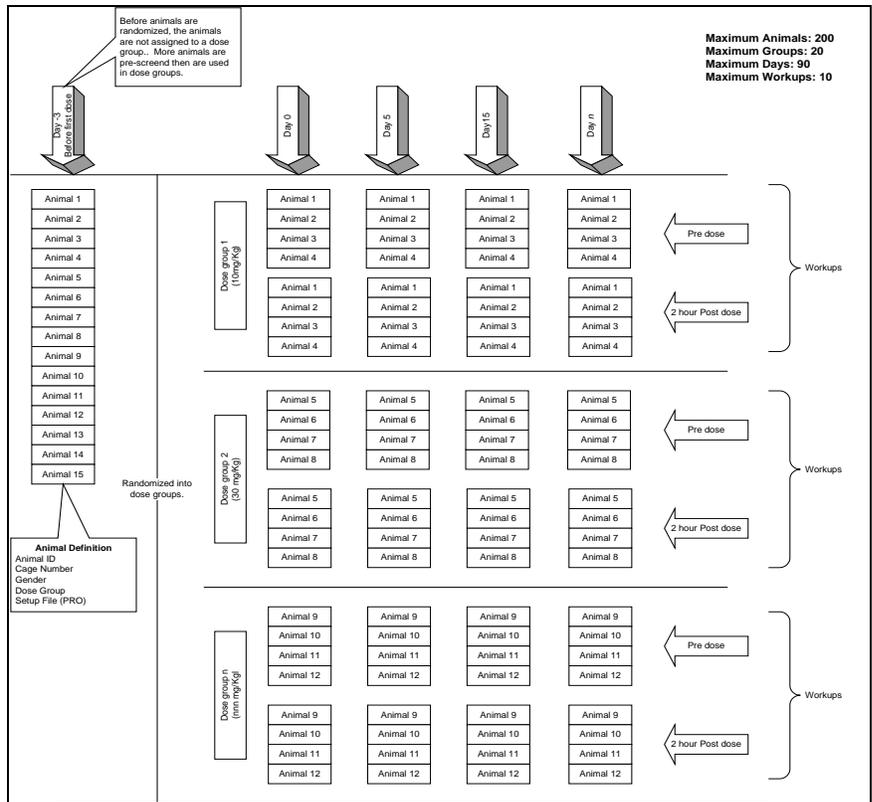


Study Protocol Option

Models: PNM-P3P-005, PNM-P3P-008, PNM-P3P-016, PNM-P3P-032, PNM-P3P-064
 Manual: MU00162-001
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Data Sciences International
119 14th Street NW, Suite 100
St. Paul, MN 55112
Phone: +1 (651) 481-7400
US: +1 (800) 262-9687
Email: support@datasci.com
www.datasci.com

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Overview

Introduction

The **Study** option will allow the user to define a complete study before any data collection/analysis begins. This capability simplifies and manages the creation of data files in a toxicology-screening scenario and a non-toxicology-screening scenario. Once the **Study** information has been entered, the system will allow a user to log on, select an animal/treatment group from a list of available setups, calibrate, collect and analyze data, and then log off.

There will be no need for the user to select a protocol setup file or enter a data set name after a study has been created. The system will perform these actions automatically from the study information that has been entered previously.

The **Study** option maintains the creation of data file names. The files that are created and stored on the current workstation (.RAW, .RVW, WMV, etc.) can be copied to other workstations using the synchronize entire study utility. This eases the management of data files created by the application.

Using the **Study** option along with the **Data Security** option allows a part 11-compliant system to be configured by an administrator before a study has begun. Once the study has been configured, a user can then select and acquire data for the study, eliminating the need to have the user manage the study data.

A study log is generated when the study is created. The study log will maintain a log of all changes made to the study, keeping track of when, by whom, and which changes were made.

Before a new study is generated, it is recommended to create the protocol file (.PRO) first. During the animal setup section, the user must select a predefined protocol file before the study can be created.

If scheduled acquisitions are to be run, note that the data reduction that is configured should match up to the times that are configured in scheduler. Also, scheduler should be configured to exceed the time needed to include the last data reduction interval.

Note: In order to use the Study feature of the system, the user must be in the **Run Study** dialog. Otherwise, no study acquisitions can be run.

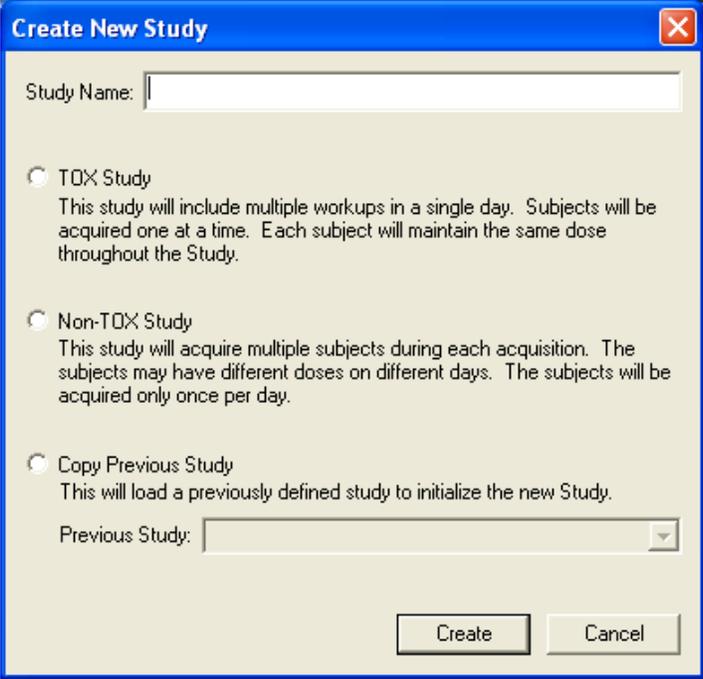
Installation

The installation of the **Study** option is done when the main **P3 Plus** application has been installed. The Study option is a purchasable option. If it was not purchased, it will not be available.

Study Setup

Creating New Study

Selecting **New Study** from the **Study** menu will bring up the following dialog.



The screenshot shows a dialog box titled "Create New Study". It features a text input field for "Study Name". Below this are three radio button options: "TOX Study" (which is selected), "Non-TOX Study", and "Copy Previous Study". Each option is accompanied by a short description of the study type. Under the "Copy Previous Study" option, there is a dropdown menu labeled "Previous Study:". At the bottom of the dialog are two buttons: "Create" and "Cancel".

Create New Study Dialog

This dialog allows the user to enter a **Study Name** and select the type of study to be created. The available options are:

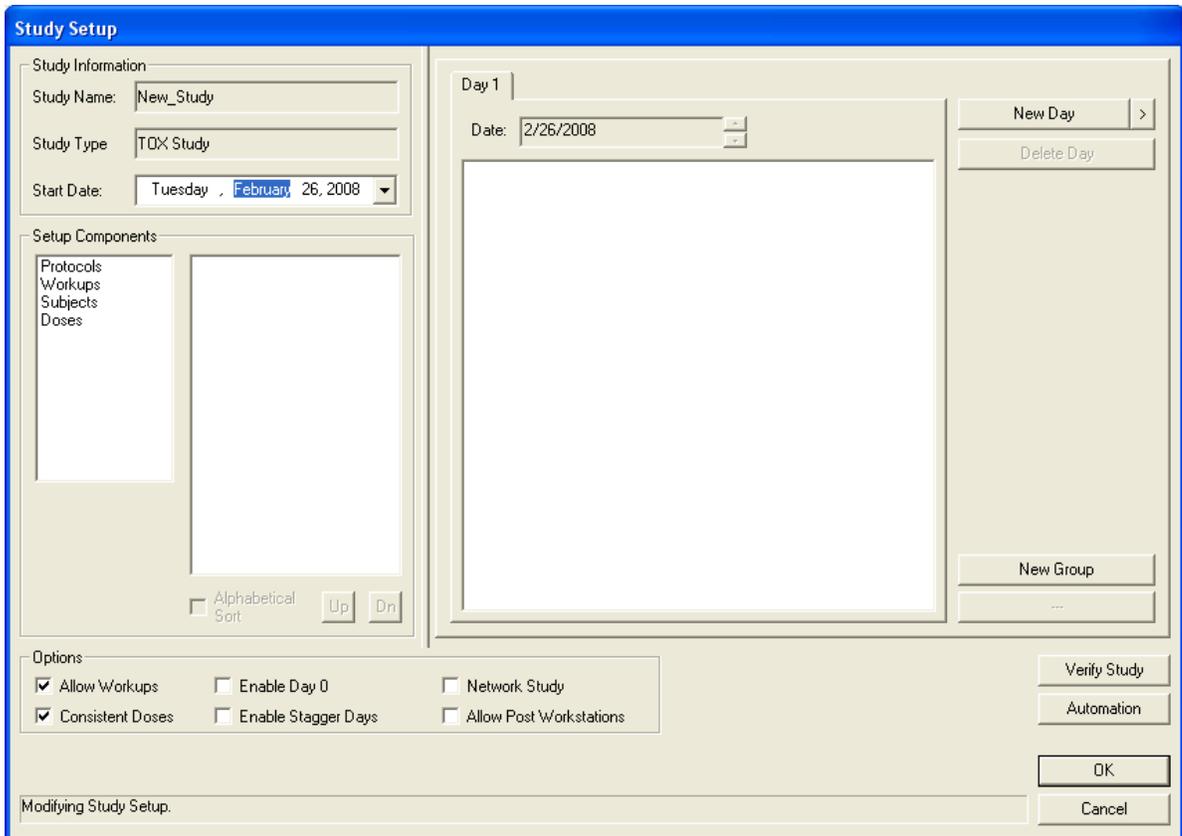
- **Tox Study** - This study will include multiple workups in a single day. Subjects will be acquired one at a time. Each subject will maintain the same dose throughout the Study.
- **Non-Tox Study** - This study will acquire multiple subjects during each acquisition. The subjects may have different doses on different days. The subjects will be acquired only once per day.
- **Non-Tox** can also be used for a Tox application that is using JET to acquire the data since it is collecting multiple animals over an extended period of time.
- **Copy Previous Study** - This will load a previously defined study to initialize the new Study. Select the previously defined study from the drop down list box.

Once the **Create** button is selected, the **Study Setup** dialog will appear.

Modifying Setup Components

Below is a screen capture of the **Study Setup** dialog. This section will show how to configure the components for the study. Each setup component can either be double clicked to add a new component, or the user can select the component and click on the associated **Add** button.

When a new Subject, Workup, or Dose is added, after the **Add** button is selected on each of the specific dialogs, the dialog will stay up allowing the user to enter a new subject, workup, or dose.



Study Information

Study Name

This is the name of the study that is currently being set up/modified. This cannot be modified.

Study Type

This is the type of study that is currently being set up/modified. This cannot be modified.

