TrialSense Console Administrator's Guide

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Selected Terms Used in this Guide

Default ID — The default ID that appears in new ID fields are placeholders. Changing them does not affect the system. When you change a default ID, the system ensures that the new ID is unique. But, certain characters are not allowed in an ID, including $', even though it is part of the default ID structure.

Exceptions – Exceptions are used to bypass a particular Protocol State if a set of conditions is met.

Expression – An expression is an arithmetic or logical formula automatically calculated by the system. The operands of that formula are literal values, such as 'true' or '42', variables created while the protocol is being administered, such as the current subject enrollment level, and items within the forms included in Manual Tasks, such as the subject's lab results.

Minimum Duration – Minimum Duration is the amount of time that an *Action State* or a *Decision State* stays idle after activation. This is a set time gap between a trigger and the beginning of the action or decision activated by that trigger. This is an optional factor.

Maximum Duration – Maximum Duration is the amount of time allotted for completion of an activated *Action State* or a *Decision State*. It is the longest time that the designated state can run.

Protocol States – Protocol States are points within a protocol where tasks are done, decisions are made, and branching and synchronizations occur. There are four types of Protocol States: *Action, Decision, Branch, and Synchronize.* These Protocol States are discussed in detail later in this document.

Protocol Event – Events are issued (fired) using a Fire Event Task within an Action State. Events are received (heard) using the Trigger Event List within an Action State and a Decision State. Events are fired to indicate that a certain operation has been performed or a state has been reached, etc. When an Event is fired, all Protocol States including that event in their Trigger Event List will start execution. The Protocol State that fires the event idles until all states that received the event finish execution.

Tasks — A Task defines an activity that is done in an Action State. An Action State may contain a group of Tasks. A Task can be iterated, have exceptions, etc. There are two types of Task: automatic and manual. The automatic Task is handled by the system, invisible to the end users; the user performs the manual Task (for example, assessment activities). Automatic Tasks are: Calculate Task, Data Task, Send Message Task and Fire Event Task.

Variable – A variable is a memory location in the system where data can be stored or referenced. In the Clinical Trial system, a variable is identified by its name and its scope. A variable name is unique within its scope. The scope of a variable indicates where in the system it is stored (Protocol level, Subject level, or State level). Any subject that participates in a trial to which a Protocol variable belongs can access that variable. A Subject Level variable is duplicated for each subject within a trial; in other words, the data stored in these variables will vary depending on the subject. A State Level variable exists only within the execution of an Action State

TrialSense Console

The TrialSense Console provides trial managers and principal investigators to setup, start, monitor, and stop clinical trials, as well review collected data and establish security and privacy policies for the users. The Console presents the trial administrator with interfaces to construct the protocol, examine the trial and data, and create and manage users.

The trial review interface is referred to as the Data Manager. From the Data Manager screen, the administrator has the ability to view the trial states, decision points, subroutines, and tasks. Additionally, the administrator can view the subjects currently involved in the trial and a full set of the data collected for each subject as well as variables associated with the trail. Lastly, the user can navigate between each of the trials within the system.
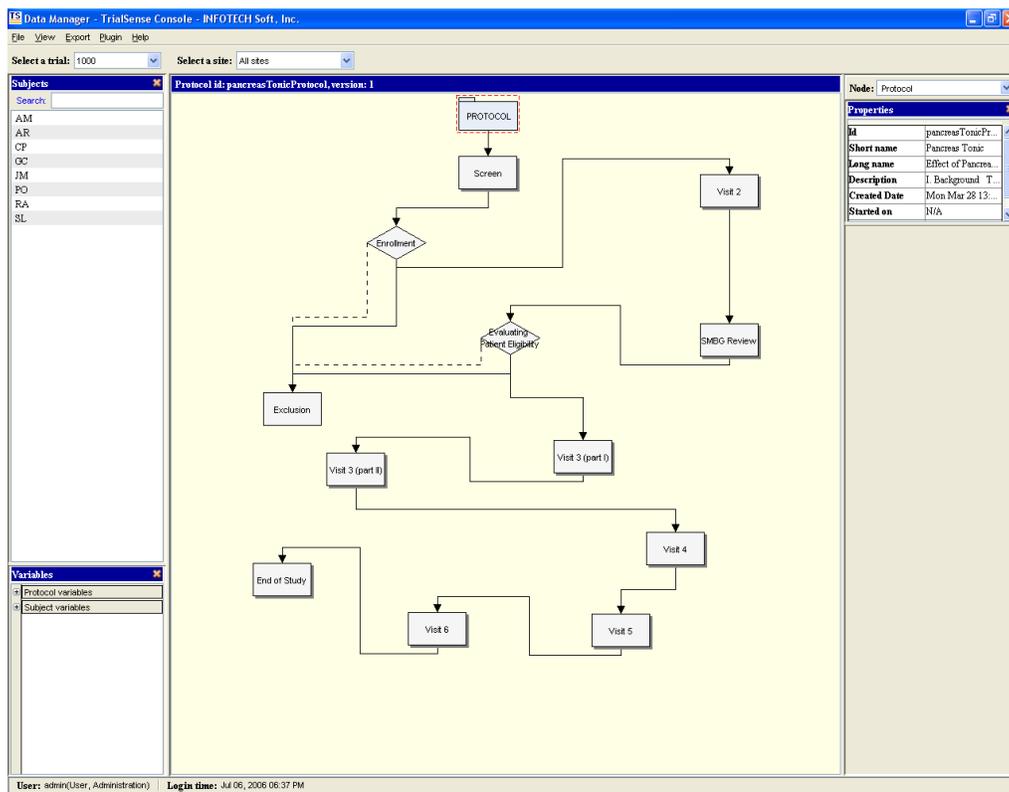

The TrialSense Console Data Manager Screen

The security interface for the trial is referred to as the Security Manager. From this screen, the administrator has the option to create and edit user, as well as assign user to user groups and sites.

