sets (or DBMS tables), remember names of variables, or perform any DATA step programming to combine data sets for a clinical trial.

For statisticians, the product gives access to the wealth of statistical procedures available in the SAS System, and provides a customized tool for managing libraries of analysis programs, output, saved graphs, and saved notes.

The Role of SAS/PH-Clinical Software

What is the Product Objective?
The objective of SAS/PH-Clinical software is to increase the productivity of physicians, clinicians, biostatisticians, and clinical data processing professionals with an easy-to-use software application that facilitates quick access, review, and assimilation of clinical trials data.

Who are the Users?
The primary users of this product are professionals in the pharmaceutical industry who need to access, review, and analyze clinical trials data. The product uses a menu-driven interface specifically designed for pharmaceutical users. During the development process, the Institute solicited detailed feedback on this interface and made substantial revisions to better accommodate pharmaceutical users.

A second type of user is a statistician, clinical data processing professional, or SAS programmer who is familiar with SAS software; and, who in fact may be an expert in using the DATA step, statistical analysis procedures, or macros. The Library feature of the product is specifically designed to improve communication among these users and help them more efficiently manage their programs, macros, output, and saved graphs. In addition, the product provides an exit to the SAS Display Manager System.

A third type of user is the Product Administrator. SAS/PH-Clinical software has a separate menu-driven interface for this user to define:

- clinical trials to the product's Resource Manager
- new users or groups of users
- security groups
- printers, plotters, or terminals
- batch processing code, such as JCL

By performing these tasks, the administrator enables all other users to more effectively use the features in the product.

Is SAS/PH-Clinical Software a CANDA?
To answer this question, first consider that the definition of a Computer Assisted New Drug Application (CANDA) is changing. You can now think of a CANDA as having two major parts:

- a data-driven component that contains relevant data sets, programs, and output the sponsor and agency jointly consider key to reviewing the application.

- a text component that contains the entire text of the NDA in a word-processing format. Additional indexes and cross-reference tables may be included to facilitate use of the word-processing files. This may include an image component that contains the NDA and some or all CRFs for the pivotal studies.

SAS/PH-Clinical software attempts to address the needs of a data-driven component. However, it goes beyond the basic approach of providing SAS data sets and programs to provide a more versatile tool that assists in querying, analysis, graphing, and more. The product is not a complete CANDA as the text component is not included.
One other point to consider in terms of CANDAs is that SAS/PH-Clinical software is designed to assist users within drug research organizations. However, this design philosophy certainly doesn’t preclude the usefulness of the product at the FDA, whether part of a CANDA or not. At the July 1990 PMA/FDA Jointly Sponsored Meeting on Computer Assisted New Drug Applications, several speakers pointed out that a key problem with many CANDAs is that they aren’t used by the sponsor before being submitted to the FDA. This product addresses the problem by focusing on the data-driven component of a CANDA and focusing on the needs of users in industry.

SAS/PH-Clinical software is also different from traditional CANDA systems in that it addresses the challenge of building a product that can be used without modification to investigate clinical data for multiple compounds.

In developing this product, it is the institute’s objective to build software that can be used for both internal review and FDA review of clinical data.

SAS/PH-Clinical Software and the SAS System
This product fits with the conceptual model of the SAS System (see figure below) in that it provides tools to access, manage, present and analyze data.

![A Conceptual Model of the SAS® System](image-url)

SAS/PH-Clinical software takes this conceptual model a step further by providing an industry-specific user interface. Prior to any development on this product, Institute developers visited several pharmaceutical sites and discussed ideas for the product and the interface. During the development process, representatives from many major pharmaceutical companies visited the Institute and participated in structured reviews of the product. Through feedback on these prototypes, Institute developers redesigned and revised the interface to better meet the needs of pharmaceutical industry users.

## Product Description and Structure

### Design Parameters

**The MultiVendor™ Architecture of the SAS System** provides a key design parameter for SAS/PH-Clinical software. The portability of SAS software makes it possible for the new product to run concurrently and look alike on a variety of platforms. Initial platforms are MVS, CMS, and VMS™. Releases for OS/2® and selected Unix® (and derivatives) environments are planned.