Study Date

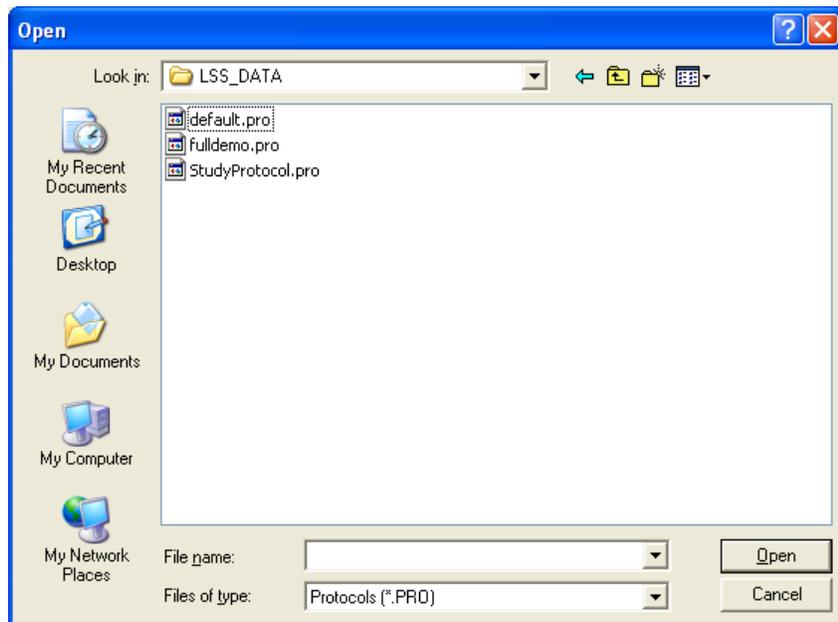
This is the start date of the study. This can be modified in several ways. One way is to click on the arrow to the right of the date. This will bring up a calendar. The new start date can be selected by just clicking on the date needed.

Another way to change the date is to select either the month, day, or year, and press the up or down arrow keys on the keyboard.

Setup Components

Protocols

This selects the protocol(s) that will be used when running the study acquisition. When you select **Add Protocol**, the following dialog will appear.



Select the protocol(s) that are needed and click on the **Open** button. The protocols have now been added to the setup components.

When protocols are added to a study, Subject Names/Sex and Dose information will automatically populate the Study setup dialog as defined in the Protocol's P3Setup Group settings, so long as the Use Study Name/Sex and Use Study Dose options are not checked. If these options are checked in the Protocol's Group settings, then Subject Names, Sex, and Dose will need to be added directly within the Study Setup dialog. The Study Setup entries for Subject Name, Sex, and Dose will then populate the Protocol's Group Settings based on these entries at time of acquisition.

When protocols are added to a study, study saves that protocol information within the associated study database. If modifications are made to a protocol outside of study, those modifications will not be reflected within the studies that use the associated protocol file. If the modifications made are needed within study, the user must open up the study, delete the protocol file in question, and then add the new protocol with the modifications that have been made.

NOTE: It is recommended to set up protocols prior to configuring a study.

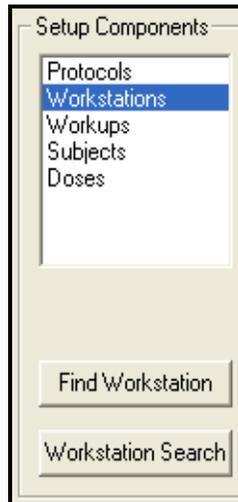
Workstations

This option is used when running studies on multiple computers. This option will only be available if the **Network Study** or **Allow Post Workstations** check boxes are checked. The workstation that will be running a specific study group should be used. Each workstation has a unique identifier when it is configured to a network. Contact your local IT department for your workstation names. When viewing the runs in the **Run Study** dialog, the **Workstation** filter can be used to show the runs that need to be done on the current workstation.

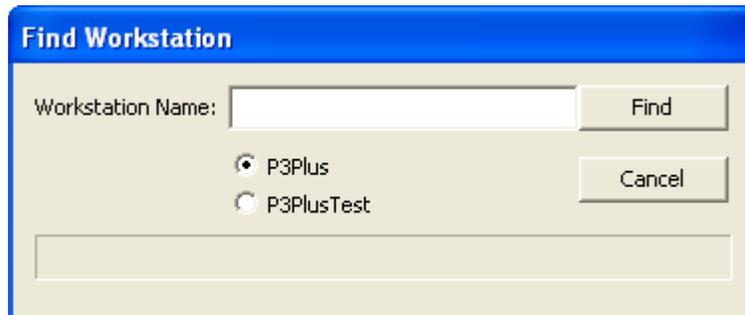
Note: It is recommended to have all workstations configured to the same domain.

When the **Workstations** component is selected, the list of available workstations will be listed. The only workstations that will be listed are ones that have the same P3 Plus version as the current workstation. Also, if the current workstation cannot gain access to other workstations, they will not be listed. Access may be denied because of firewall settings. See the Firewall Settings section for firewall settings.

When **Workstations** is selected, the user has two buttons available: **Find Workstation** and **Workstation Search**.



The **Find Workstation** button brings up a find dialog.



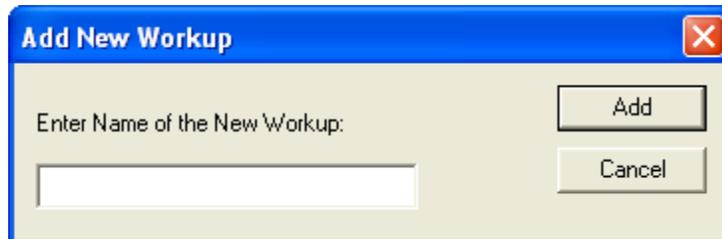
In this dialog the user can type in the workstation name if it is known. Also, the user must select which SQL database instance the workstation is used. Clicking on the **Find** button will search for the workstation that was inputted. If the workstation cannot be found, a message will appear. The workstation may not be found because of firewall settings. See Firewall Settings section for firewall settings.

The **Workstation Search** button allows the user to search the network for workstations that are available. Depending on the size of the network, a workstation search may take several minutes. Because of this, when P3 Plus is started, a search for available workstations is automatically started in the background.

Workups

Workups will be available if the **Allow Workups** check box has been enabled.

This sets up the workups that will be running for the current study. When the **Add Workup** button is selected, the following dialog will appear.

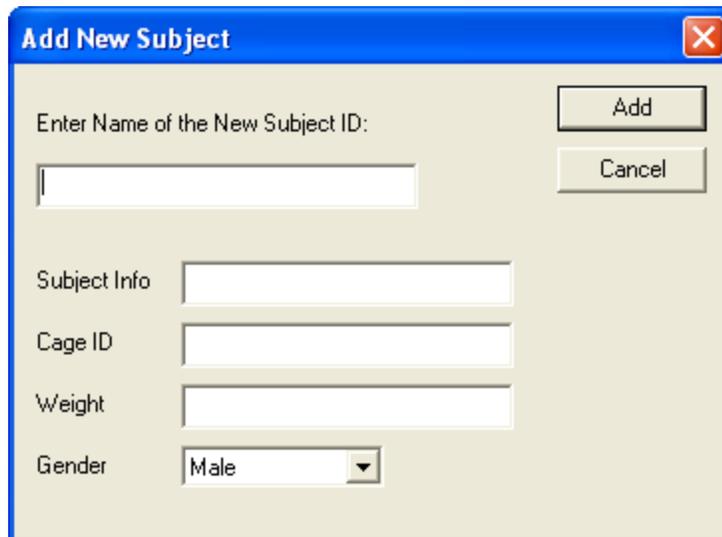


The dialog box titled "Add New Workup" has a blue header bar with a close button (X) in the top right corner. Below the header, there is a label "Enter Name of the New Workup:" followed by a text input field. To the right of the input field are two buttons: "Add" and "Cancel".

Enter the workups to be used and click on the **Add** button. Examples would include pre dose, post dose, etc.

Subjects

This configures various items for a subject. The user has the capability of entering a subject ID for each subject along with any miscellaneous subject info, cage ID information, weight, and gender.

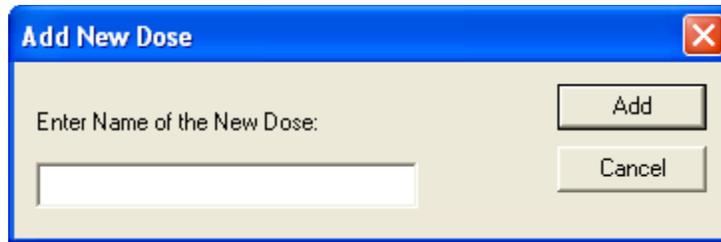


The dialog box titled "Add New Subject" has a blue header bar with a close button (X) in the top right corner. Below the header, there is a label "Enter Name of the New Subject ID:" followed by a text input field. To the right of the input field are two buttons: "Add" and "Cancel". Below this, there are four rows of input fields: "Subject Info" with a text input field, "Cage ID" with a text input field, "Weight" with a text input field, and "Gender" with a dropdown menu currently showing "Male".

If the user is using the 6000 Series BioMedics wand, the user can scan an animal and have the information from the animal populate the Subject Info field. See the BMDS Wand Manual (MU00264) for more details.

Doses

This dialog allows the user to configure doses for the study.



It is not recommended to configure a dose as "n/a" because pre dose days will be listed as "n/a" in DSI Reporting (a P3 Plus purchasable option to generate individual and group reports from Study data). Pre dose days do not have associated doses and when a report is configured that shows pre dose days, "n/a" will be shown as the dose.

Doses are used in the generation of DSI Reporting reports.

Alphabetical Sort

The **Alphabetical Sort** option allows the setup components (protocols, subjects, etc.) to be sorted alphabetically if the option is enabled. If the option is not checked, the user has the capability of sorting the components in any manner. When the option is not checked, the user can select components and use the **Up** and **Dn** buttons to move the components up or down. Multiple components can be selected and moved up and down.

Options

Several options are available dependent on the type of study configured.

Allow Workups

This option allows the user to configure the study with or without workups. By default, for a Tox study this check box is selected. A Non Tox study has this check box not selected.

Consistent Doses

This option allows the user to configure if doses will be consistent across all days. If this check box is selected, the doses for each subject will be the same for every day. By default, for a Tox study this check box is selected. A Non Tox study has the check box not selected.

Enable Day 0

Studies can be configured so that the first day of the study is either listed as Day 1 (the option is disabled) or as Day 0 (the option is enabled). This only alters how the days are viewed.

Enable Stagger Days

Studies can be configured so that different study groups can be acquired on different days even though they may be associated with the same day of the study.

Network Study

This option allows the user to configure a study to be acquired on other workstations connected to the network. Studies can be configured so that different study groups can be acquired on different workstations. Multiple workstations will be used if studies will be acquired on different workstations.

Allow Post Workstations

This option allows post workstations to be configured to the study. When the entire study is synchronized, the post workstations will be updated with the study data. This option is used so that the users can review the data that has been acquired. There are no restrictions applied to post workstations. If needed, the post workstations can make modifications and acquire/replay/review study acquisitions.

Status Area

At the bottom of the **Study Setup** dialog is an area where messages are posted. This area will inform the user of any issues with the study.

Verify Study Button

The **Verify Study** button allows the user to verify that the study setup is correct and does not have any problems. It checks to make sure of the following:

- Study Components are defined in the study structure. This makes sure that the study structure has been filled out.
- Data reduction is enabled for each group that is enabled in the protocol.
- The data reduction setup is the same for each group and for each protocol.
- The channels are configured the same for each protocol.
- Consistency among the derived/calculated parameters selected for each protocol.

Modifying Study Group Structure

The study group structure brings all of the setup components together to create the study runs.

Study Groups

For Tox studies, study groups consist of a protocol file, workups, and subjects/doses.

For Non Tox studies, study groups consist of a protocol and subjects/doses. When a protocol file is added to the study group structure, study reads in the protocol groups and sets up the amount of animals based on the protocol groups.

To start, click on the **New Group** button. This will add a new study group to the study structure. This group will consist of the items required by the study type and any other items that the user has configured. The other items are indicated in the **Options** section. Each study group can be annotated with a specific name. When a new study group is added, the name is highlighted and is editable. The user can type in the name required for the study group. At any time the study group name can be modified by selecting it and left clicking once.