Managing the Trial

The TrialSense Console will first ask the user to log into the system by providing a username and password. Once the user has logged, the Data Manager screen will startup by showing information relating to one of the trials in the system (unless none exist). In order to select a trial to view, the user can choose a trial id from the dropdown list.
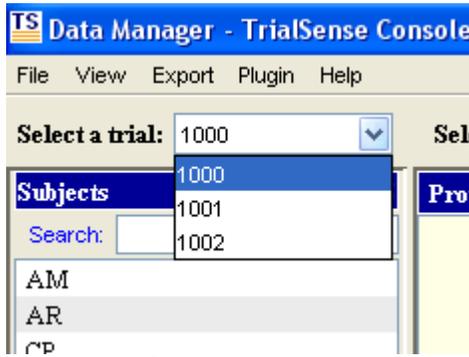
**The Trial Selection Dropdown List**

To select a site for which different trials may exist, the user can choose a site name from the site dropdown list.

The Site Selection Dropdown List

Working with Subjects

A list of subjects involved in the trial that has been selected is displayed on the left side of the screen. By selecting a subject identifier from this list, the user can view the current status of the subject within the trial, the path that the subject has traversed, and all of the trial data collected for the subject.
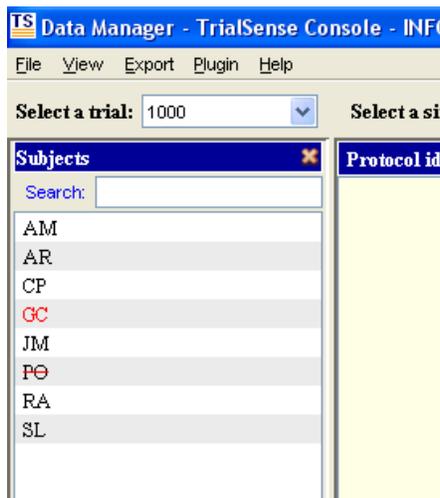
The List of Subjects Participating in the Trial

> **i** Subjects that are currently being accessed within the system are indicated by changing their identifier color to red. Subjects that have been dropped from the trial are indicated with a red slash trough their identifier.

> **i** The user can search for subjects by entering text into the search bar. The subject list will then be filtered to show only those containing the search text.

Right-clicking on a subject identifier provides the user with a set of options. These options include dropping the subject from the trial or reinstating the subject into the trial (if applicable) and viewing a history of events related to the subject.
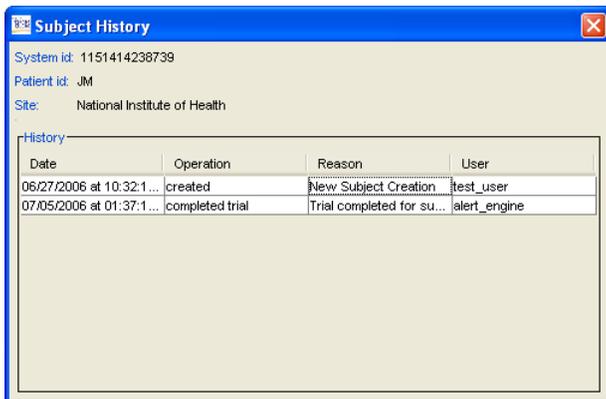
The Subject History Screen

Working with Trials

Once a subject has been selected, their specific graphical trial view is presented in the middle of the Data Manager screen. The path traversed by the subject is highlighted by green lines connecting the different states and decision points. A green check mark ✔ indicates that the state has been completed or that a decision has been made. The hourglass ⌛ icon indicates that a state or decision is currently active.
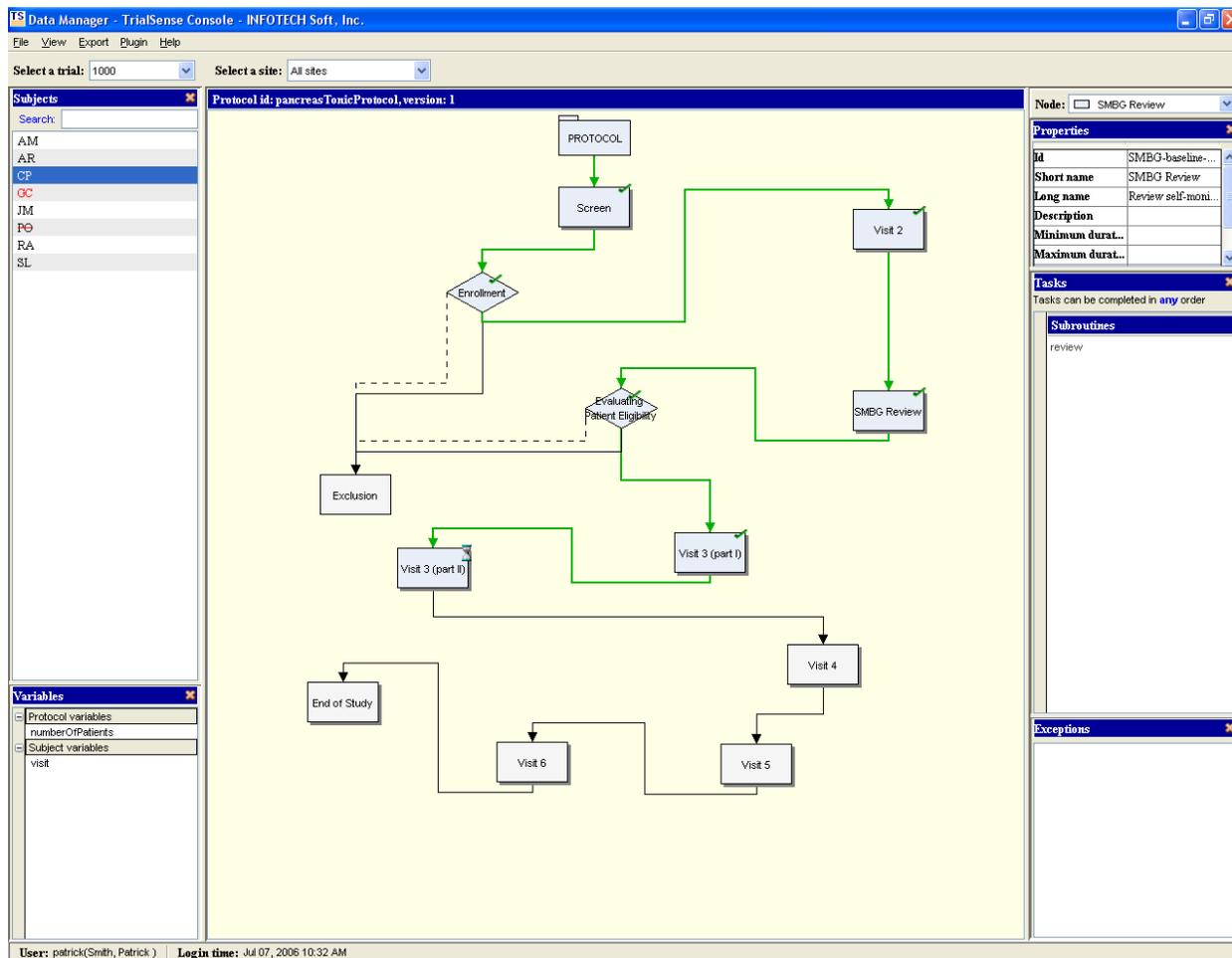

