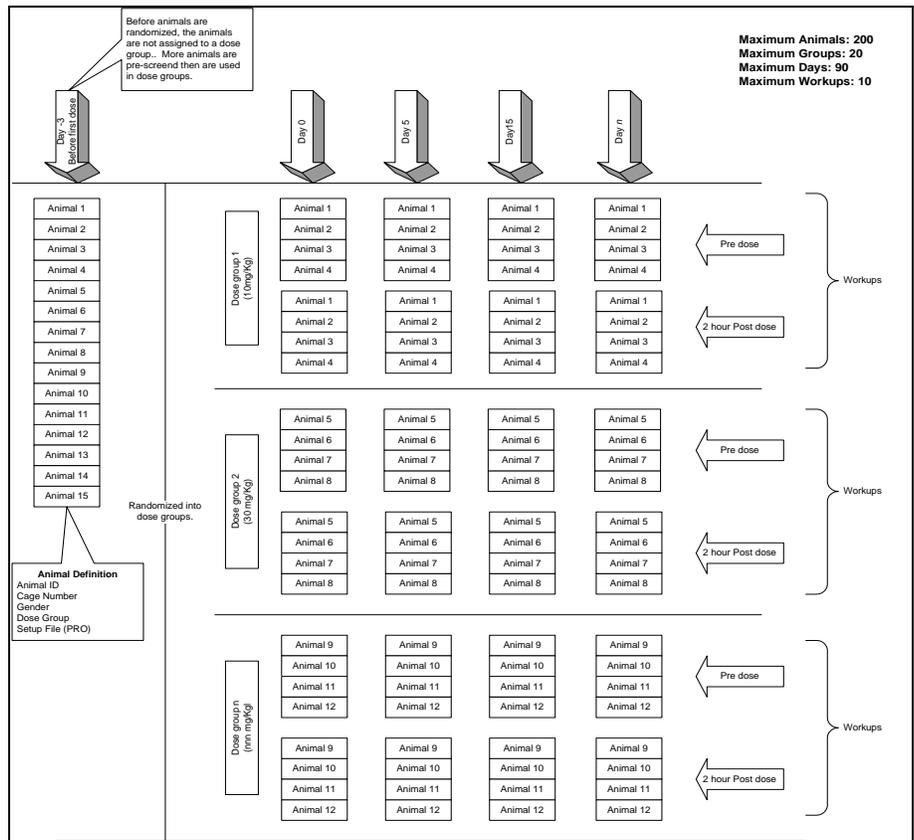


# Study Tutorial Manual

Models: PNM-P3P-005, PNM-P3P-008, PNM-P3P-016, PNM-P3P-032, PNM-P3P-064  
 Manual: MU00244-001  
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# Introduction

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## Study Characteristics

This tutorial manual runs through typical configurations of different studies. Each type of study is configured for either running on one P3 Plus workstation or multiple P3 Plus workstations. For these cases we have a tox study and a non tox study which simply serve as guidelines for configuring the studies and does not necessarily depict specific experimental designs. Below are general definitions of each type of study.

- **TOX Study** typical characteristics
  - Only one test subject at a time per analysis period is collected and analyzed. Each test subject is collected in a serial fashion. (Ex. An acute TOX ECG study).
  - Short data collections and analysis periods to get a single data point.
  - Multiple workups - allows the user to collect and analyze data for a subject, remove the subject, add the next subject, analyze data, etc. and then, for example, 2 hours later repeat the same process.
  - Once dose days start, the same test subject always gets the same dose.
- **Non-TOX Study** typical characteristics
  - Multiple test subjects can be collected and analyzed at one time.
  - Typically longer collection and analysis periods (Ex. 24 hour for a telemetry setup, OpenART or JET).
  - Once dose days start, each test subject gets each dose. Typically this would be suitable for Latin Square and Escalation studies.