Another design parameter is protection of the clinical data. Within the product, users can read the clinical data, but cannot update it. This design parameter evolved from concerns about inadvertent changes to clinical data. This doesn’t limit you to using only variables that exist in the data; as will be covered in the product tour, you have the ability to create new variables that aren't added to the actual clinical data but are available to you within the product.

Another key design parameter is the concept of the product administrator. This person defines trials, users, and devices to the product, and performs installation and maintenance tasks. Your site can have more than one administrator, so a company can choose, for example, to identify one administrator for each therapeutic area.

A final general design parameter is that the product is written using SAS software. Specifically, the source code is written in SCL and SAS/GRAPH® software, and uses procedures in several other SAS products. The procedures used have undergone rigorous Quality Assurance testing at the Institute, and have been used extensively not only in the pharmaceutical industry, but in virtually all major industrial, educational, and governmental data processing centers throughout the world.

### Functional Components and the Resource Manager

To visualize the product structure, consider two major building blocks, each with its own interface. These blocks are the functional components and the Resource Manager, and they are linked by a component called the View Generator.

At the core of the product is the **Resource Manager**. This component tracks the location of all data sets for a study (or of the tables in a DBMS), maintains a list of variables and labels for each study, performs error-checking to handle variable name inconsistencies within a study, and ensures that certain key identifiers are defined for each study.
The Resource Manager is the key to successfully using the product to handle the wide variety of data organization methods used in the pharmaceutical industry. The enormous advantage of the Resource Manager is that it gives the product the flexibility to be used from drug to drug, from one division of a company to another, and from one company to another without modifying SAS/PH-Clinical.

The Resource Manager is designed for use by the product administrator. Like the rest of the product, it uses a menu-driven interface; but unlike the rest of the product, the Resource Manager requires an experienced computer user. Familiarity with SAS software is preferable, but detailed knowledge of SAS syntax is not required.

The functional components of the product provide a menu-driven interface for users to

- browse patient information
- produce graphs
- analyze clinical data
- generate tables and reports
- manage programs and output
- explore data with SAS/INSIGHT software
- obtain an overview of clinical studies
- learn about the product.

The functional components are available to all users, and are discussed in more detail in the product tour.

The View Generator links the Resource Manager and the functional components. With the View Generator, you follow the menus to define the patient group of interest. Behind the scenes, this component captures study information from the Resource Manager, combines that information with the patient group information you provide (for example, all men over 65 who reported a headache), and dynamically builds a view into the clinical data.

The figure to the right summarizes the product structure and shows the two levels of interface for users and administrators.

Product Support
SAS/PH-Clinical software is a fully-supported Institute product. It will undergo the Institute's rigorous Quality Assurance and testing process. As with all Institute products, free technical support will be available. The documentation consists of three manuals:

- a user's guide that gives an overview of the product and shows several examples of using the product to accomplish certain tasks
- an administrator's guide that gives a technical overview of the product and describes the administrator's tasks in detail
- a programmer's guide that gives technical details and provides guidelines for product modification.

Training will also be available at your site.

The Institute will provide additional support for product installation. After installation, consulting services are available to assist with your SAS programming, perhaps to interface a custom SAS/AF application with this product.

A Conceptual Model of SAS/PH-Clinical

Product Tour
Introduction
SAS/PH-Clinical software has 10 choices on the main menu:

- Patient Group
- Browse Patients
- Tables and Reports
- Analysis
- Graphs
- Visualize Data
- Library
- Study Overviews
- Tutorial
- Exit

The first choice, Patient Group, is the View Generator, which provides the link between the functional components and the Resource Manager. The remaining nine choices are the functional components. If you are a
product administrator, the main menu will have one more choice, Administrator Utilities, which gives you an interface to the Resource Manager.

When you start to use SAS/PH-Clinical software, you can choose any of the 10 buttons (or 11 if you are a Product Administrator). If you choose a button that requires a patient group, Graphs for example, you'll be prompted to create a new patient group or to restore the last patient group used in your most recent session with SAS/PH-Clinical. (For first-time use, the second choice is available if you already have patient groups that have been defined for you by a product administrator.)