The Graphical Trial View for a Selected Subject
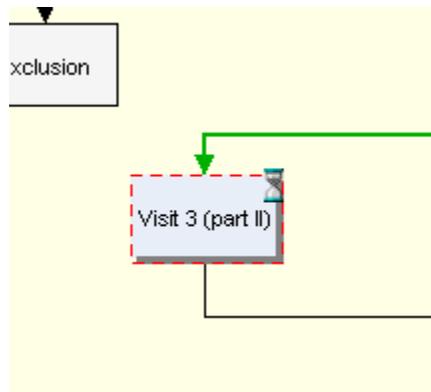
States

States are represented within the graphical trial view as a rectangular-shaped object. States contain all of the form tasks and instructional tasks within a trial as well as automatically calculated variables. States may also contain subroutines that include additional states and decisions to traverse.

When the user selects a specific state or decision from the graphical trial view, they will be presented with information related specifically to that state or decision. The user can also select a state or decision from the dropdown list in the upper right corner of the display.
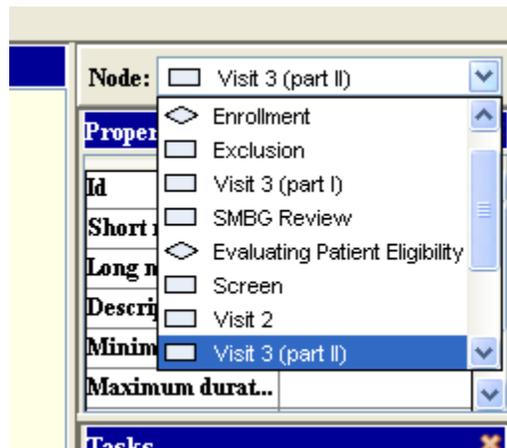

A Dropdown List of States and Decisions in the Trial

Once a selection has been made, the state or decision is highlighted in the trial view panel with a dashed red line.


A Selected State with Highlighting

Properties relating to the trial are listed in the Properties panel on the screen. The user has the option to open the long name and description areas into larger popup boxes that display the full text of the item by clicking on the ellipses on the right side of the row.
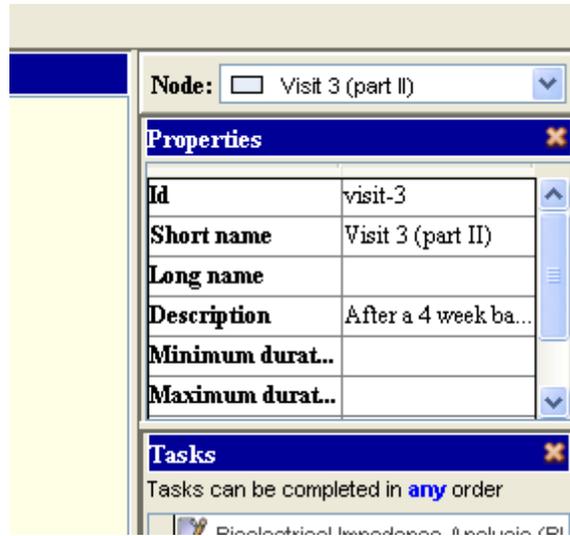
The Properties Panel for the Selected State