To add the setup component information to the study groups, click and drag each item from the left window to the window on the right. For example, if **Protocols** is selected in the **Setup Components**, click and drag one of the associated protocol files over to the study group onto the **PRO:** section. The cursor will change from the 'No sign' to a cursor with an arrow, indicating that the selection can be added. Repeat this process for each of the study group selections. When adding subjects to the groups, one subject cannot be configured to multiple groups.

The user has the ability of selecting multiple components of the same type and then dragging and dropping them to the study structure. This can be done for workups, subjects, and doses. This cannot be done for protocols and workstations.

If stagger days are needed, the **Enable Stagger Days** option should be checked. This will add a **Stagger Day** option to the study group. When **Stagger Day** is selected, a + and - button appear to the right. This allows the user to modify the offset of the stagger day.

New Days

To configure a new day to the study structure, click on the **New Day** button. When the **New Day** button is selected, it will add a new day one day after the currently selected day. The user can also use the advanced new day button (the > button right next to the **New Day** button) to add a new day. This advanced button allows the user to add a new day after the currently selected day, add a pre dose day, or select a day from a calendar.

The user also has the capability of changing the date of the currently selected day by clicking on the up and down arrow buttons to the right of the current date.

If a day has been configured that is not needed, the user can highlight the day to be deleted, and click on the **Delete Day** button. Day 0/1 cannot be deleted from a study.

The user has the ability to configure predose days. This can be done by clicking on the arrow next to the **New Day** button and selecting the **Insert Day -1** option.

Delete/Clear/Remove Button

In the lower right hand corner of the dialog is a button that changes dependent on which study structure item is selected.

If a study group is selected, this button becomes a **Delete Group** button. When this button is selected, the group that is highlighted will be deleted.

If a protocol is selected, this button becomes a **Clear Protocol** button. When this button is selected, the protocol associated with the group will be removed from the group.

If a workstation is selected, this button becomes a **Clear Workstation** button. When this button is selected, the workstation associated with the group will be removed from the group.

If a stagger day is selected, this button becomes a **Reset Stagger** button. When this button is selected, the stagger day will be reset back to zero.

If the main **Workups** item is selected, this button becomes a **Remove All Workups** button. When this button is selected, every workup in the associated study group will be removed.

If a single workup is selected, this button becomes a **Delete Workup** button. When this button is selected, the selected workup will be deleted.

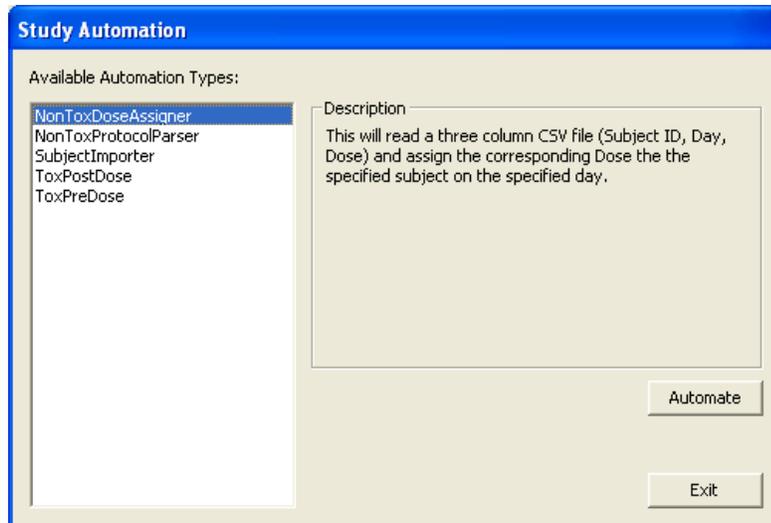
If the main **Subjects** item is selected, this button becomes a **Remove All Subjects** button. When this button is selected, all of the subjects from the associated group will be removed.

If a single subject is selected, this button becomes a **Delete Subject** button. When this button is selected, the selected subject will be deleted.

Automatic Study Setup

Study supports the use of automation scripts which imports data generated by third party software packages such as LIMS systems. Third party packages capable of creating CSV files of the study design may be imported into Ponemah to automatically create or modify a study. This includes creating the number of days for the study, number of animals on study, number of workups and so forth.

Clicking on the Automation button in the Study Setup menu will bring up the following dialog.



Five Automation Types are available for selection depending on the type of study performed. Clicking on the available types will provide a description in the right hand side of the dialog.

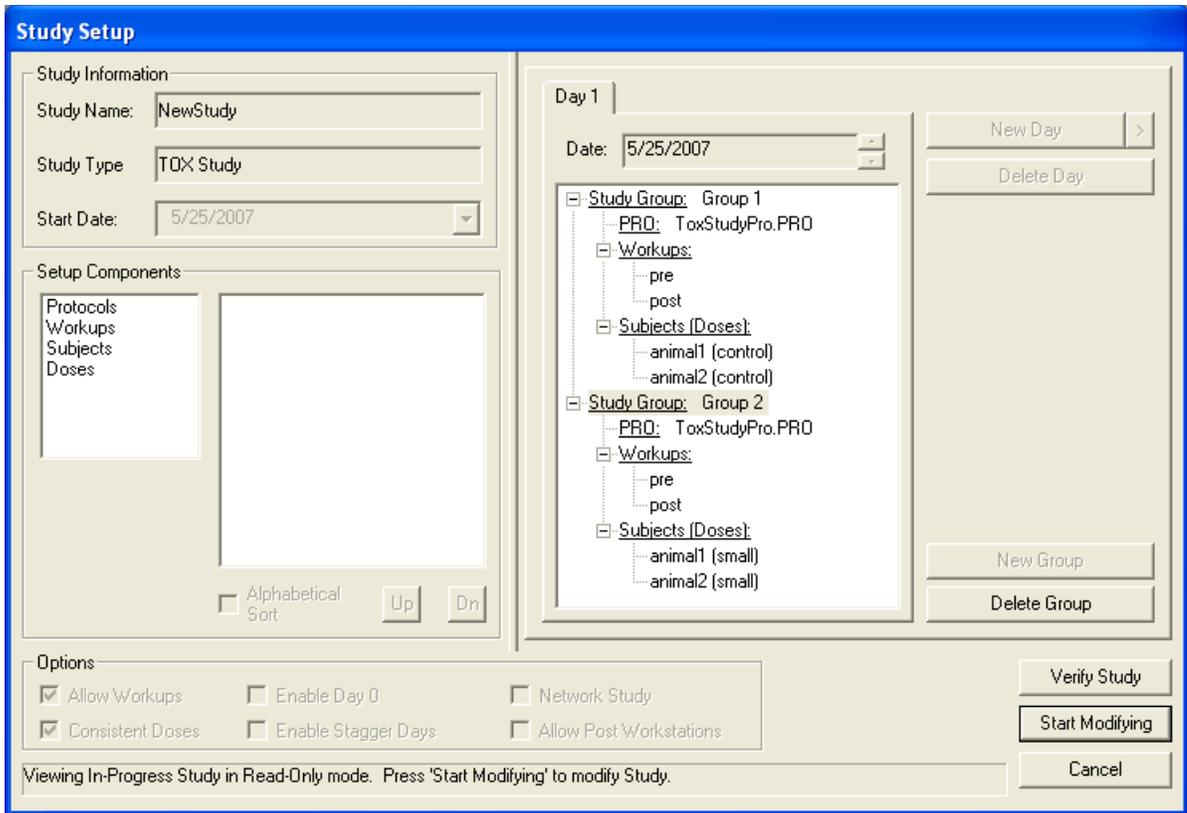
The following Automation Types are currently available:

- Tox Pre Dose – Imports subjects and Genders to a Tox Pre Dose day
- Tox Post Dose – Assigns a Subject Info string to an existing Subject and assigns the subject and a dose to a Dose Day
- Non Tox Protocol Parser – Scans the assigned Protocols and adds the P3 Group Names as subjects to the existing Study Groups
- Non Tox Dose Assigner – Adds the specified subjects to the specified Dose Days while assigning them the specified doses.
- Subject Importer – Imports a list of Subjects and related Info to the Subjects List.

Selecting an Automation Type and clicking on the Automate button will open a dialog which will allow browsing to the location of the CSV file. Selecting the CSV file will automatically result in the Study structure being filled in (setup components and days) based on the Automation Type selected.

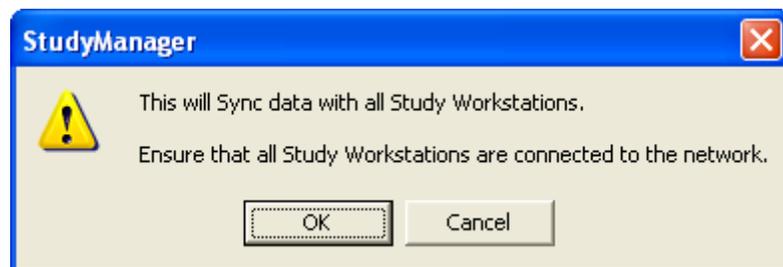
Modifying Study after Acquisition

P3 Plus limits the information that the user can modify after an acquisition has been performed. Below is the dialog that appears when the user opens the **Study Setup** dialog after an acquisition (Tox study shown).



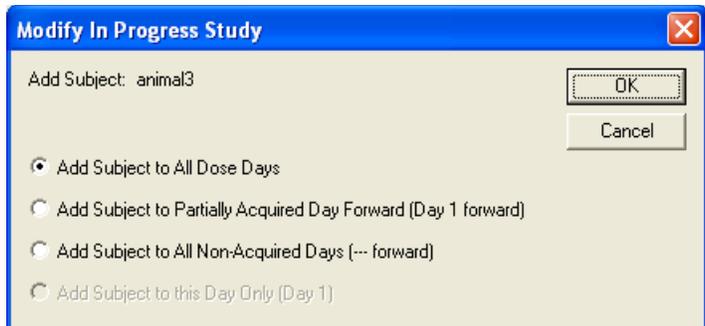
To start modifying the study, the user must click on the **Start Modifying** button. If a network study was configured, the message below will appear. Data must be synchronized across all workstations prior to modification of the study.

NOTE: If the Study has been restored from a different workstation, then the **Start Modifying** button will be **Become Primary**. See section **Restoring a Database** for more information.



Below is a list of items that can be modified after an acquisition has been performed:

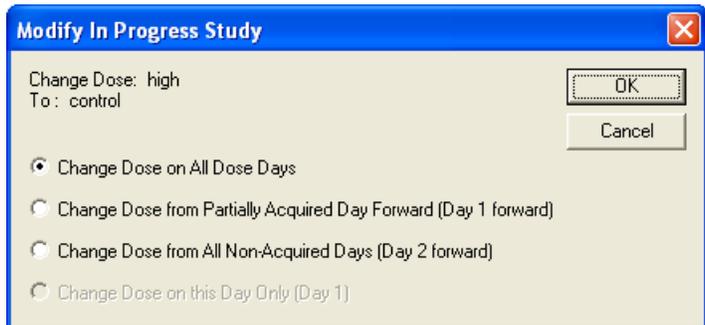
- New Day can be created (not a pre dose day)
- An animal can be added/deleted/modified to the Subjects list (Study Structure) (addition dialog shown)



If an animal is modified on a post dose day, the above dialog will appear. This will allow the user to configure which day(s) the animal will be added/deleted/modified.

If an animal is added/deleted/modified on a pre dose day, only the last option will be available.