Scenario
To better illustrate the features of SAS/PH-Clinical software, suppose you want to review data for a recently completed clinical trial. You looked at the data while the trial was in progress, but now the blind has been broken and you want to perform further investigation. Specifically, you want to:

- thoroughly investigate all information for patients 6, 27, and 45. These patients are of particular interest since you noticed a potential problem while the study was in progress. You want to selectively include or exclude these patients from graphs, analyses, and reports.
- examine the distribution of patient age.
- obtain descriptive statistics on several efficacy and safety variables.
- calculate percentage change, and replace missing values with values from other visits.
- generate several tables and reports.
- selectively print or save patient groups, graphs, and output.
- make notes on your concerns and conclusions.

In addition, you want to perform some tasks for other studies, perhaps even for other drugs.

Select a Patient Group: Using the View Generator
The main menu in the View Generator has the following choices:

- Access a previously saved patient group
- Create a new patient group
- Combine studies.

Each of these choices takes you to a primary task screen, with additional screens as needed.

Accessing a previously saved patient group brings up a list of patient groups that either you have saved or an administrator has saved for you. The list tells you:

- the patient group name (WONDERAL, for example)
- a description of the patient group (Wonder Drug All Patients, for example)
- whether the patient group is one you created (Private) or not (choices vary, depending on your site).

Using the scenario above, suppose none of the saved patient groups meets your needs. You return to the main menu for the View Generator.

Creating a new patient group takes you through a three-step process:

- Choose the study of interest. As shipped, the product uses the key identifiers of Drug, Protocol, Study, Investigator, and Site. When the product is installed at your site, your product administrator can dynamically change these key identifiers to best fit your site. This paper assumes the default key identifiers. For example, suppose you choose:
  
  - the Wonder drug
  - Protocol PH-HYP-9374
  - Denver, Colorado as the site.

- Choose the patients of interest. Here, you can select all patients, select patients by patient number, or select patients by criteria. For example, suppose you choose:
  
  - Patients 6, 27, and 45. Since you noticed a potential problem with these patients, you want to include them in the group, regardless of whether they meet any other criteria.
  - Patients who meet the following criteria:
    - Under 65, and
    - Receiving either the test drug or the already approved competitive drug, and
    - Reported having headaches while taking the drug.

When you select patients by criteria, the product provides information to assist you in building the criteria. For a numeric variable, such as age, you receive the minimum and maximum values for the study. For a categorical variable, such as whether or not the patient experienced headaches (Yes, No), you receive the list of values in the data.

- Choose the variables of interest. Now that you have selected the study and the patients, select the clinical data you want available. You can either choose all variables in the study or a subset of variables. Choosing all combines variables
across all data sets (or DBMS tables) for the study. Choosing subset brings up a list, and you choose which variables to include. For the example, suppose you choose all variables.

When you complete the third step, the product informs you of the number of patients and the number of patient records that meet the criteria, and gives you an opportunity to save this patient group. (If you don’t save it now, you can save it later.)

**Combining Studies** adds another step to the process. First, you choose the studies to be combined. Then, the activities of selecting patients and selecting variables have the added dimension of selecting which study the criteria apply to, or which study the variables are selected from. In this scenario, you are interested in data from only one study.

**Browsing the Patient Group**

After defining a patient group, you want to browse the information for patients. You can choose to browse

- patient records one patient at a time. This gives you all the variables that you selected with a screen for each patient.
- several patient records at once, in a spreadsheet format.
- patient records with drilldown capability. With this feature, you first select some variables of interest, then look at patient information in a spreadsheet fashion. With drilldown, you can then select a patient and look at all the variables (in the current view) for that patient.

Suppose you decide to browse patient records one at a time, and then realize you are only really interested in patients 6, 27, and 45. At this point, you can choose to subset the patient group and browse the subset. So you create the subset for patients 6, 27, and 45, and browse the patient records. You want to show these records to a colleague, so you save the subset as a new patient group. Now this special patient group is available to you in this and future sessions. A key point is that the patient group is re-created each time you select it; thus, as the clinical data change (perhaps errors are corrected, or new data are added), your patient group reflects these changes.