Additionally, a list of associated tasks and subroutines is shown in a column on the right side of the display. If the user double-clicks on one of the subroutines, they will be presented with the subroutine view that was previously described.
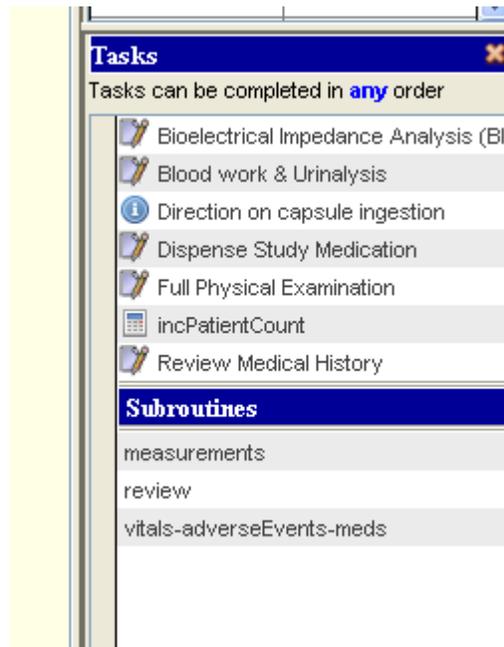

The Task and Subroutine Lists for the Selected State

Tasks

The different types of tasks are indicated in the task list with unique icons. Tasks that require a form to be filled out are represented with a paper and pencil 📝 icon. Tasks that perform an automatic calculation of some piece of data are indicated with a calculator 🖩 icon. Finally, tasks that instruct a user to follow a set of instructions are symbolized by the use of an instruction ⓘ icon.

By double-clicking on a task, the user will see a popup with information relating to the task including an id, name, and indicator of whether or not the task is required. Additionally, if a subject has been selected, the user will see a data id and creation date. From a manual task, the user may choose to open a form in order to view the subject data or to edit the data. The _View Data_ option will open a read-only form, while the _Edit Data_ option will open a form with the current set of data that may be edited. If a subject has completed the trial or is currently in use within the trial, the user will not have the option to edit the data. If no subject has been selected, the user will simply have the option to view a blank form.
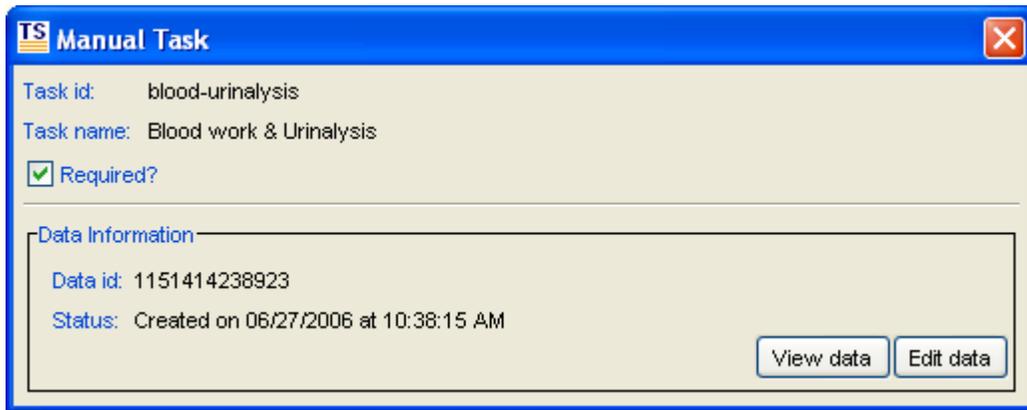
A Manual Task Popup with Additional Information

Subroutines

States that include subroutines are indicated by the use of a shadowing effect under the rectangular state icon. Any state with subroutines will open up a new panel in the middle section of the screen. If there are multiple subroutines for a given state, the user can select from among the different subroutines by using the dropdown list in the middle panel. Once a user has finished viewing data for a subroutine, they can return to the previous screen by closing the subroutine with the close ❌ icon in the upper-right portion of the panel.
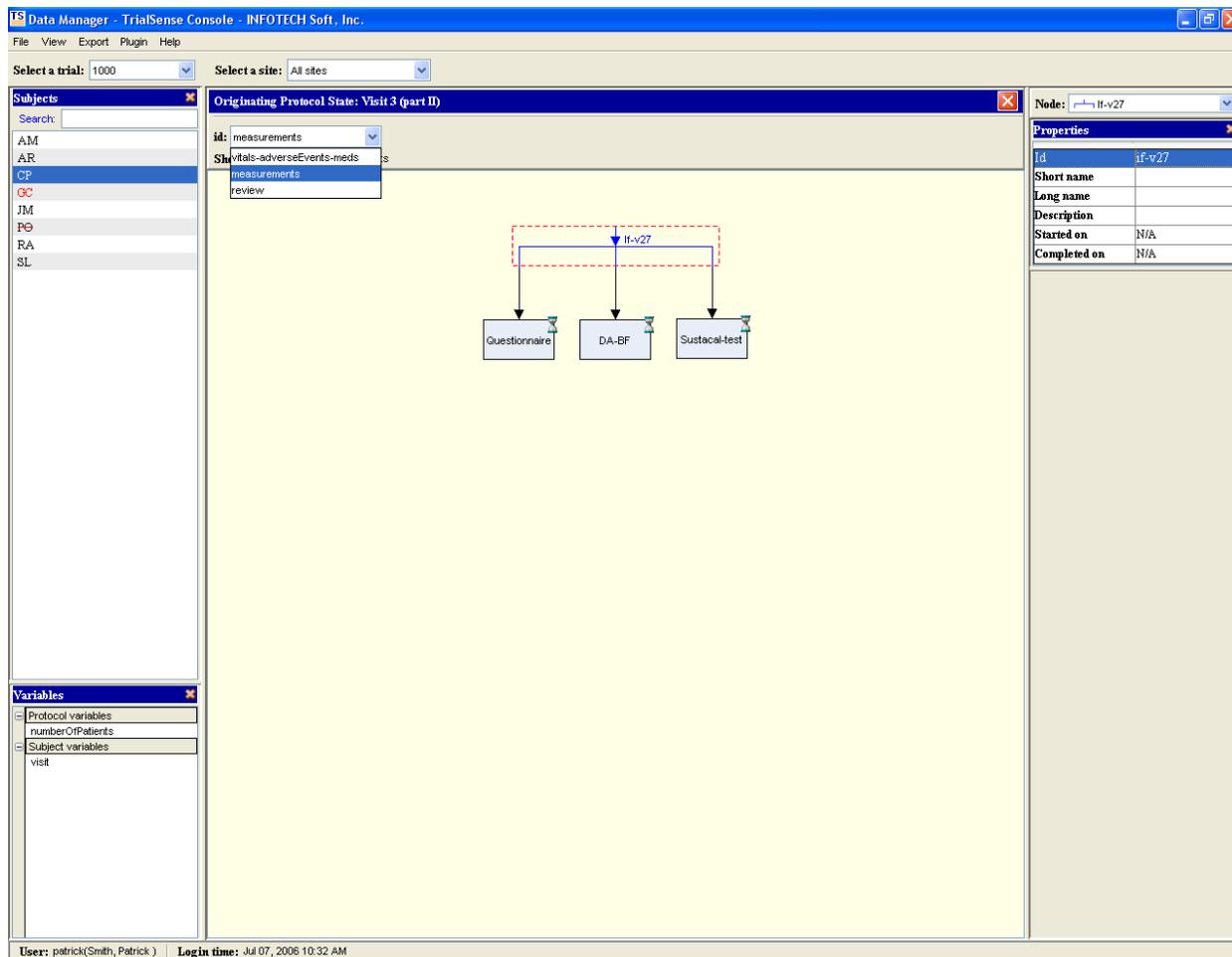
The Subroutine Screen of the Graphical Trial View
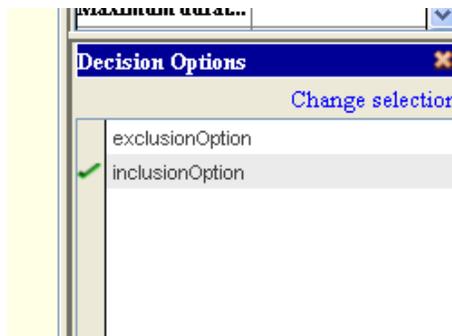
Decisions