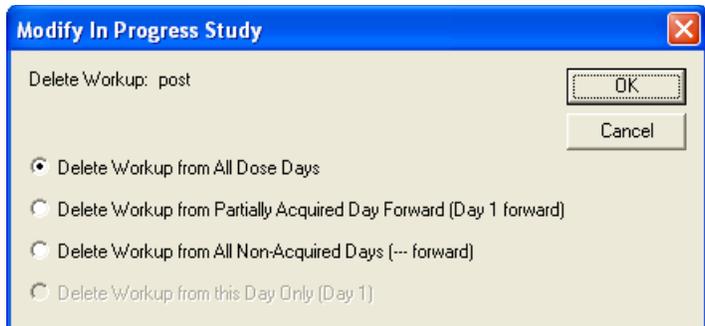
- Days can be deleted (only after the days that were acquired)
- Doses can be modified in the Group structure



If a dose is modified on a post dose day, the above dialog will appear. This will allow the user to configure which day(s) the dose will be modified.

If the Consistent Doses option is disabled, the dose will only be modified on that day.

- If an acquisition has been performed only on pre dose days, any modification can be performed
- Workstations can be added/deleted
- Post Workstations can be added/deleted/modified
- Workups can be added/deleted/modified from the Group structure (deletion dialog shown)



If a workup is deleted from a post dose day, the above dialog will appear. This will allow the user to configure which day(s) the workup will be deleted.

If a workup is deleted from a pre dose day, only the last option will be available.

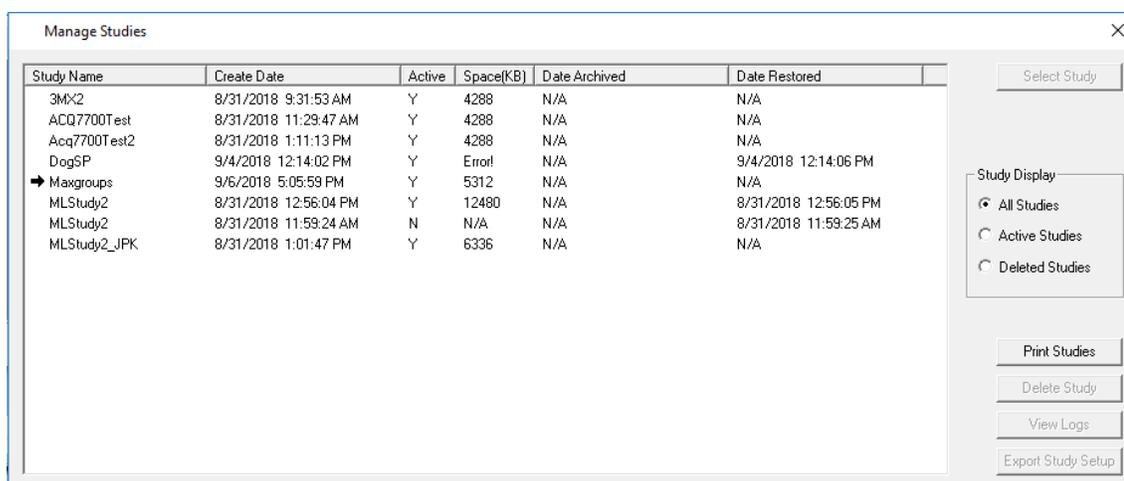
Managing Studies

Manage Studies Dialog

The **Manage Studies** dialog is opened by selecting **Manage Studies** from the **Study** menu. From this dialog the user has the capability of selecting a different study, printing study information, deleting older studies, or viewing the logs for the study that is highlighted.

The current study that is selected will have a black arrow next to the study name. A highlighted study is the study that is highlighted in blue.

The **Manage Studies** dialog can be resized if needed.



This dialog shows each study name, the date created, if the study is active, the approximate size of the study (not including .RAW files or text generated files), the date that the study was archived, and the date that the study was restored. An **N/A** will be listed for **Date Archived** and **Date Restored** if the study has not been archived or restored.

A study is considered active if it has been created or restored onto the local system. A study will be marked as **N** if it has been deleted.

Study Display

This allows the user the ability to display which studies are listed.

- **All Studies** list both the Active Studies and the Deleted Studies.
- **Active Studies** list only the active studies. This helps keeping the study list manageable.
- **Deleted Studies** list only the deleted studies for the audit trail.

Select Study

The **Select Study** button allows the user to load the currently highlighted study. This button will be disabled if no study is highlighted, the currently selected study is

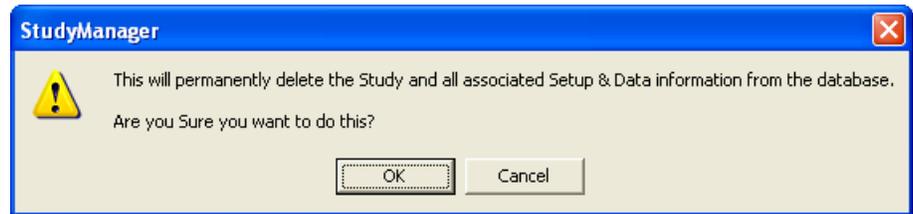
highlighted, or the study selected is inactive. The user can also double click on a study to select the study.

Print Studies

The **Print Studies** dialog prints the information listed in the **Manage Studies** dialog along with the date and time that it was printed.

Delete Study

Deleting a study will permanently delete a study from the database. When **Delete Study** is selected, the following message will appear asking if you are sure.



When a study is deleted, all of the information in the database is removed. However, the files that are created in the study directory are not deleted.

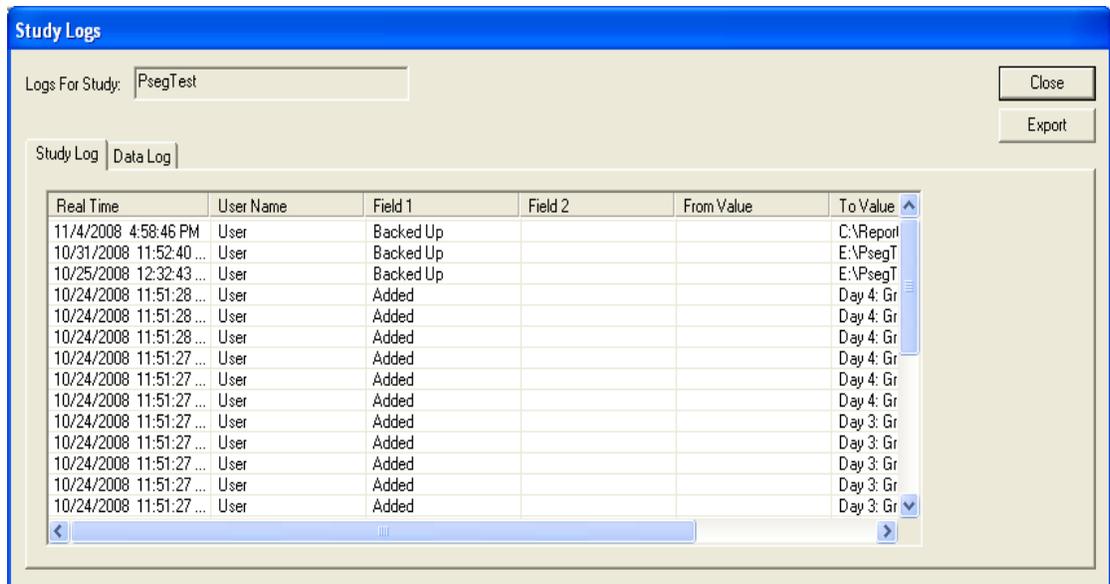
NOTE: This action cannot be reversed. A study that is deleted cannot be recovered.

View Logs

The **View Logs** button brings up the **Study Logs** dialog. This allows the user to view the study and data log for the current study. The currently selected study is listed at the top of the dialog. Refer to the **Application Log** section in this manual for a list of application specific study information.

Study Log Tab

The **Study Log** tab lists general study information regarding the currently selected study.



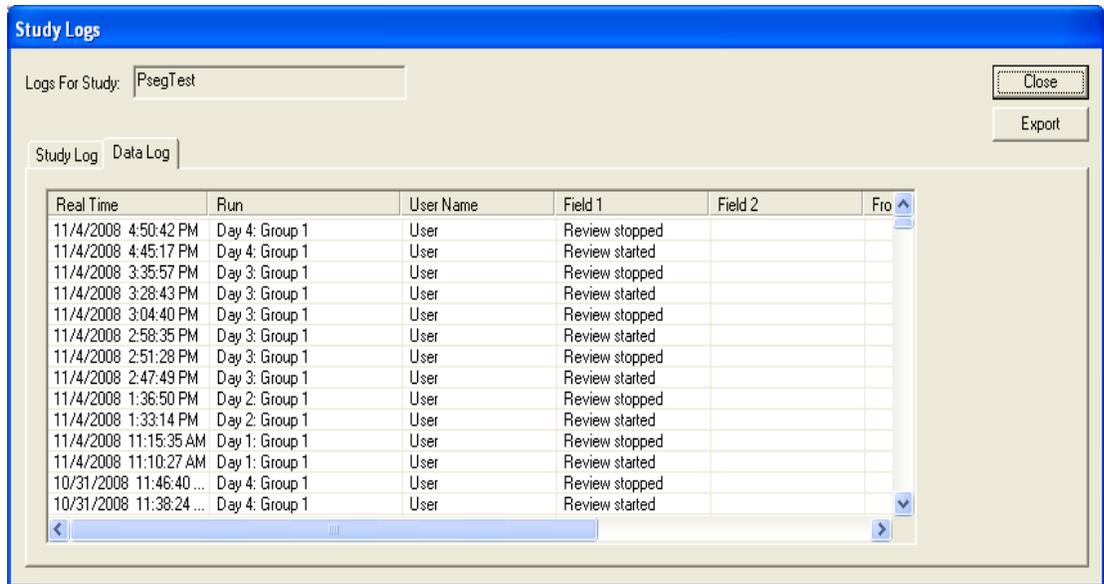
The information included in the **Study Log** tab is the **Real Time**, **User Name**, **Field 1**, **Field 2**, **From Value**, **To Value**, and **Reason**. Information will be entered at various times during the running of the study. The “Export” button enables the user to export the Study Log to an Excel file.

The times when information will be logged include:

- The current study setup information will be logged on the first dose day acquisition. The **To Value** column will include the days configured, group information, workups, and subject/dose information. The **Field 1** column will be noted as added, and the **Reason** column will indicate that it is the initialization of the study.
- Any modifications made to the study contents will be logged on a dose day acquisition. This includes the date and time, user, study contents change (in the From/To Value columns) and the reason.
- Protocol modifications will be logged.
- The runs that are selected for DSI Reporting will be logged.
- A synchronize study data is performed.
- A synchronize entire study is performed.
- An on demand binary synchronization is performed (when the entire study has not been synchronized and a replay/review is performed where the search paths have been configured).
- The study has been backed up.
- The study is restored.

Data Log Tab

The **Data Log** tab lists acquired study information regarding the currently selected study.



The information included in the **Data Log** tab is the **Real Time**, **Run**, **User Name**, **Field 1**, **Field 2**, **From Value**, **To Value**, and **Reason**. Information will be entered at various times during the running of the study. The “Export” button enables the user to export the Data Log to an Excel file.

The times when information will be logged include:

- Acquisitions that are started and stopped will be logged.
- Replays that are started and stopped will be logged.
- Reviews on data, only when a marks section is saved, will be logged.
- External data that is loaded from a non study acquisition will be logged.
- Runs that have been aborted will be logged.
- Calibration information will be logged when a calibration is performed.
- A/D range information will be logged when the range is changed.