# Tutorial for Tox Study

---

## Introduction

This section will run through creating a tox study. The general outline will include:

- Creation of a protocol file
- Creation of the study
- Copying the setup to multiple P3 Plus workstations (not needed when running on one P3 Plus workstation)
- Running the acquisitions
- Backing up the study data to the main P3 Plus workstation (not needed when running on one P3 Plus workstation)

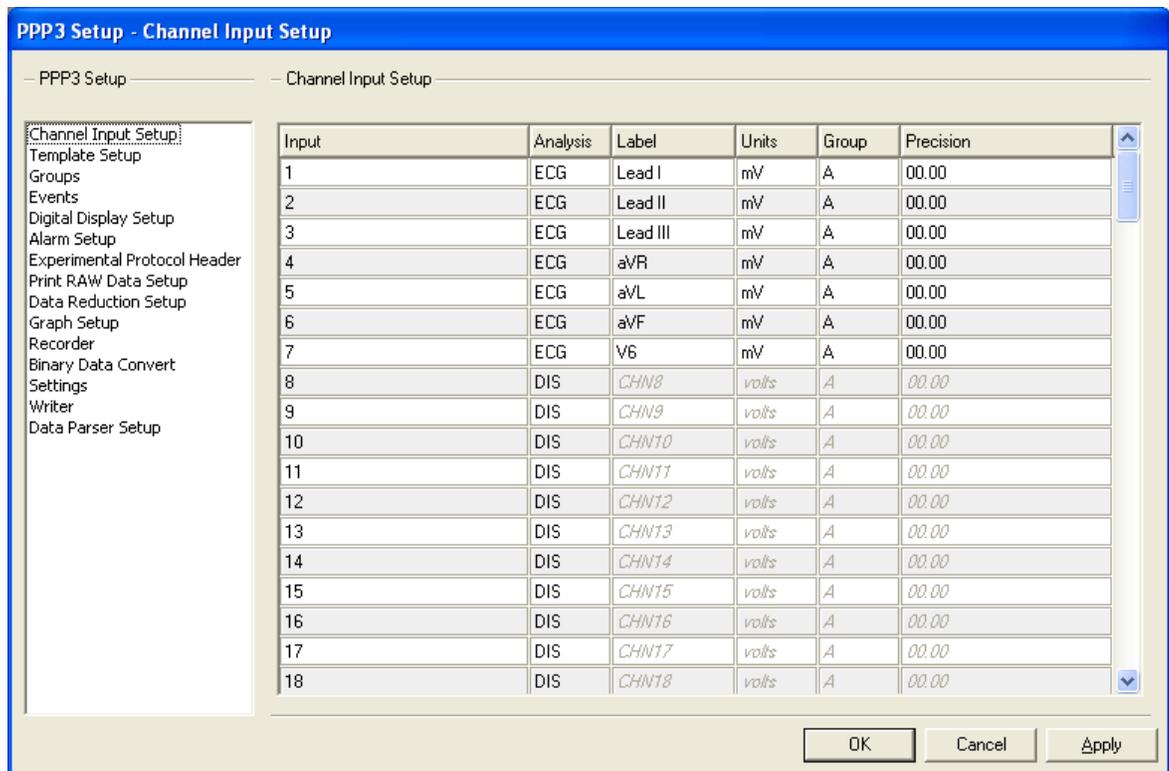
This tox based study will be configured for 45 subjects, 5 study groups, 4 days, and 2 workups per day.