Using the original patient group, you want to use the drilldown feature. Out of all the data in the patient group, you want to see only the patient identifier, age, sex, and systolic and diastolic blood pressures. You make these choices in the browse screens, and then look at the patient records in a spreadsheet format. Suppose you notice one patient with a systolic blood pressure of 182; to view all other information selected for this patient, you simply click on the spreadsheet row for the patient and drilldown to the patient’s record.

**Creating Graphs**

After browsing, you decide to generate some graphs for the study. Rather than returning to the main menu for the product and then selecting graphics, you can choose to Jump across from the browse menu to the graph menu.

**Types of graphs available in SAS/PH-Clinical software are**

- horizontal and vertical bar charts
- scatterplots
- joined-line plots, with an optional classification variable to create multiple lines on the plot
- regression plots, with optional confidence interval lines
- mean-and-standard-error charts
- box plots
- histograms, with optional normal and lognormal distributions overlaid
- bubble plots
- regression lines with outlier detection (requires SAS/INSIGHT software).

For each graph, you select the variables to be plotted and specify details for the graph. For example, suppose you want to examine the distribution of ages for patients in the study. You select histograms and then

- select AGE as the variable to plot. When selecting variables, the product shows you a list of all variable names and, more important, the variable labels, in the patient group. In many cases, it will be easier to select a variable by reading the label.
- generate the plot.

Optionally, you can

- add a normal or lognormal distribution (or both) to the histogram. You can either estimate the parameters for the distribution from the data or specify parameters.
- add titles or footnotes to the histogram.
- specify the color and pattern for filling the bars on the histogram.
- specify general text colors and fonts.
- generate a low-resolution histogram that can be printed on a line printer.
Suppose after looking at the initial histogram, you want to exclude patients 6, 27, and 45, and also want to look at the age distribution by sex. You can

- choose Subsetting to include all patients except 6, 27, and 45
- choose Grouping to obtain separate histograms for men and women.

After generating these histograms, you decide to

- produce a hard copy on your plotter. Here, you select a plotter from a list of descriptions—not device names—so the list is customized to your site. Then, you have the option to attach output documentation to the histograms; this provides a hard copy of the program used to create the patient group, and identifies the time, date, and user who ran the program.
- save the histogram on-line. Here, you can use either the name and description automatically provided or you can fill in your own.
- save the program. Again, you can use either the name and description automatically provided, or you can fill in your own.

The program and saved graphs are available for you to view, edit (the program), rename, or delete in the Library. One important feature is that the graphs generated with grouping variables are saved together.

Obtaining Descriptive Statistics
After looking at the histograms for ages, you decide to examine descriptive statistics for some efficacy and safety variables in the study. But, you want to examine these variables separately for some age categories. The clinical data set doesn’t have a variable that defines the age categories you want. Without modifying the clinical data sets, you can create a new variable. This new variable is available whenever you use the patient group.

Select Redefine data, and you can create a new variable by

- collapsing values of another variable (to form age group categories, for example)
- summing two or more variables
- taking the log of a variable
- multiplying variables
- adding a constant to a variable
- and more.

There is also an expert editor that provides a window where you can type in your own SAS programming statements to create a new variable. This feature assumes you are familiar with SAS syntax.

You choose to collapse the values of age into categories. You’ll see a list of unique values for ages of patients in this study and can form either groups (for example, 24, 27, 29) or ranges (for example, 21-45). The groups you want are: 21-45, 45-60, and over 60. After giving this information, SAS/PH-Clinical software creates the new variable and gives you the name; in this case, AGEGRP. The ability to create a new variable is available in all functional components of the product.

Now, to obtain descriptive statistics, you select

- the efficacy and safety variables, and the visits of interest for these variables.
- the statistics. Available statistics include the number of observations, the minimum and maximum, range, interquartile range, mean, standard deviation, and standard error of the mean.
- optionally, a confidence interval. You can modify the default of 2-sided 95% confidence intervals to get 1-sided upper or 1-sided lower intervals, with confidence levels of 90%, 95%, 99%, or a level that you provide.