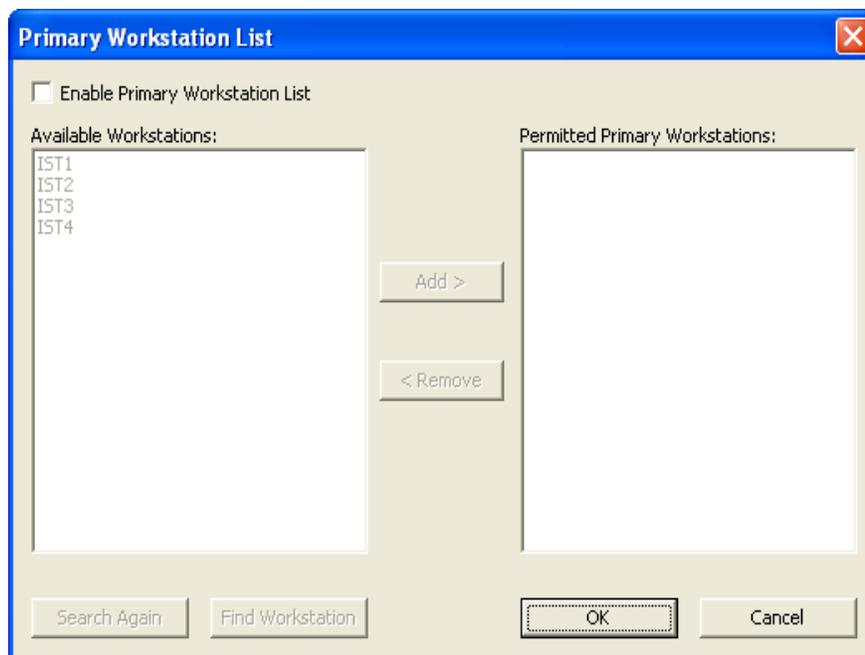
Export Study Setup

This exports the current study setup after study creation for purposes of verification and printing.

Network Options

Edit Primary Workstation List

The **Edit Primary Workstation List** brings up the **Primary Workstation List** dialog. This allows the user to select which workstations will have the capability of creating a network study on the current workstation.



The **Enable Primary Workstation List** check box allows the user to permit only specific workstations to have the capability of creating a network study on the current workstation. When this check box is disabled, any workstation will be able to create a network study on the current workstation. This is the default setting. Once this check box is enabled, the user must select which workstations will be permitted to create a study on the current workstation.

The **Available Workstations** list shows the workstations that the current workstation is able to see on the network.

The **Permitted Primary Workstations** is the list of workstations that the current workstation will allow to generate a study on the current workstation.

The **Add >** button will move a workstation from the **Available Workstations** list to the **Permitted Primary Workstations** list. The **< Remove** button will move a workstation from the **Permitted Primary Workstations** list to the **Available Workstations** list.

The **Search Again** button will search the network for all available workstations. This option may take several minutes to complete depending on the size of the network.

The **Find Workstation** button will bring up the **Find Workstation** dialog.

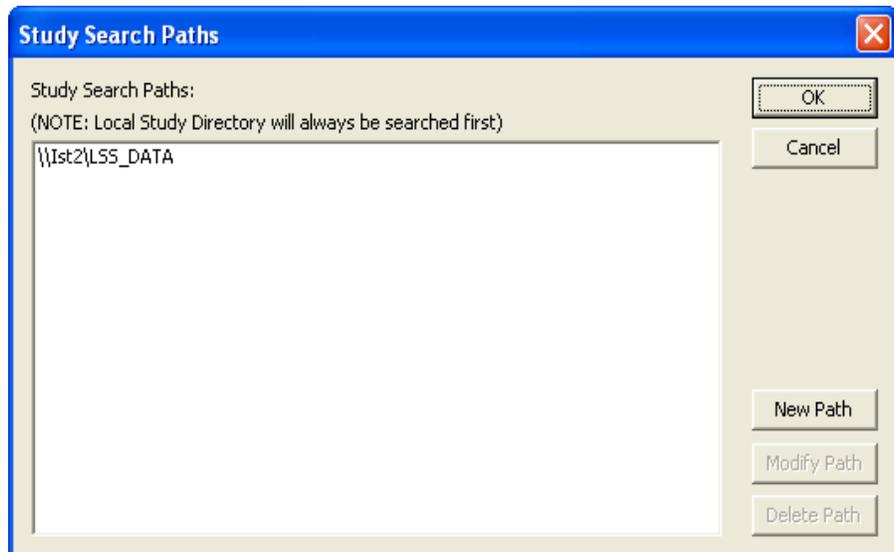


In this dialog the user can type in the workstation name if it is known. Clicking on the **Find** button will search for the workstation that was inputted. If the workstation cannot be found, a message will appear. The workstation may not be found because of firewall settings. See Firewall Settings section for firewall settings.

The **OK** button accepts all changes and the **Cancel** button discards all changes and closes the dialog.

Edit Study Search Paths

The **Edit Study Search Paths** menu selection brings up the **Study Search Paths** dialog.



The **Study Search Paths** dialog allows the user to configure a link to the data paths of other workstations that will be involved in network studies. This allows the current workstation to search other locations for binary data for replay and review purposes. When a workstation searches for data, the local data directory will be searched first. When configuring a data path, it is recommended to use the workstations default data directory since subdirectories will be searched as well.

The **New Path** button allows a new path to be configured. The **Modify Path** button allows the currently selected path to be modified. The **Delete Path** button will delete the currently selected path.

Firewall Settings

Dependent on the operating system settings, the firewall may need to be modified to allow study to see other workstations. Contact your IT department to make these modifications.

Please refer to the Ponemah IT Guide for these settings.

Run Study

Run Study Dialog

The **Run Study** dialog is the main dialog that will be used during a study. This dialog is where all acquisitions, calibrations, replays, and reviews will be done. The **Run Study** dialog is split into various sections (Filters, Run Study, Information, Previous Runs, and Status) defined over the next few pages. Typical Tox and Non Tox Study dialogs are presented below.

Run Study: TestTox

Filters

Day: Day 1 | Date: All | Workstation: All
Study Group: All | Dose: All | Acquired: All
Subject: All | Gender: All | Replayed: All
Workup: All | Cage: All | Reviewed: All

Run Study

Subject ID	Subject Info	Date	Dose	Workup	Acq	Rep	Rvw
NHP1		Day 1	0 mg/kg	Pre	1	0	0
NHP1		Day 1	0 mg/kg	1 hr	1	0	0
NHP1		Day 1	0 mg/kg	3 hr	1	0	0
NHP2		Day 1	0 mg/kg	Pre	1	0	0
NHP2		Day 1	0 mg/kg	1 hr	1	0	0
NHP2		Day 1	0 mg/kg	3 hr	1	0	0
NHP3		Day 1	0 mg/kg	Pre	1	0	0
NHP3		Day 1	0 mg/kg	1 hr	1	0	0

Hardware > | Acquire > | Other >

Previous Runs

Run ID	Type	Date - Time	User	Note	Report
80890001	Acq	10/29/2008 8:27:58 AM	Bob	-----	Default

Replay | Review

Status
No Run Performed. | Save PRO

Filters

By selecting various filters, the user will be able to minimize the amount of study acquisitions listed in the **Run Study** section. The different filters include Day, Study Group, Subject, Workup, Date, Dose, Gender, Cage, Workstation, Acquired, Replayed, and Reviewed. The filter settings selected are saved when the Run Study dialog is closed. If a study is copied, the filter settings will be applied to the new study.

Most of the filters listed above will have a list of each entered item along with an **All** selection. For example, if the doses **Control**, **5mg/kg**, and **15mg/kg** are used, the **Dose** filter will have the selections **All**, **Control**, **5mg/kg**, and **15mg/kg**.

Other filters will have slightly different options. These filters include Date, Workstation, Acquired, Replayed, and Reviewed. The Date filter options will include **All** and **Today**. The Workstation filter options will include **All** and **This Workstation**. The Acquired filter options will include **All** and **Not Acquired**. The Replayed filter options will include **All**, **Not Replayed**, and **Not Replayed by 'User'**. The last selection will list the current user who is logged into P3 Plus. If security is enabled, it will use the name set on the Access Card. The Reviewed filter options will include **All**, **Not Reviewed**, and **Not Reviewed by 'User'**. The last selection will list the current user who is logged into P3 Plus. If security is enabled, it will use the name set on the Access Card.

The Workstation filter will be disabled if the Single Workstation option is checked.

Study Acquisitions (Run Study)

The Run Study section on the Run Study dialog shows the list of study acquisitions that are available after the filtering has been applied. The study acquisition buttons will become enabled once one of the study acquisitions is selected.

If the user is using the 6000 Series BioMedics wand, the user can scan an animal to select the appropriate animal in the Run Study dialog. See the BMDS Wand Manual (MU00264) for more details.

Study Acquisition Buttons

The buttons shown in the Run Study section include a hardware button (with options), an acquisition button, and a **Other** button. The hardware button options depend on the type of hardware that will be used.

- For the ACQ7700 USB and ACQ16 USB, the option will be **7700 Amplifier Setup**. This will bring up the **7700 Modules** dialog.
- For a DSI setup, these options will be **Edit DSI Setup** and **Select DSI Sources**. The **Edit DSI Setup** button will bring up the configuration dialog for DSI. The **Select DSI Sources** button will bring up the **Select DSI Sources** dialog.
- For a JET setup, the option will be **JET Device Configuration**. This will bring up the **JET Device Configuration** dialog.

For each available hardware option, another selection will be available. This is **Video Configuration**. This allows the video configuration to be modified. See the P3 Plus Video Manual for details.

The acquisition button will either be shown as **Acquire** or **Sched. Acq**. This button also has an advanced selection by clicking on the arrow button next to the acquisition button. The **Acquire** button is used to start the acquisition for the study acquisition that has been selected. The **Sched. Acq** button is used to start a scheduled acquisition. When it is selected the **Scheduler Setup** dialog will appear. This dialog appears so that the user can make any modifications that are needed to the scheduler setup. When a study is initially set up with a specific protocol, the Experiment Start time will probably not be known. This will allow the user to make the necessary modifications to the Experiment Start time. Also, when the same protocol is used for different scheduled acquisitions, the Experiment Start time and date will need to be changed for each acquisition.