---

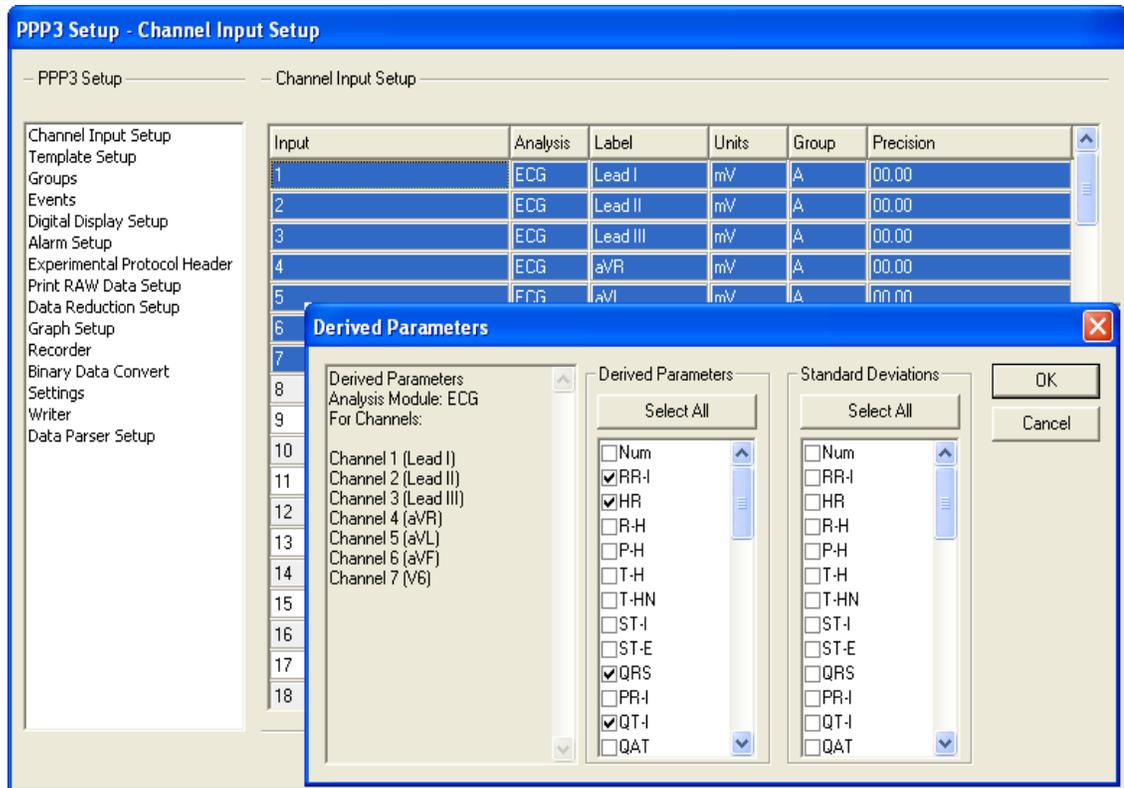
## Creation of a Protocol File

The first part of the tutorial will be to create the protocol file used. Once P3 Plus is started, open the **PPP3 Setup** dialog and select the **Channel Input Setup** configuration.

For this configuration, the user needs to set up the channels that will be used. In this case, we will be setting up a multi lead ECG configuration. Inputs 1 through 7 will be used. The following leads configured are Lead I, Lead II, Lead III, aVR, aVL, aVF, and V6. The Units for the channels being used were also modified. The results are shown below. Also, make sure that only Group A is used.



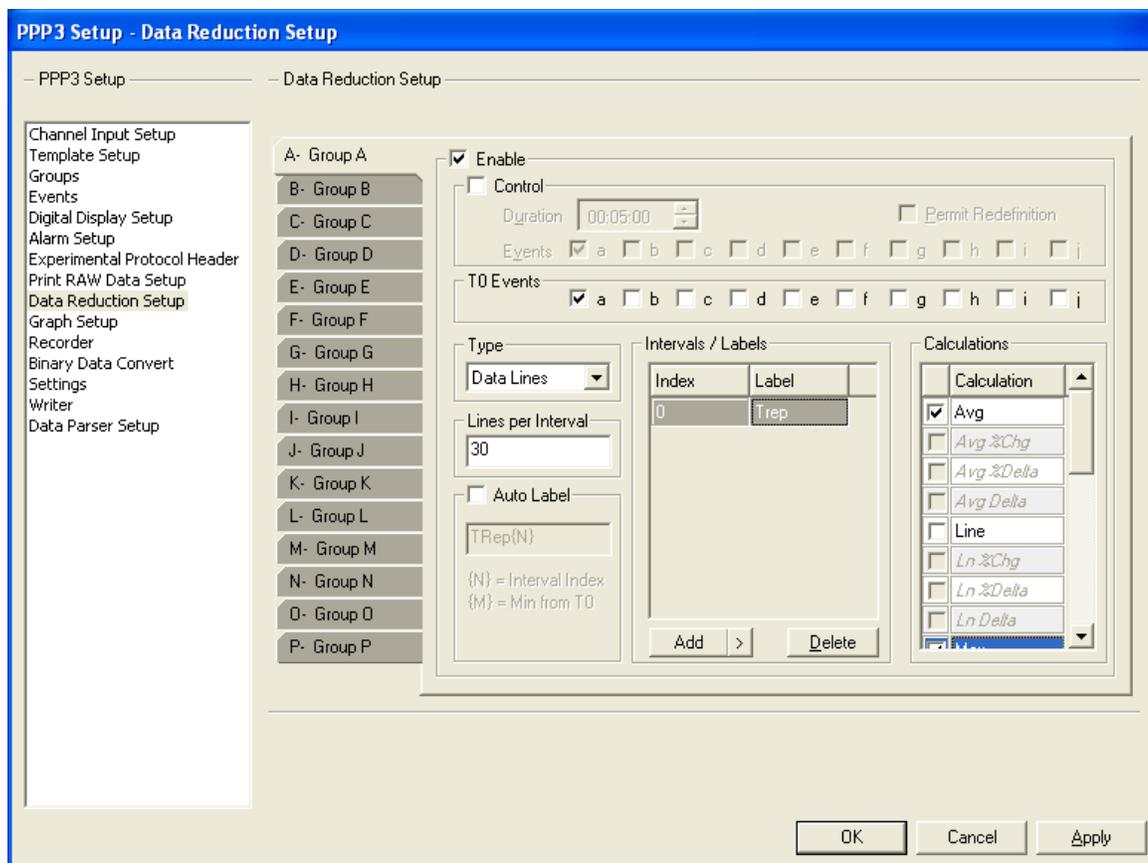
From here the derived parameters that are needed can be set up. Select every input that will be used, right click on one of the selected channels, and select **Derived Parameters**. Select the required derived parameters, as shown below.