Decision points within the trial are indicated by a diamond-shaped ◇ object in the graphical trial view. The solid lines extending from a decision object indicate the possible paths that could be taken at this point in the trial. A dashed line indicates the default decision path.
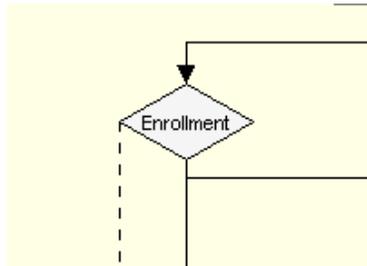

A Graphical View of a Decision Point

If both a subject and decision are selected, the possible decision options will appear in a panel on the right side of the display.


A List of Available Decision Options

If the decision has already been completed, the current user will have the ability to change the selection by clicking on the Change Selection link. This will display a popup that will allow the user to select a new option or choose none of the available options which will result in the default decision.
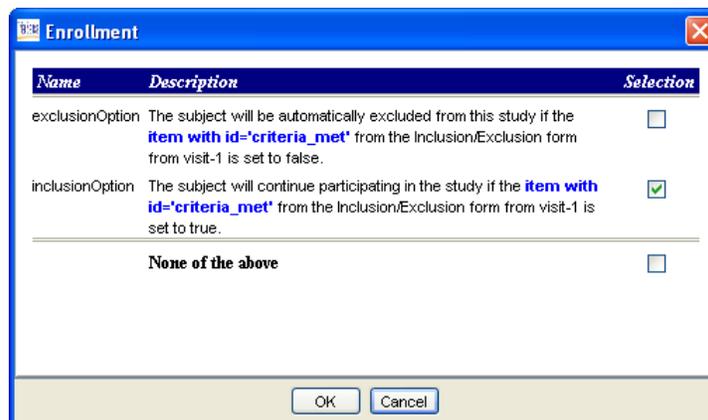
**A Popup Allowing for Decisions to be Changed**

Variables

Included within certain trails are automatically calculated variables. These variables can be used to account for information such as subjects taking part in the trial or the number of a specific type of visit that a subject has had. The variables panel is located on the lower left portion of the Data Manager screen.
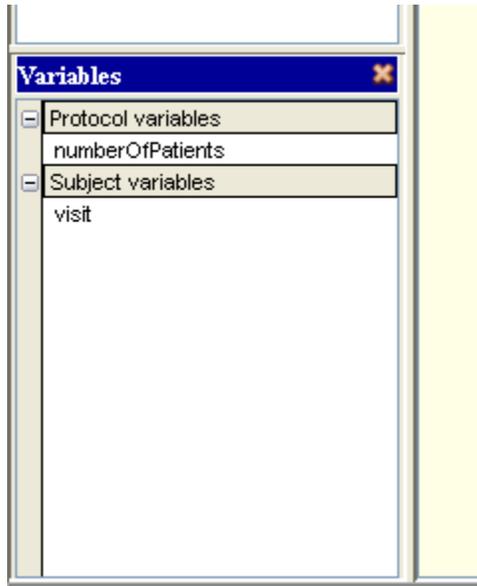
**A Panel with Variables for the Trial and Subject**