If the advanced portion of the acquisition button is used, and the selection made is changed from the original option, the button will change to what was selected. This will be saved so the next time the Run Study dialog is opened, the selection made is the selection that will appear. For example, if the **Acquire** button is listed, the user

selects the advanced arrow button and selects **Sched. Acq.**, every time the Run Study dialog reappears, the button will now come up as **Sched. Acq.**

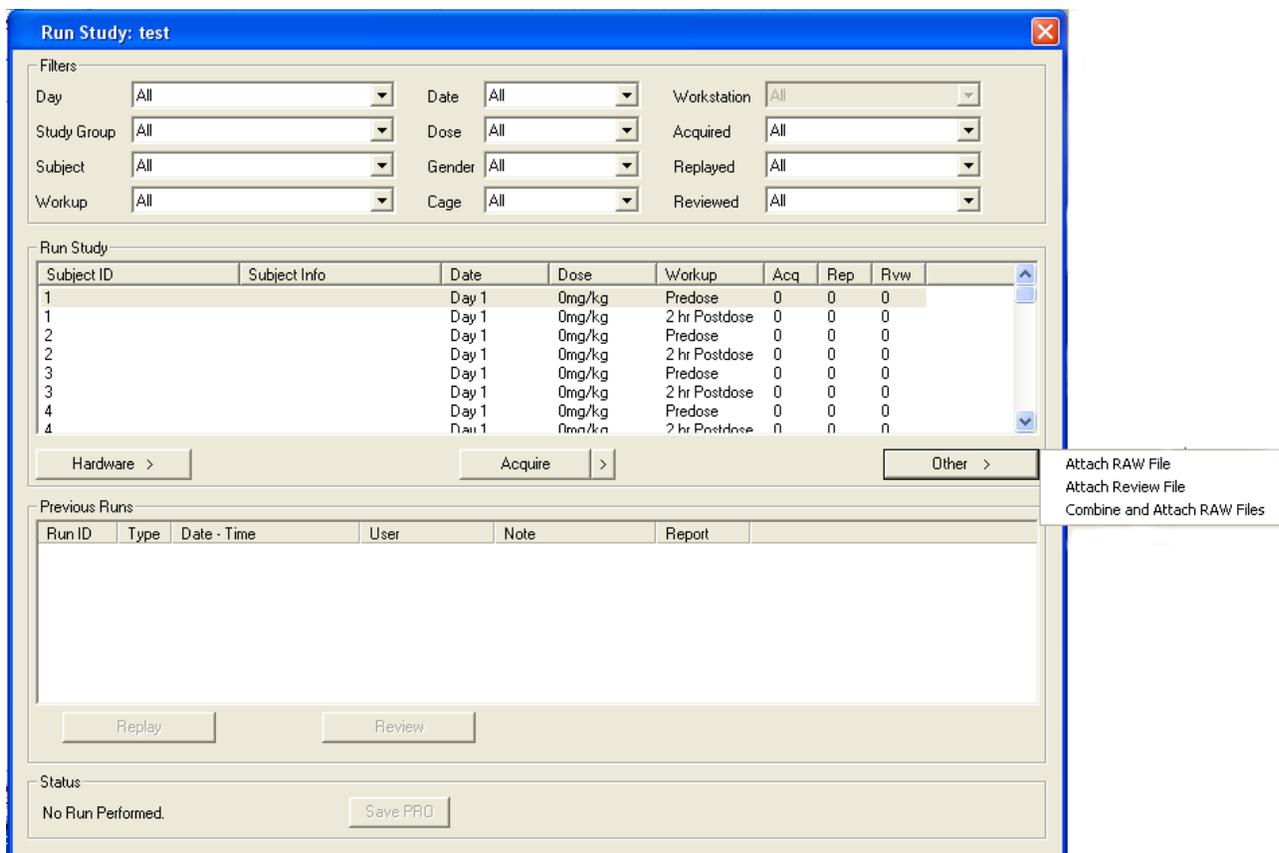
The **Other** button gives the user the option to Attach RAW File, Attach Review File, or Combine and Attach Raw Files that were acquired outside of study. These options are means to loading selected data into the Study. The data that is loaded must have the same configuration as what was set up in data reduction for the protocol that was selected for that study. If there are incompatibilities with the Review file being loaded, a warning message will appear and ask if the user wants to continue with the Attach. Note: if the user elects to continue with the incompatibilities in place the DSI Reporting feature may not function properly. This does not apply when attaching a RAW file since there is no configuration information contained in this file, only waveform data

The Attach Review File feature extends the Attach RAW feature and replaces the Load External Data feature found in earlier versions of the Study module. This feature provides better functionality by allowing a full review session to be imported into a Study. Upon selecting a Review file to attach the user will be prompted to select a RAW file from the Study Directory. Note: The software will not validate that the selected RAW file matches the RAW file associated with the Review file.

Combine Raw Files allows the combining of RAW files into a single file. In the event of a catastrophic failure, acquisition is stopped unexpectedly. To continue the acquisition, a user must create a new file name and continue collecting data which creates two sets of files for a single collection period. These two sets of files must be managed when reporting results of the data.

For long duration acquisitions, it is not advantageous to manage multiple files to report final results of the data. Therefore combining RAW files allows the user to create a single RAW file for the collection period if acquisition is stopped unexpectedly.

NOTE: This feature does not allow all files to be combined together. The files must have the exact same configuration and must have been collected within a short period of time (days) from one another.



Information

The Information section shows information about the study acquisition selected.

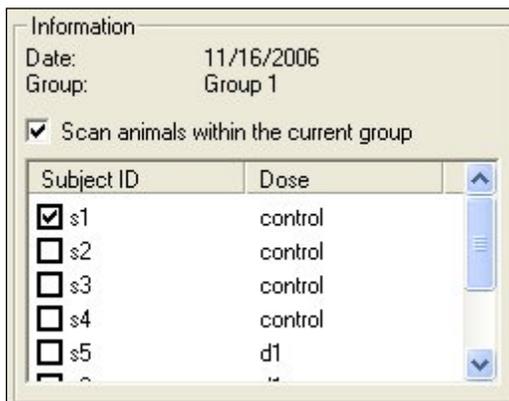
If a tox study is being run, this information is provided in the Run Study list view and will show the date that the currently selected study acquisition should be acquired, the group that the study acquisition is within, the subject for the current study acquisition, subject information for the current study acquisition, and the workup associated with the current study acquisition.

If the user is using the BioMedics wand, the user can scan an animal to select the appropriate animal in the Run Study dialog and have the information from the animal populate the Subject Info field. See the BMDS Wand Manual (MU00264) for more details.

If a non tox study is being run, this section will show the date that the currently selected study acquisition should be acquired, the group that the study acquisition is within, and the Subject ID and Dose for each animal.

If the user is using the BioMedics wand, the user can scan an animal to select the appropriate animal in the Run Study dialog and have the information from the animal populate the Information section. With each scan of an animal, the appropriate animal lists a check mark next to it, to let the user know which animals have been scanned and which animals have not been scanned. The **Scan animals within the current group** check box allows the user to only scan the animals in the current group. The check boxes next to each animal in the Information section can be used by users that do not have the BMDS wand. The check boxes are used for

informational purposes and will not affect acquisition. See the BMDS Wand Manual (MU00264) for more details.



Previous Runs

The Previous Runs section lists all the runs that have been done for the study acquisition selected and has buttons for replaying and reviewing the run selected.

Both types of studies have the **Replay** and **Review** buttons. If a run is selected and the raw data exists on the current computer, these buttons will be selectable. The **Replay** button allows the user to replay an acquisition (or replay) similar to running replays outside of study. Changes can be made within review if attributes were not configured correctly in the initial acquisition. Replay can only be done if the raw files were saved, and those raw files exist on the current workstation. Reviews can be done on the selected run in a similar manner.

Any workstation can replay/review data from any other workstation if the current workstation has synchronized the entire study. If only the study data was synchronized and the current workstation has configured the study data paths to the workstation that acquired the data, then a synchronize on demand will be performed. This will automatically search all workstations for the required data (as long as the search paths have been configured), copy the data from the acquired workstation to the current workstation, and then replay/review the data without the user needing to synchronize the entire study.

The Previous Runs section shows the previous run history for the study acquisition selected. The columns listed are Type, Date - Time, User, and Note. The Type column will list if an acquisition, replay, review, or manual attachment was performed. The Date - Time column will list the date and time for that run. The User column will list the user who is logged into P3 Plus. The Note column lists hand entered information which can be added or modified at any time.

When a Synchronization is performed for a network study the notes associated with the study runs are also synchronized. If a run has only one distinct note that note shall be synced to all study workstations. If a run has multiple distinct notes (conflicting) the note for each workstation will remain unchanged. Following Synchronization a dialog box will inform the user of the conflict and log the conflicts to the Study log.

A Summary Report Setup Panel is displayed to show which run is selected (by Run ID), for each subject and whether Data Reduction values exist. If Data Reduction values exist, these will be listed under Line. If Use Default is selected, the last run for that animal in the Previous Runs panel will be automatically selected for reporting.

The Show Subject Info check box allows the display to switch between showing the Subject ID or the Subject Info in the Information panel.

Status

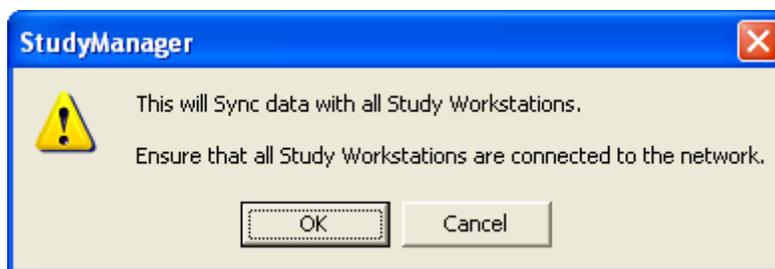
The status area will indicate if any changes were made to any attributes during an acquisition or replay. A button is available so that the user can save the protocol as the primary protocol if any modifications have been made. The primary protocol is the protocol that will be used when new acquisitions are started.

If any modifications are made to the sizes of graph page windows, the main P3 Plus window, or the list views on the main P3 Plus window, it will **NOT** be stated the protocol has been modified. The changes can be saved to the primary protocol by selecting the save protocol button.

Study Database Utilities

Synchronize Study Data

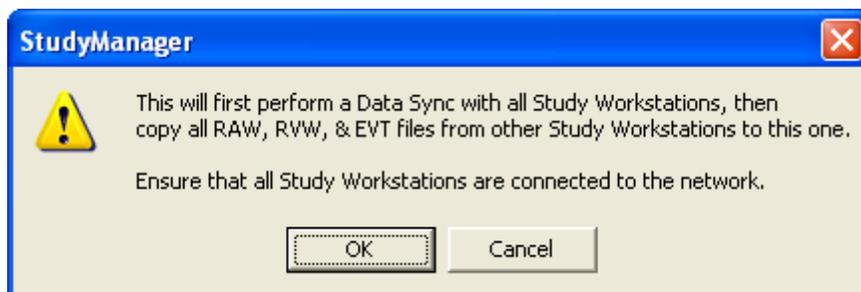
When **Synchronize Study Data** is selected from the **Study** menu, the following dialog will appear.



This allows the current workstation to synchronize data across all workstations. This includes the run information in the Run Study dialog and does NOT include binary files (.RAW, .RVW, .EVT, and Excel .XLSX/.XLSB files).

Synchronize Entire Study

When **Synchronize Entire Study** is selected from the **Study** menu, the following dialog will appear.