It is recommended to set up all channels with the same derived parameters.

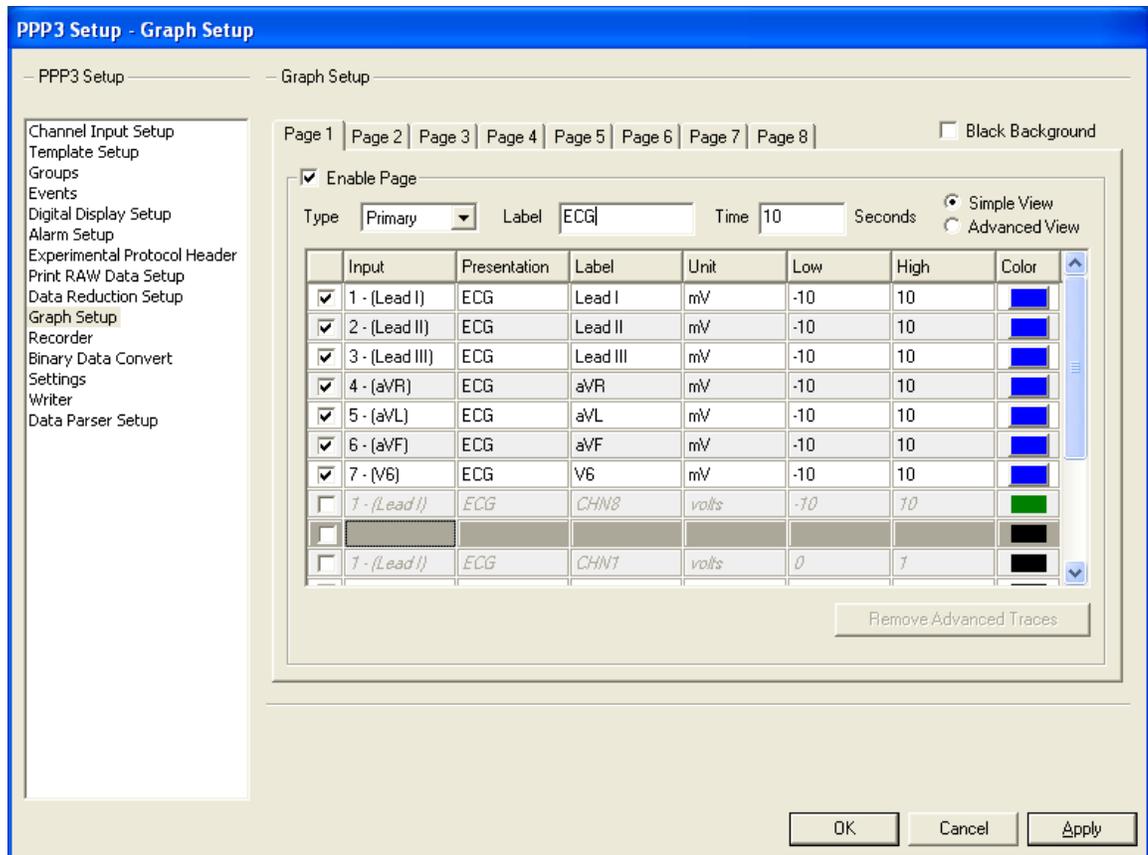
**NOTE: Once data has been collected in a Study, the Channel Input Setup and the Derived Parameters cannot be changed.**

Now the user will need to configure Data Reduction. Select the Data Reduction Setup configuration. Enable the Data Reduction Group A and set up the configuration needed. If <Alt><O> is going to be used, consult the Writer/Recorder Manual for the correct configuration. Shown below is a typical Data Reduction configuration. Only Group A needs to be modified since all of the channels being used are in Group A.