These selections will produce output for the entire patient group. However, you want to exclude patients 6, 27, and 45, and generate statistics separately for each age group. So you select

- Subsetting to exclude specific patients
- Grouping, and select AGEGRP as the grouping variable. Now that you have created this new variable, it’s available in the list of variables for this patient group.

These additional two selections generate the descriptive statistics you want.

Calculating Percentage Change
Suppose you now want to investigate the percentage change for an efficacy variable in the study. Specifically, you want to

- calculate percentage change between Visit 12 and Visit 4
- replace missing values for visit 12 with those from the prior visit (11)
- replace missing values for visit 4 with the minimum value from visits 3 and 5
- order the output by the value of the percentage change
- add other variables to the output, specifically age, sex, and blood chemistry variables
- perform calculations for all patients. Subsetting is available, but you want to see the percentage change calculations for everyone in the patient group.

These features are available in the Percentage Change component. You simply select choices from the task screens, and make selections (for example, choose the efficacy variable) on the screens that appear. In the output, patients whose percentage change is calculated using imputed values are highlighted. So you can tell at a glance if the values used are the actual values from visits 4 and 12, or are values carried forward from another visit.

Generating a Report
At this point, you want to generate some summary tables of the data. Specifically, you want to

- create a one-way frequency table of the new age category variable, AGEGRP, so you know how many patients are in each age category
- produce several two-way and n-way cross-tabulations, including: AGEGRP x sex x treatment, EKG result x treatment, and AGEGRP x EKG result
- generate a more complex table, where the rows are defined by the age, sex, and race of the patient and the columns give the averages and standard deviations for two key efficacy variables; in addition, you want this table produced separately for each treatment group.

Choose (or jump to) the Tables and Reports component to perform these tasks. After generating the tables, you decide to print the output and to save the output as WONDTAB1. The saved output is now in your personal library, and will be available for you to look at later.

In addition, you want to write a brief note that summarizes your concerns and conclusions about the clinical data, based on your investigation so far. You select Make a note, type in your comments, and save them. This, too, is saved in your personal library, and will be available for later review, revision, and printing.

Viewing Study Overviews
After completing the tasks above, you want to refresh your memory on the other trials for this drug. Select Study Overviews, and then select the drug of interest from a list of all drugs defined to the product. If you want, you can further subset the overviews to look at by subsetting the studies for the drug based on the

- Phase of the study
- type of blinding
- control method
- type of study
- values of any of the key identifiers used at your site.

Recall that the product is shipped with Protocol, Study, Investigator, and Site as key identifier fields, but that your company can change these key identifiers to best suit the company's needs.

After you have made selections, the product shows you a series of screens containing general information on each study selected. For example, you can review the

- patient inclusion and exclusion criteria
- schedule of visits
- medical monitor, statistician, and project leaders at your company
- FDA or other regulatory agency information, such as the IND number
- and more.

After viewing the study overviews, you decide to review the analyses you performed on Protocol PH-HYP-9074.

Using the Library
When you save a patient group, a graph, output from an analysis or report, a program, or a note, these items are placed in your personal library. In addition, your administrator may have placed patient groups, outputs, graphs, or programs in one of several public libraries that other users can access.

In the library, if you select Programs, you receive a list of program names, descriptions, and a private/public identifier. Now, you can

- edit the program. This assumes that you know the SAS syntax for the procedures used in the program.
- save a new program.
- delete the program from your library.
- run the program interactively or in batch (background processing, where appropriate).
- add an entirely new program.
- choose to view only those programs in your private library, or only those in the public library, and so on.
Select the administrator to move a program from your private library to a public library.

If you select Graphs or Output, you can view the graph or output, print or plot it (as appropriate), save it with another name, delete it from the library, and more.

For patient groups, you can review the criteria used to select patients for the group and the variables available in the group. Other activities, such as deleting or renaming groups, are available.

With the Note selection, you receive a list of all saved notes. You can add to the list by creating a new note or editing an existing note, save the edited note as a new note (or re-save the existing note), print notes, or delete obsolete notes.