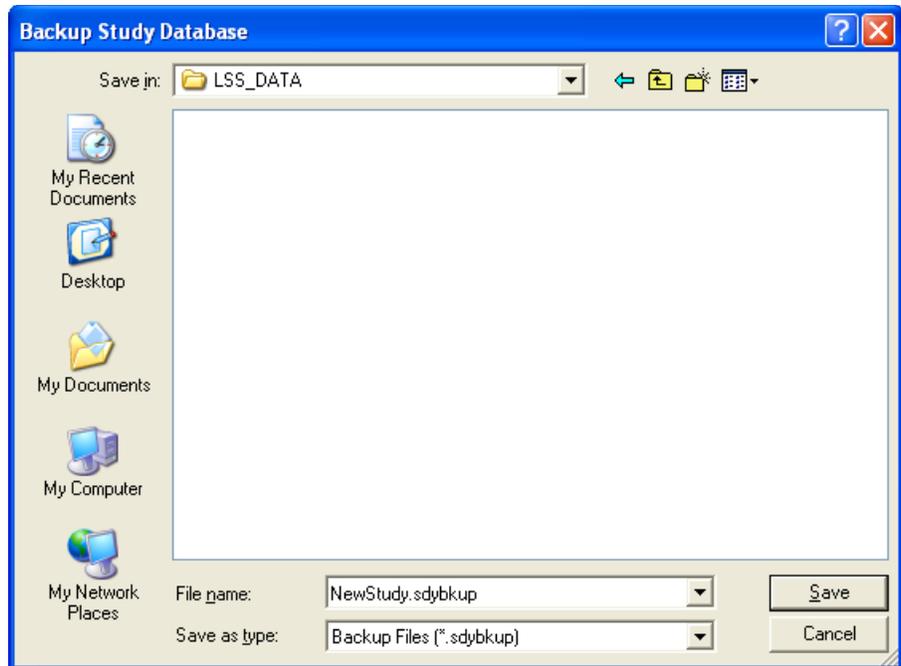
This option first performs a Synchronize Study Data and then copies all binary data from all other workstations to the current workstation. This only copies the binary files to the current workstation and does NOT copy binary files to any other workstations.

If data files are missing when a Sync Entire Study is executed, a message box will be displayed offering the user options on how to handle the missing files.

The user can choose to continue and copy the available files or to cancel the sync. The Study Log will record the actions taken in this dialog and maintain a list of the missing files.

Backing Up a Database

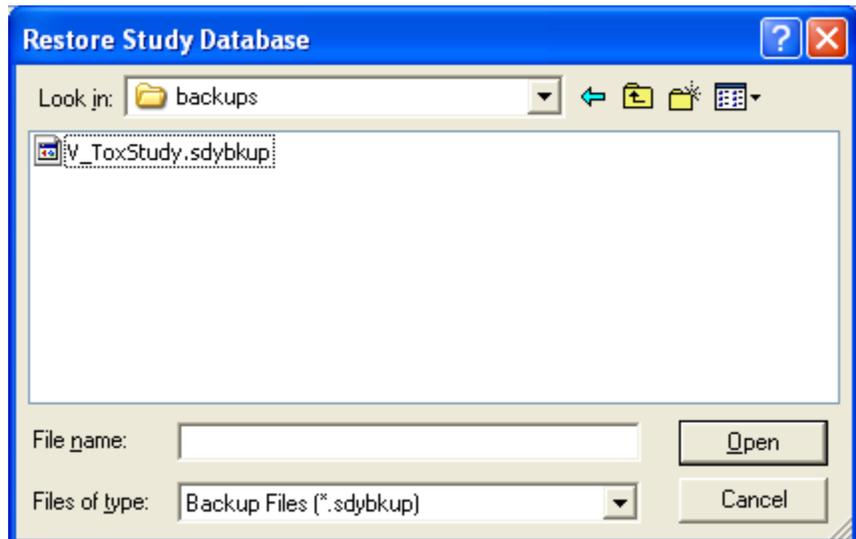
By selecting **Backup Study** from the **Study** menu, the **Backup Study Database** dialog will be opened. This allows the user to back up the current study database.



Backing up a study will save the study configuration and all of the data runs that were acquired. Backup will NOT back up binary data (.RAW, .RVW, .EVT, and Excel .XLSX/.XLSB files).

Restoring a Database

To restore a database, select **Restore Study** from the **Study** menu. A dialog will appear similar to the one shown below.



Navigate to the location of the backed up file, select the file, and click on the **Open** button. This will restore the database selected onto the current machine.

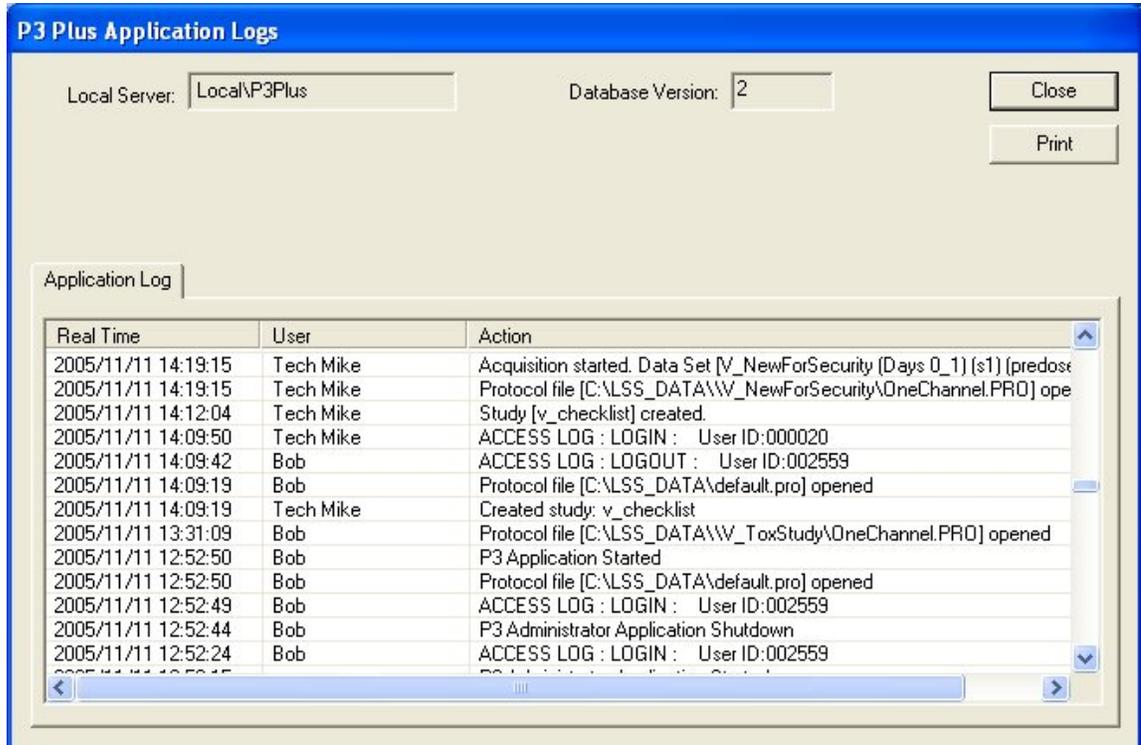
Conversion of older Study Databases

If a Study from an older version of Ponemah is loaded, a message will be displayed allowing the Study to be converted so that it is compatible with the current version. An option to cancel this conversion is also available. If a Study is converted, it will not be able to be opened in the previous version of Ponemah. Attempting to load a newer Study into an older version of Ponemah will post a message stating that this action is not allowed.

Application Log

P3 Plus Application Logs Dialog

Log information based on general study information is listed on the **P3 Plus Application Logs** dialog in the **Application Log** tab.



The information included is **Real Time**, **User**, and **Action**. Information will be entered at various times during the running of study. The times when information will be logged include:

- The creation of a study.
- When a study is selected.
- When a study is deleted.
- When a study is backed up or restored.

Security and Study

Available/Restricted Features

There are several available/restricted features for Study. These features may be dependent on other available/restricted features. These features include:

- **Study - Backup Database**

This option allows the user to back up a study database. If this option is not available, the Backup Database option under the Study menu will not be available.
- **Study - Change Filters**

This option allows the user to change the filters that are available on the Run Study dialog and the Backup Database dialog. When changing the filters on the Run Study dialog, the user will need the feature Study - Run Study.
- **Study - Delete Study**

This option allows the user to delete studies on the Manage Studies dialog. The user will need the feature Study - Select Study to access the Manage Studies dialog.
- **Study - Modify**

This option allows the user to make modifications to the current study. If this option is not available, the Modify Study option under the Study menu will not be available.
- **Study - New Study**

This option allows the user to create a new study on the Create New Study dialog. The user must have access to the Study - Modify option to be able to complete the creation of the study.
- **Study - Overwrite Deleted Study**

This option allows the user to create a new study with the same name as a study that was previously deleted. The user must have access to Study - New Study and Study - Modify Study to be able to completely overwrite a deleted study.
- **Study - Restore Database**

This option allows the user to restore a study onto the current workstation. If this option is not available, the Restore Database option on the Study menu will not be available.
- **Study - Run Study**

This option allows the user to run studies on the Run Study dialog. If this option is not available, the Run Study option on the Study menu will not be available.

To have access to the filters that are on the Run Study dialog, the user will need the feature Study - Change Filters.

When using the ACQ7700 USB, or ACQ16 USB only the 7700 Amplifier Setup option will be available. To have access to the 7700 Amplifier Setup option, the user will need the features Setup 7700 Amplifiers and Protocol - Save.

When using DSI the options Edit DSI Setup and Select DSI Sources will be available. To have access to the Edit DSI Setup option, the user will need the features Edit DSI Setup and Protocol - Save. To have access to the Select DSI Sources option, the user will need the features Select DSI Sources and Protocol - Save.

When using JET hardware, the options 7700 Amplifier Setup and JET Device Configuration option will be available. To have access to the 7700 Amplifier Setup option, the user will need the features Setup 7700 Amplifiers and Protocol - Save. To have access to the JET Device Configuration option, the user will need the features JET Device Configuration and Protocol - Save.

The Video Configuration option from the Hardware button will only be available if the Video - Setup feature is available.

When selecting the Acquire button (or Acquire from the advanced button), the user will need access to the Acquisition - Start feature. When selecting the Sched. Acq button, the user will need access to the Scheduler - Start and Scheduler - Setup features.

To have access to the Replay button, the user will need the feature Replay - Start.

To have access to the Review button, the user will need the feature Review - Open File.

To have access to the Save PRO button, the user will need the feature Study - Save Primary Protocol.

- Study - Save Primary Protocol

This option allows the user to save the current protocol as the primary protocol. After an acquisition has been performed and attributes have changed, the Save protocol button will be available if this option has been enabled.

- Study - Select Study

This option allows the user to select a study. If this option is not available, the Select Study option on the Study menu will not be available.

To have access to the Delete Study button, the user will need the feature Study - Delete Study.

- Study - Sync Study Data

This option allows the user to synchronize study data. If this option is not available, the menu selection will not be available.

- Study - Sync Entire Study

This option allows the user to synchronize the entire study. If this option is not available, the menu selection will not be available.

- Study - Primary Workstation List

This option allows the user to edit the primary workstation list. If this option is not available, the user will not be able to make any modifications to the primary workstation dialog.

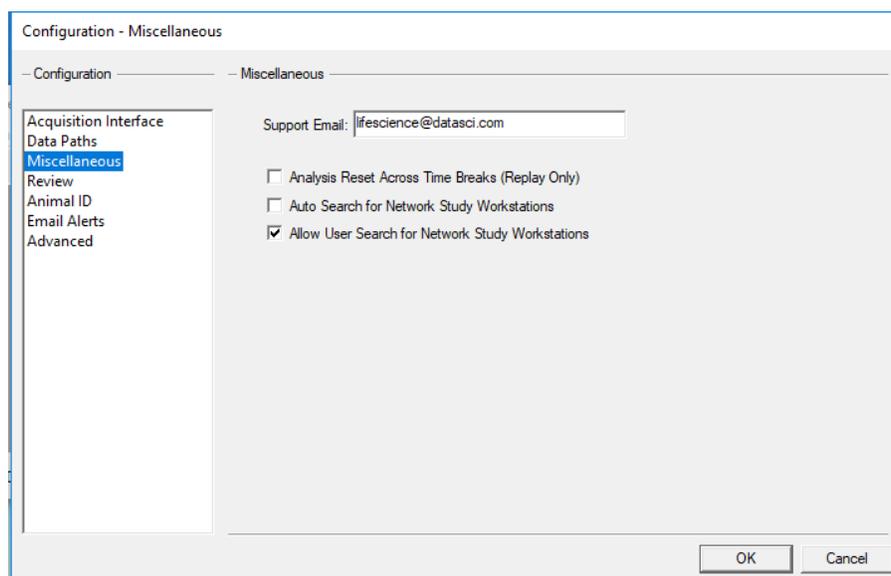
Application Configuration

Miscellaneous

From Options, select Application Configuration. The Application Configuration allows the configuration of global, or system wide, settings. Settings for the Network Options can be configured in the Miscellaneous configuration.