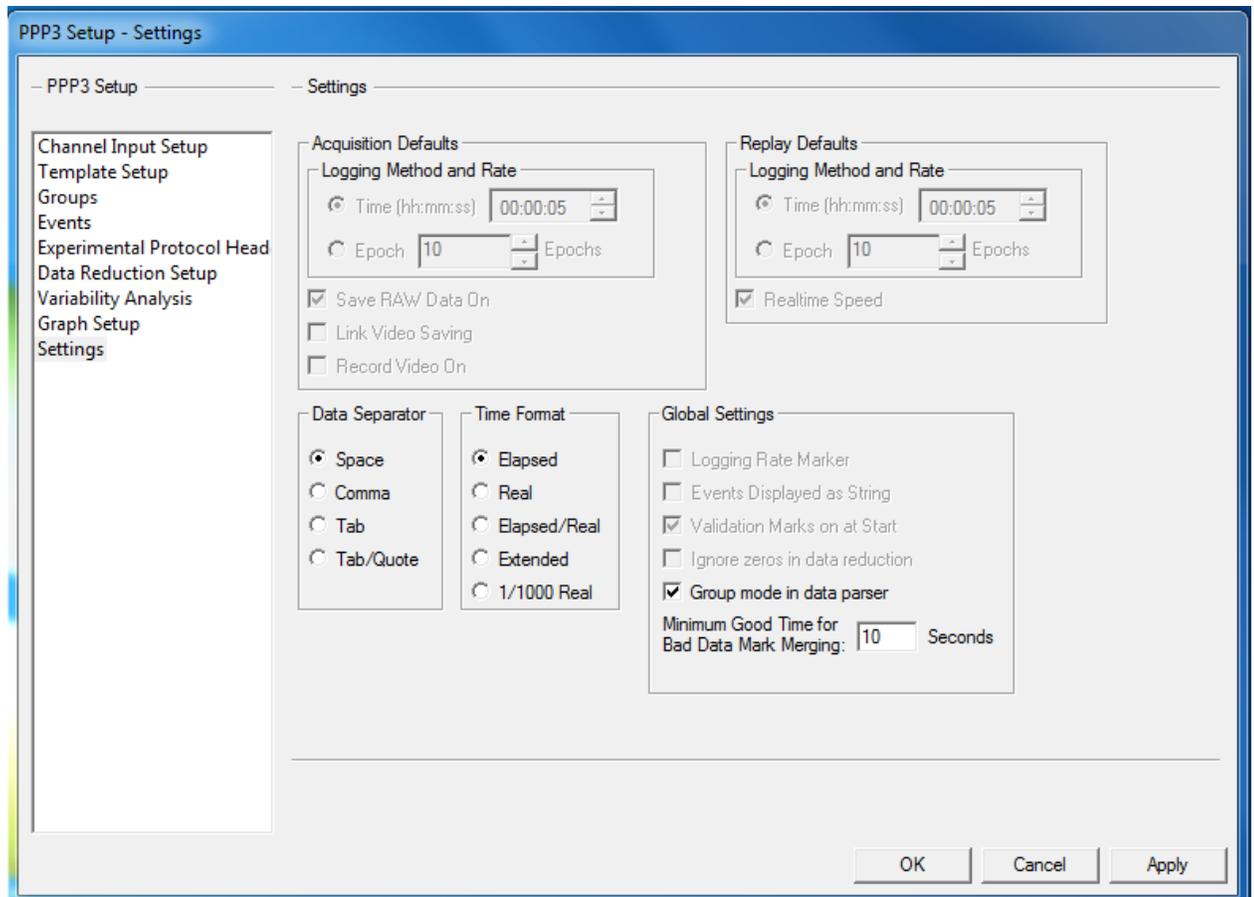


The graph pages can now be configured. Select the Graph Setup configuration.

Configure the graph page(s) as needed. Note that the labels from the inputs are not copied to the graph pages. They will need to be reentered. View the P3 Plus Manual for details on configuring graphs. Shown below is an example of a typical configuration.



Once the graphs have been configured, the basic settings can be configured, as shown below. View the P3 Plus Manual for details on configuring basic settings.



Close the **PPP3 Setup** dialog by clicking on the **OK** button.