Protocol variables contain information that relate to the trial as a whole, whereas subject variables store data as it relates to the subject that is currently selected. Double-clicking on the name of the variable will produce a popup screen with a history of data stored to that variable each time it was automatically calculated by the system.
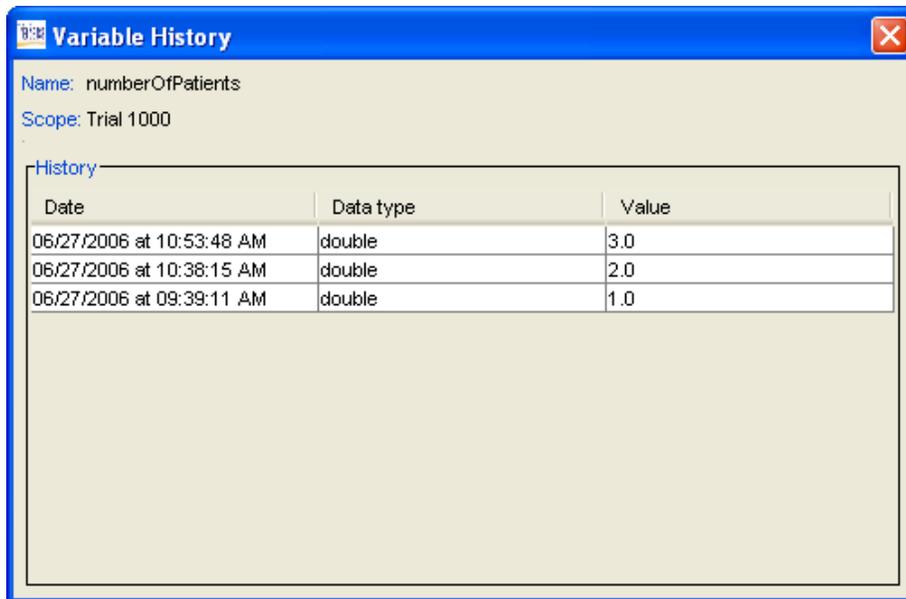
**A Popup with an Extended History for the Variable**

Menus and Options

The View menu of the data manager allows the user to display additional information related to the subjects, tasks, decisions, and subroutines. The Show Ids, Show Dates, and Show Site options can be toggled on or off by the user. The Refresh option will unselect a currently selected subject, state, task, decision, or variable as well as update all of the patient data.
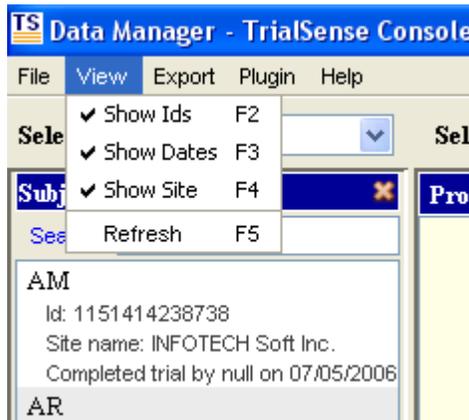
The View Menu for the Data Manager

The user can also change the informational view on the main Data Manager screen by closing or expanding different panels with the close icon [icon] and expand [icons] icons.
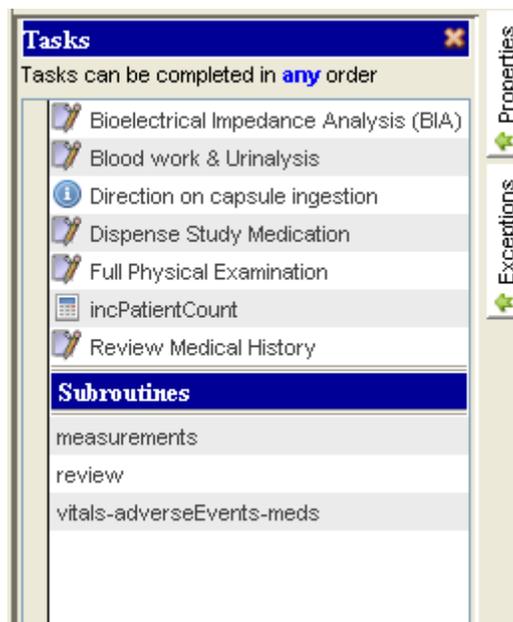

Panels can be Expanded or Collapsed to the Side

The information panels can be expanded horizontally and vertically as well by clicking-on and dragging the separating bars between the different panels.

Exporting Data

The Export menu allows the user to extract and save subject or trial data in several different formats. The user can select from CSV, SAS, or SPSS data formats. Once a format is selected, the user is presented with a popup that instructs them to select a filename for export, a trial, the site(s), and the subject(s) that will be used for the data export.
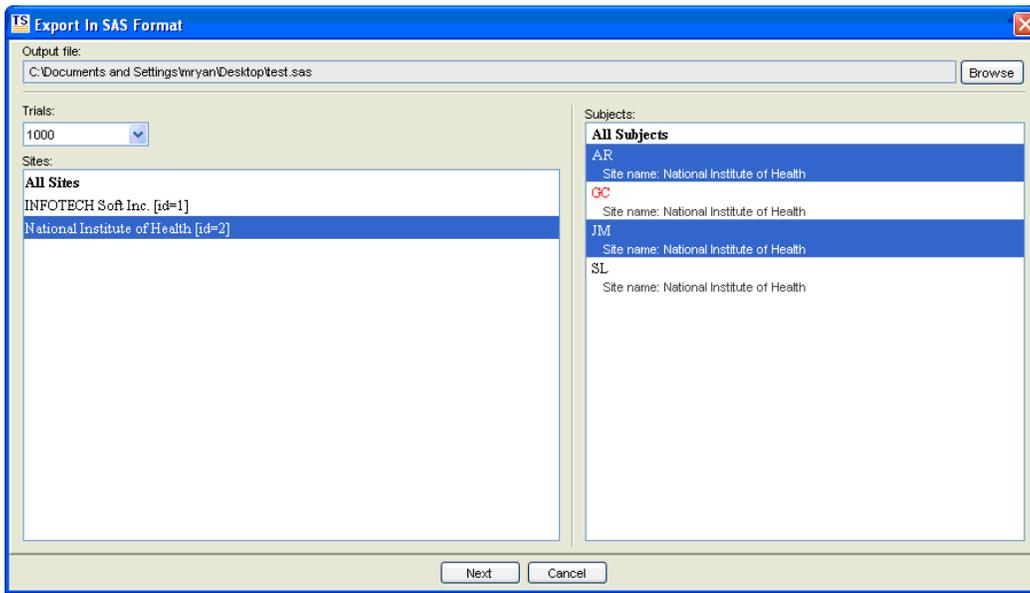