Three settings are available:

- Auto Search for Network Study Workstations: will automatically begin searching the network for study workstations upon opening the Ponemah program.
- Allow User Search for Network Study Workstations: allows the user to manually search for network study workstations using the Find Workstation or Workstation Search buttons located in the Study Setup menu during study configuration. Additionally, this will allow access when searching for workstations using the Edit Primary Workstation List function (this is the default setting upon loading the Ponemah software).
- Disabled: if both of the above options are not checked, the auto search capability will be disabled and the user will not have access to search for networked workstations.

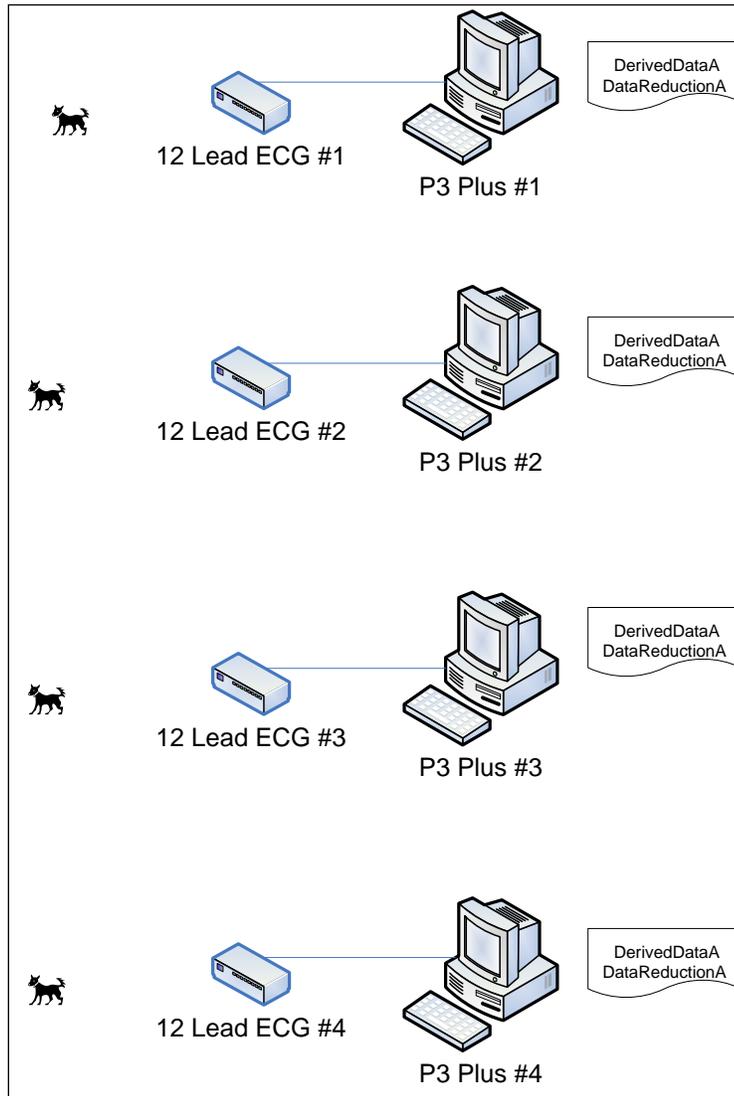


If the ability to perform a workstation search is disabled, attempting to search for a workstation will result in the following message being posted.

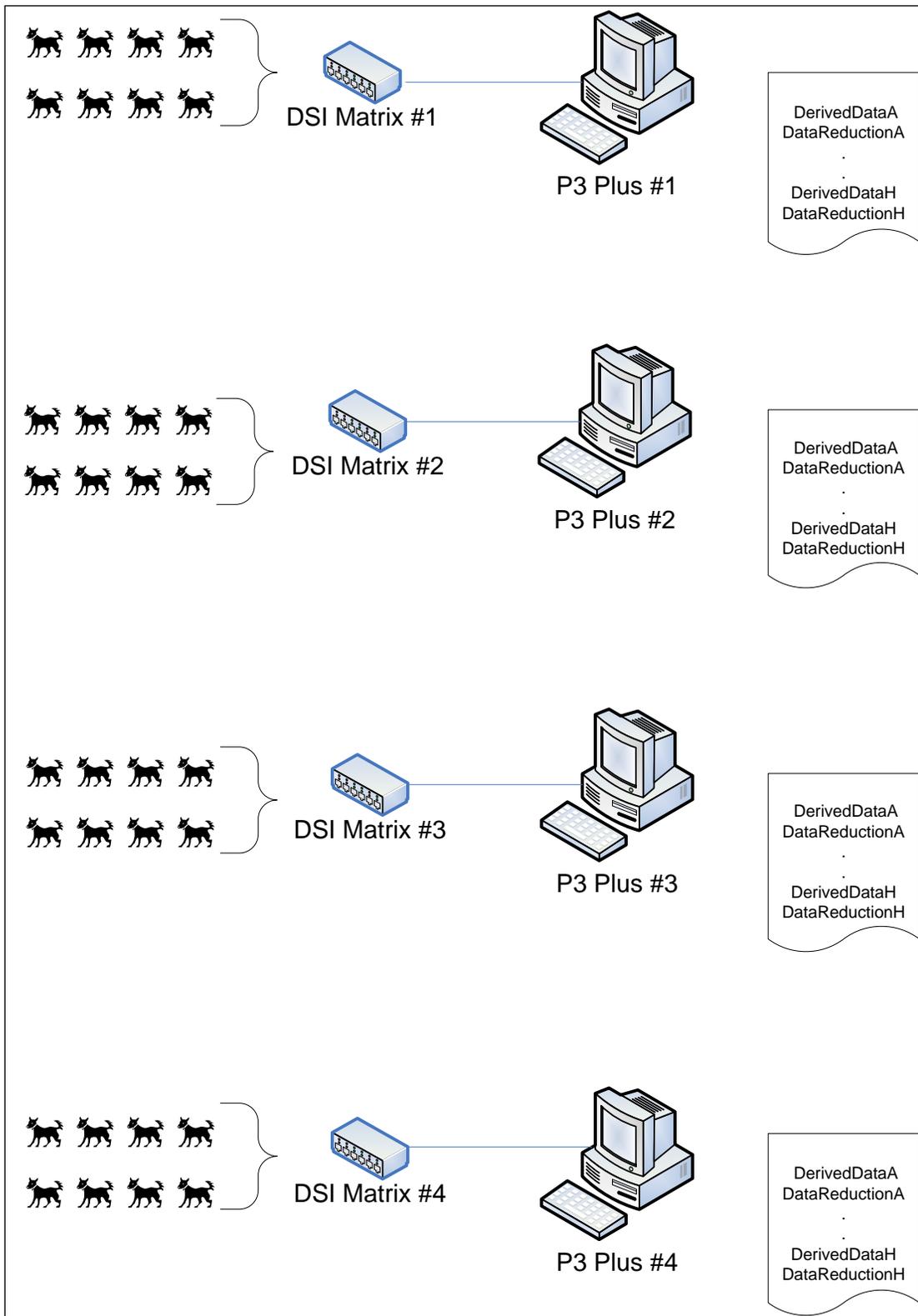


Appendix A

Typical Tox Study Diagram

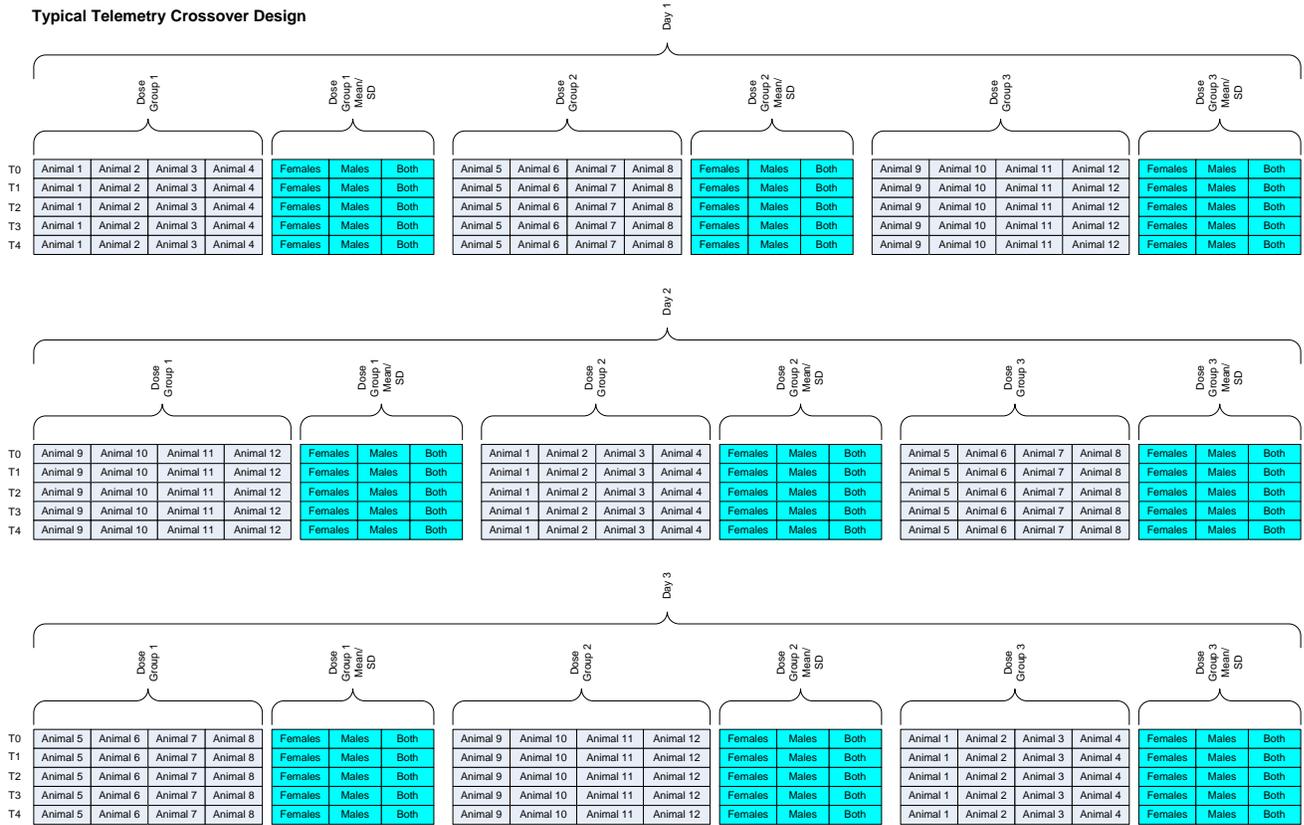


Typical Non Tox Study Diagram



Typical Crossover Design

Typical Telemetry Crossover Design



Notes:

Gray blocks are data reduction derived parameters. Examples of these parameters are MBP, HR, etc...

Cyan blocks are calculated values created by the Summary/Report application.