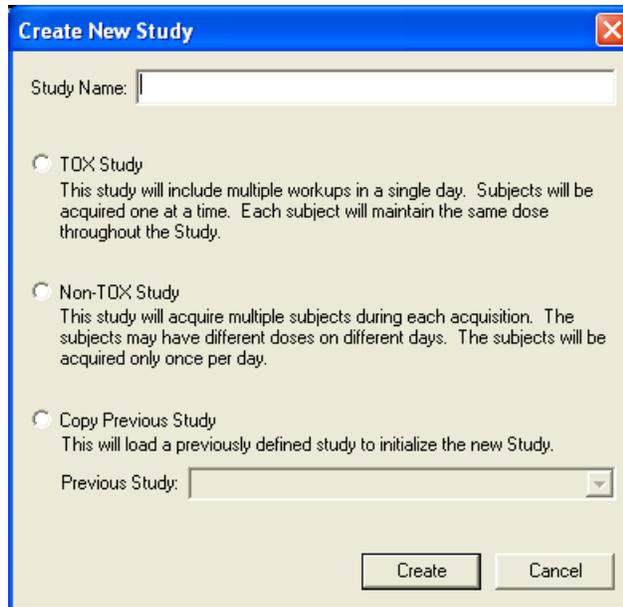
Other options, such as acquisition sample rate and the ODBC Interface can be configured now as well.

Save the protocol by selecting **Save As** from the **File** menu (the name StudyProtocol.PRO has been used for this tutorial), type in a specific name, and click on the **Save** button. The protocol has now been configured.

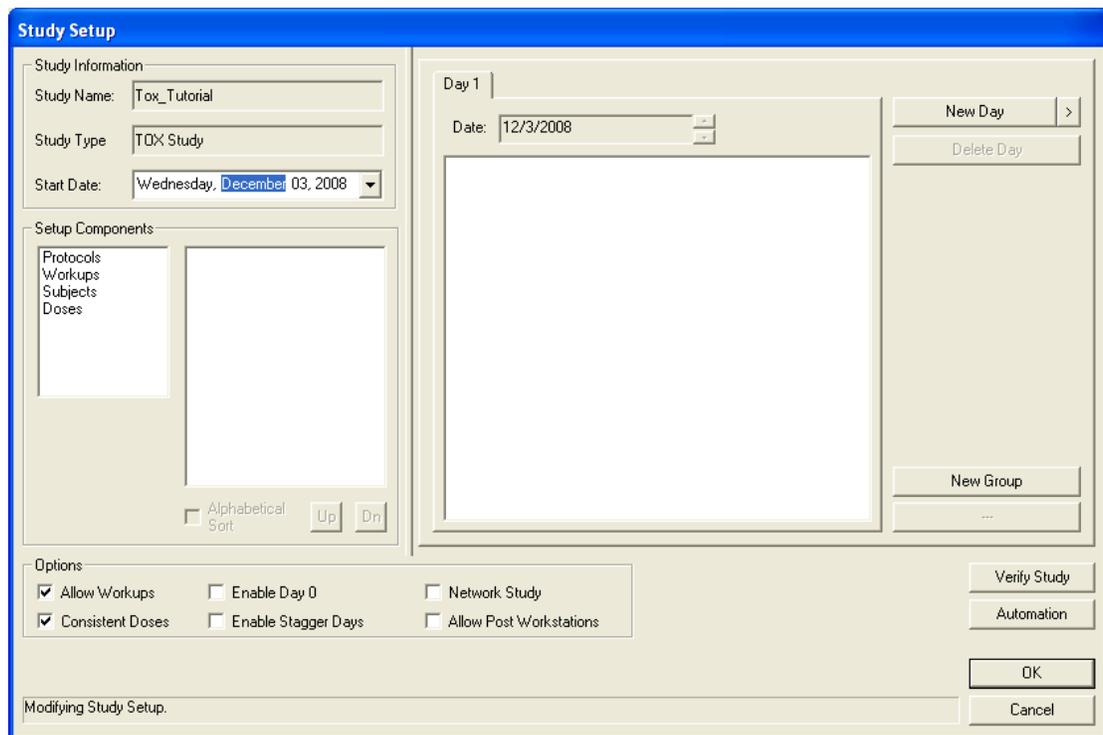
---

## Creation of the Study

The next part of the tutorial will be to create the study. Select **New Study** from the **Study** menu. The dialog below will appear.