The Trial, Site, and Subject Selection Screen for Data Export

The next screen provides the user with a list of the visits and forms. The user can select a form to use, and has the option to select all of the form items for export. If the user wishes to choose individual items they can proceed to the final screen.
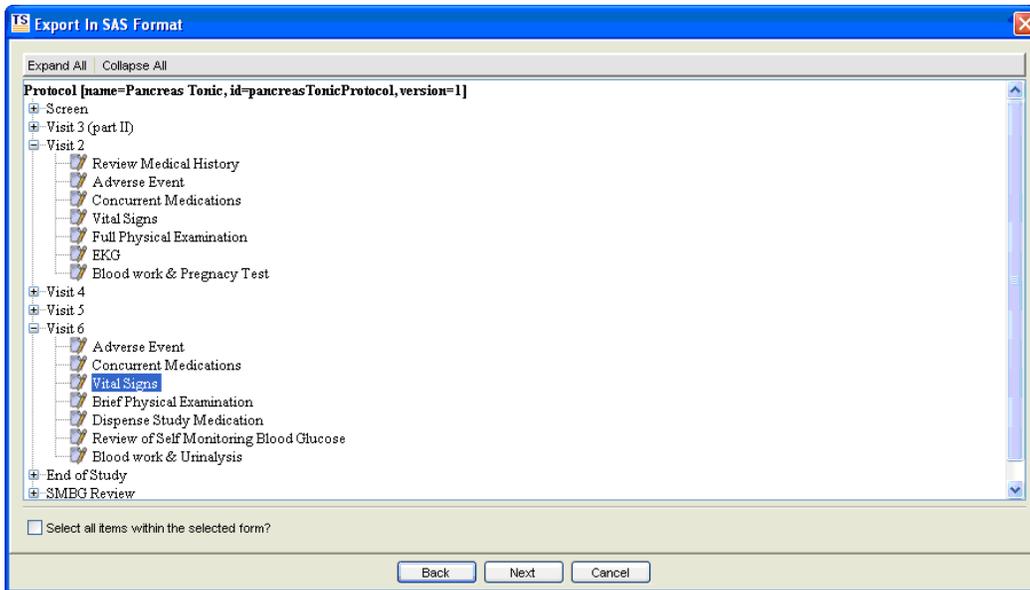
**The Form Selection Screen for Data Export**

The final screen of the data export process will provide the user with a list of the items in the form. The user can select as many or a few items to export data from as necessary and then select the Export button to collect the data.
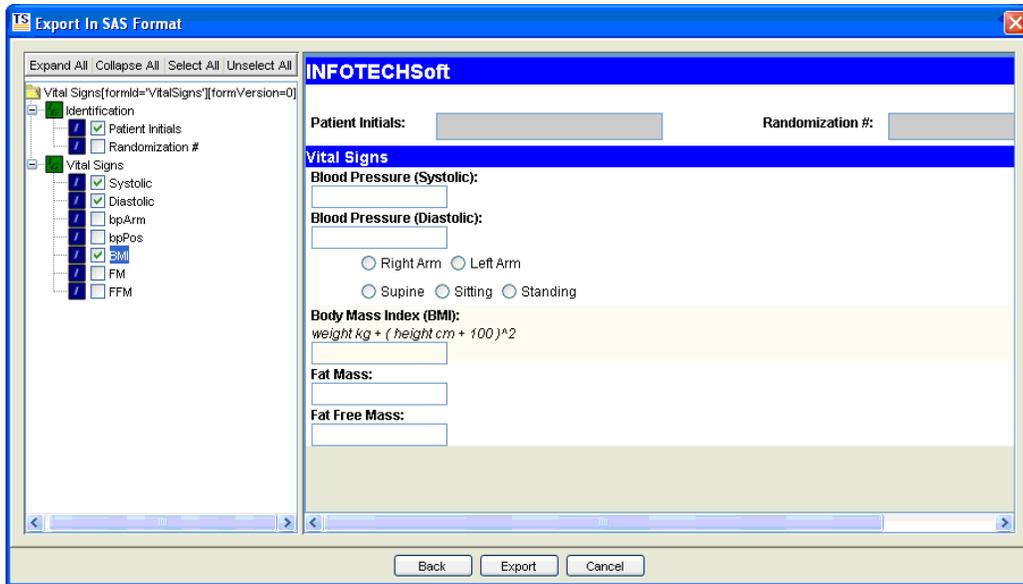
**The Item Selection Screen for Data Export**

Plugins

The *Plugin* menu of the TrialSense Console allows the user to switch between the Data Manager and Security Manager displays.
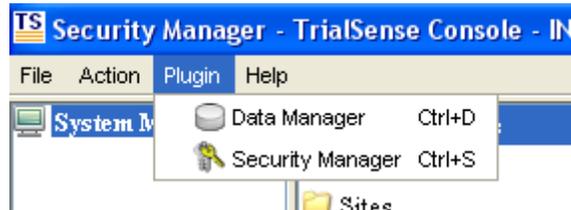
The Plugin Menu for the TrialsSense Console