Additional Activities
To further investigate the data with SAS/PH-Clinical software, you can perform several additional activities not discussed in detail in the product tour. Some of these activities are discussed below:

- Perform some basic statistical analysis. You can
  - compare treatment groups using two-sample t-tests, one-way analysis of variance, or the nonparametric analogues
  - compare initial and final visits within a treatment group using a paired-difference t-test or the Wilcoxon Signed Rank test
  - perform a test for normality
  - compare two variables with a Chi-square test or with Fisher's exact test.

- Investigate the clinical data using SAS/INSIGHT software. This interactive graphical tool provides tools to interactively manipulate multiple variables with spinning plots, to create matrices of scatter-plots, to evaluate the effects of changing bins for histograms, and to perform a variety of powerful statistical analyses as appropriate.

- Generate 1-way, 2-way, or n-way tables with drilldown capability. With this feature, you first generate the table. Then you can select a cell in the table and obtain detailed information on all patients in the cell.

- Exit to SAS/ASSIST software, with the current patient group defined as the active data set in SAS/ASSIST. The entire menu system is then available for you to use to perform complex statistical analysis, generate other types of graphs or reports, design experiments, and more.

- Exit to the SAS Display Manager System. With this feature, you can temporarily leave the product to perform some other task.

- End the session. When you exit SAS/PH-Clinical software, you can
  - save the last patient group used. For example, if you have created a subset of patients from the patient group, but have not saved this subset, you can save it now.
  - print a copy of the SAS log. This provides a listing of all submitted SAS code, and lets you audit your activities.

- Submit programs to run in batch. This feature is available through the Library.

Performing Administrator Tasks
Instead of thinking of yourself as someone who wants to investigate data from a clinical trial, now think of yourself as a Product Administrator. Serving as a Product Administrator for SAS/PH-Clinical isn't your only task; it is just one of the many tasks that keep you busy each week. Through the Administrator Utilities feature, you can define, modify, or delete

- users and groups of users
- devices
- clinical studies.

In addition, the product provides a set of administrative reports to summarize information contained in the Resource Manager.

Defining Users and Groups of Users
Several features in the product pull user information from the administrator utilities; for example, the output documentation feature captures the user's name and places it in the output. To define a user to the product, you

- identify the user's id
- give the user's name
- optionally, define a default printer and plotter for the user
- optionally, establish which product security groups the user belongs to.

By defining security groups, you establish whether the user has access to statistical inference, SAS/ASSIST

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software or the SAS Display Manager System, and whether the user is a Product Administrator.

In addition to these product-specific security groups, you can define site-specific groups. For example, you can define a group of users associated with a particular drug research team, or define a group of statisticians.

Rather than maintaining these security groups on a user-by-user basis, you can manage the groups. Just as you define new users, you can define new groups by providing a name and description, identifying users in the group, and determining whether all new users are automatically added to the group or not.

All of these activities are dynamic; at any time, you can modify membership in a group, modify which groups an individual user belongs to, add new users or groups, delete users or groups, or change the name and description of users or groups.

Defining Devices
Throughout the product, users choose to print or plot their output by selecting the printer or plotter from a list of descriptions. As an administrator, you maintain this list. Thus, if Dr. Jones selects "Printer in Room H2-331" and a new printer is installed, s/he doesn't need to know the new type of printer but can continue to select based on the description. To define a device, you

- select the device name from a list of all devices that SAS supports
- give a description to the device
- identify the device as a monitor, text printer, or plotter.

With utility functions, you can update information on a device or delete devices from the list.

Defining Studies
When defining studies, you interact directly with the core of SAS/PH-Clinical software, the Resource Manager. Defining a study is a four-step process, where you

- provide general information
- identify the location of all clinical data
- classify the variables for the study. In this step, you can also create new variables that will be available when any user chooses the study. These variables are not added to the clinical data since SAS/PH-Clinical software reads but does not write to this data.
- provide key identifiers at your site, the patient identifier, and the visit identifier. These identifiers can be either existing or newly created variables; for example, the visit identifier may be a concatenation of a date and time variable.

At each step, the product performs extensive error-checking to minimize any problems users might have in working with the clinical data.