Type in a Study Name, select **TOX Study** and click on the **Create** button. The **Study Setup** dialog will appear as shown below.



## Setup Components

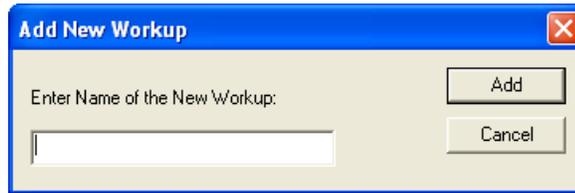
There is no specific order in which the Setup Components need to be configured. The only requirement is that the setup components are configured prior to configuring the study structure.

## Protocols

Double click on **Protocols** to open a common dialog to select the protocol(s) that will be needed. The user can also select **Protocols** from the list and click on the **Add Protocol** button. This is the case for all of the different **Setup Components**. For the tutorial, the protocol StudyProtocol.PRO will be selected. When configuring the in-house study, select all of the protocol files that will be used. If different animals require specific attributes, multiple protocol files will need to be used. Select the protocol and click on the **Open** button.

## Workups

The Workups can now be configured. Double click on **Workups** in the **Setup Components** section and the dialog below will appear.

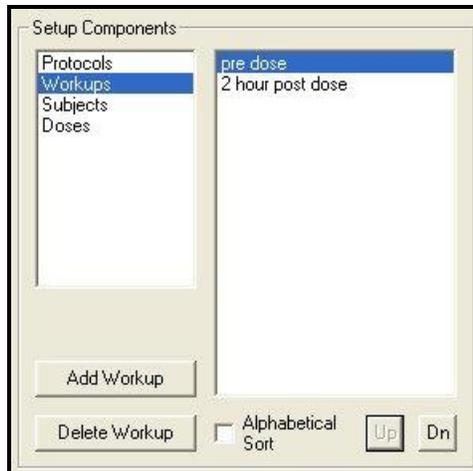


Type in one of the workups to be used and click on the **Add** button. In this case we will configure a pre dose and a 2 hour post dose workup. When the first workup is entered and the **Add** button is selected, the **Add New Workup** dialog will reappear. This is the case for all of the **Setup Components** except for Protocols.

If the user views the list of workups that were added, it can be seen that the workups are out of chronological order. Later, when DSI Reporting is used (view the DSI Reporting Manual), the order that the Study is saved will be the order that DSI Reporting will report data. The sort option initially lists data in alphabetical order.



To change this, disable the **Alphabetical Sort** check box. Once that is done, select the workup **pre dose** and click on the **Up** button located next to the **Alphabetical Sort** check box. This will move the selected workup. The workups should now be configured like the picture below.



## Subjects

The subjects can now be entered into the study. Double click on the **Subjects** setup component. The dialog shown below will appear.

Enter the name of the subject, any subject information, cage ID, weight of the subject, and the subjects gender. Repeat this for all of the subjects in the study. The Cage ID and Gender are used as filters on the **Run Study** and **Backup** dialogs. The Subject Info and Weight are used for documentation only.

If the user is using the 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.

**NOTE: Once the Study has data, the Subject ID cannot be changed.**

## Doses

The doses can now be entered into the study. Double click on the **Doses** setup component. The dialog shown below will appear.

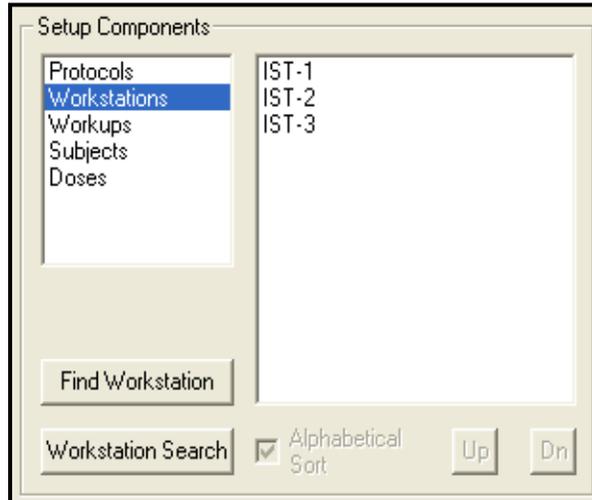
Enter a dose and click on the **Add** button. Repeat this for the other doses. In this the doses configured will be Control, 5mg/kg, 10mg/kg, 20mg/kg, and 35mg/kg.