Securing the Trial

The Security Manager allows a trial administrator to create and modify users, user groups, and sites. The display for the Security Manager is divided into two sections. On the Left is a panel allowing the administrator to select between the entities of User Accounts, User Groups, and Sites. On the right is a list of the current entries that have been created for the entity type selected by the administrator along with additional information about each entry. The Security Manager portion of the TrialSense Console can be accessed from the *Plugin* menu.
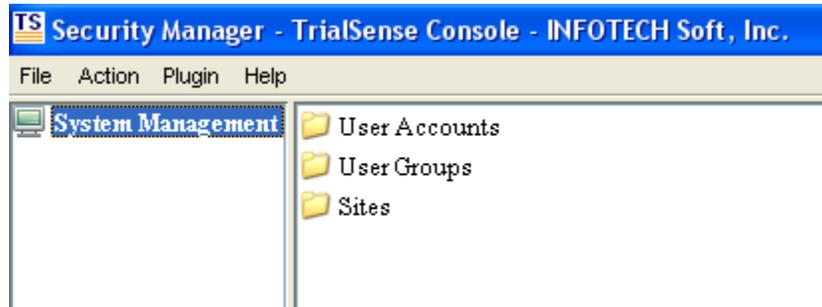
The Security Manager Entity Selection Screen

Working with Users

The Security Manager allows the administrator to add users to the system, lock users out of the system, edit user information, reset passwords, and assign or move users to one of the existing user groups. In order to create a new user, the administrator can select the *New User* option from the *Action* menu. The administrator can then enter different pieces of general information about the user including the user's name, telephone number, and email address. The administrator must also assign a new username and password to the user. Usernames cannot be duplicated within the system. Next, the administrator must select the period of time for which the user's certificate will be valid. Once a user's certificate expires the user will no longer be able to access the TrialSense Collection Station or Console until the certificate is updated or the user is recreated in system.   The administrator must also select a group to which the user will belong. Finally, the administrator must select the sites of which the user is a member. The user can be a part of multiple sites from among which they will choose when logging into the Collection Station.
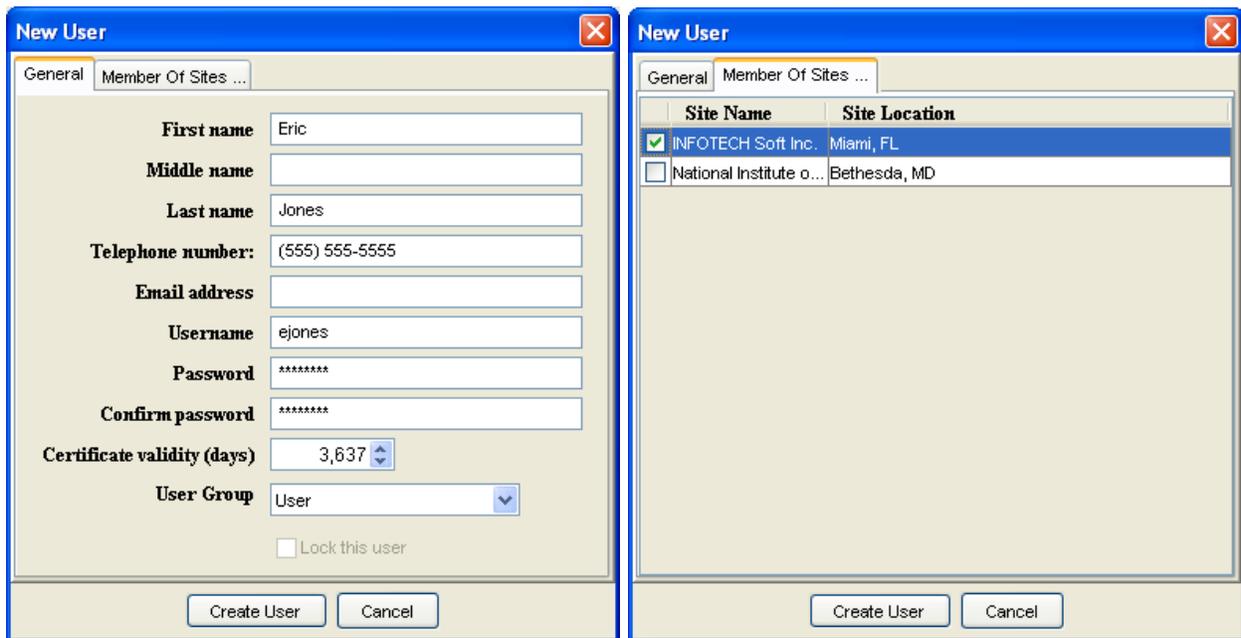
The New User Creation Screens

For users that already exist within the system, the administrator has to option to change a user's password or general information including the site and group to which the user belongs. Additionally, the administrator can lock the user account in order to prevent the user from being able to login and access the system. The Users list that appears on the right side of the Security Manager screen displays the user's id number, username, full name, group assignment, and site assignment.

The User Accounts List

Working with User Groups

Every user created within the system must belong to one of the user groups that have been established. The Administrators group provides its members with complete access to the system including the Data Manager and Security Manager within the TrialSense Console. Additional user groups may limit some members to the use of only the TrialSense Collection Station or to a reduced access of the TrialSense Console. The User Groups list that appears on the right side of the screen displays the id number of the group, the group name, and a short description about the group.

The User Groups List

Working with Sites

For a user to been created, they must be assigned to a site. The Site list that appears on the right side of the screen shows the id, name, type, and location for each of the sites in the system.

The Sites List