Providing General Information In the first step, you fill in a series of screens that provide summary information for the study. This information is later used by the Study Overviews component. None of this information needs to be in the clinical data; in fact, most often, much of the information is in the protocol for the study.

Identifying the Clinical Data In the second step, you identify the location of the clinical data. If the data are stored in SAS data sets, they can be stored in multiple libraries. In addition, you can selectively include or omit data sets. For example, suppose your site maintains treatment codes in a separate data set; you can simply choose not to include that data set as part of the clinical data. (Later, when the study has been completed, you can update the study definition and add the data set.)

Classifying the Variables In the third step, you receive an alphabetical list of all variables in all data sets selected for the study. This step has the following parts:

- The product performs error-checking to prevent numeric and character variables with the same variable name. These variables will be renamed in the Resource Manager (not in the clinical data sets), and you have the opportunity to change the label for the renamed variables.
- For all variables, you can change the labels. For example, suppose there are two variables named PATIENT, but they have incorrectly been assigned different labels. You can assign the same label to both variables; again, this affects only the Resource Manager, not the clinical data.
- Each variable has an attribute of A (analysis), C (categorical), or N (nondisplay). You can modify these attributes, thus affecting which variables users see. For example, you can change the attribute for the treatment variable to N, and maintain triple-blinding while the study is in progress.
- New variables can be created. For example, suppose a quality-of-life survey was answered by the patients. You can define a new variable that sums the responses to all questions in the survey.

As you end this step, the product performs some housekeeping functions; for example, variables that
have been relabeled are once again identified to the Resource Manager.

Providing Key Identifiers. The final step is to assign variable names to the key identifiers. Your site either uses the key identifiers provided, or modifies the list. In either case, you identify

- variables that define the study. These may be a protocol number, study identifier, site, investigator, or other variables you choose. You can choose up to six key identifiers.
- the patient identifier. This can be a patient number or patient name, or can be a new variable (for example a concatenation of the investigator number and patient number).
- the visit identifier. Again, this can either be a variable in one of the data sets or a newly created variable.
- the treatment identifier.

After completing this step, the product adds the study to the list of studies available to the Resource Manager. You can update Information for the study at any time.

Obtaining Reports
To facilitate the administrator's tasks, SAS/PH-Clinical software provides a set of reports, including

- a summary of general information for a study
- detailed information on the study definition, including the location of all data, the names and attributes of all variables (and created variables), and so on
- summaries of security group information
- and more.

Additional Information

Other SAS Software
If you are familiar with Institute software, you probably recognized features from SAS procedures as you read through the product tour. Recall that SAS/PH-Clinical software is written using SAS software, so some other products are required in order for SAS/PH-Clinical software to run. Specifically, the products required are Base SAS software, SAS/FSP® software, SAS/STAT® software, SAS/GRAPH® software, and SAS/CALC™ software.

Under certain conditions, other products are necessary:
- SAS/QC® software, to obtain histograms and low-resolution box plots.
- SAS/SHARE® software, for simultaneous use by product administrators and users.
- SAS/INSIGHT software, to use the Visualize Data feature. This is available only for selected platforms.
- SAS/ASSIST software, to exit to SAS/ASSIST from this product.
- SAS/AF software, to modify the product.

Conclusion
SAS/PH-Clinical software represents the Institute's first vertical product—a software product specifically designed for users in a particular industry. From its inception through the development process, Institute developers solicited ideas, comments, and feedback from professionals in the pharmaceutical industry. SAS/PH-Clinical software is designed to explicitly meet the needs of both users who are familiar with SAS software and of physicians, CRAs, and managers. The menu-driven interface and product features are designed to provide you with tools to easily access, review, and assimilate data from clinical trials.

Additional Information

Other SAS Software
If you are familiar with Institute software, you probably recognized features from SAS procedures as you read through the product tour. Recall that SAS/PH-Clinical software is written using SAS software, so some other products are required in order for SAS/PH-Clinical software to run. Specifically, the products required are Base SAS software, SAS/FSP® software, SAS/STAT® software, SAS/GRAPH® software, and SAS/CALC™ software.

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