### **Workstations (not needed when running on one P3 Plus workstation)**

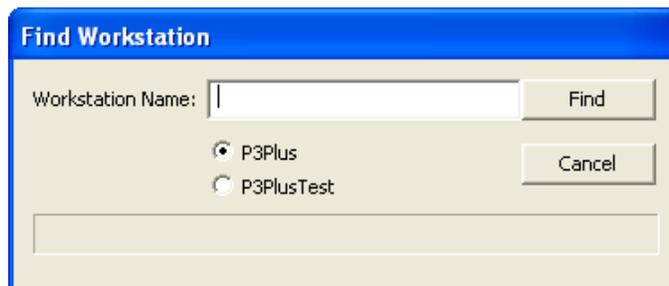
Since this study will be run on multiple P3 Plus workstations, select the **Network Study** check box in the **Options** section at the bottom of the **Study Setup** dialog, shown below.



Once the **Network Study** option is enabled, the **Workstations** setup component will become visible. See below.



By default P3 Plus searches for all available workstations connected to the network that have the same P3 Plus version. When the **Workstations** option is selected, a list of these workstations will appear. See the Study Manual for the specifics on workstation configuration. To search for a workstation that is currently not listed or one that has just been turned on, click on the **Find Workstation** button. A dialog like the one below will appear.

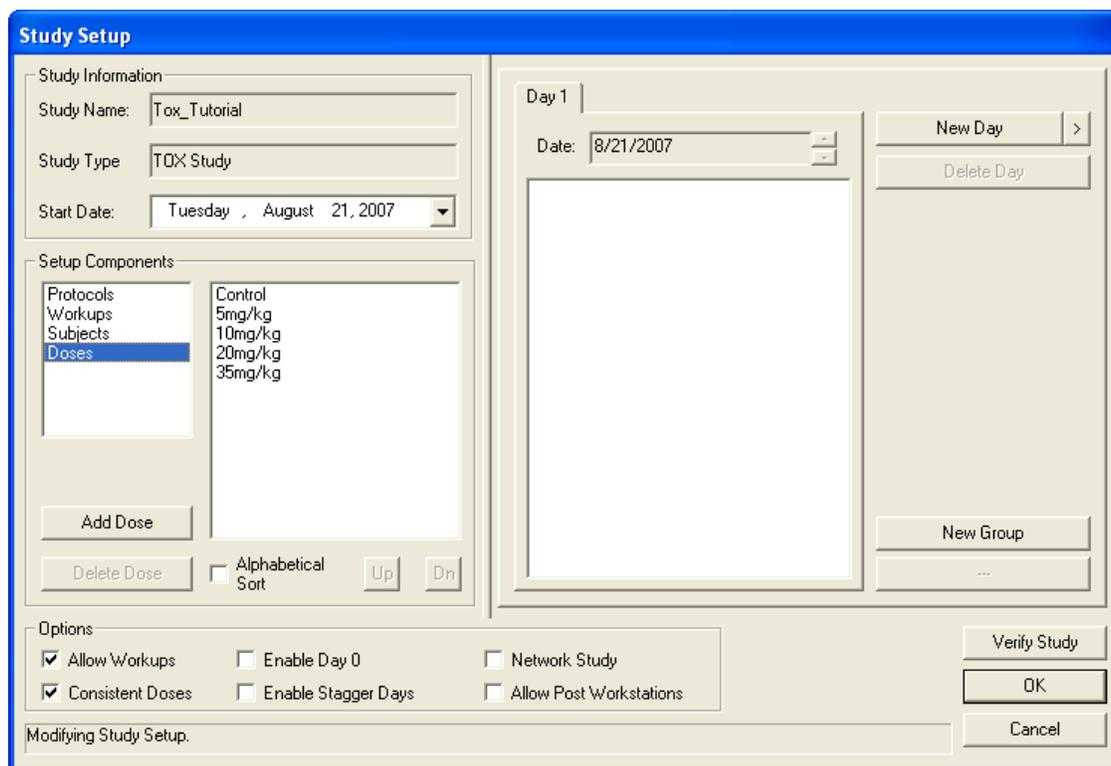


Enter the name of the workstation and select the instance of the database being used and click the Find button.

If the workstations are enabled, the filter selection **Workstation**, located on the **Run Study** dialog can be used. The filter selections are covered in the **Running the Acquisitions** section on Page 19.

## Study Structure

After all of the study components have been added, the study structure can be configured. This is done in the right hand section of the **Study Setup** dialog.

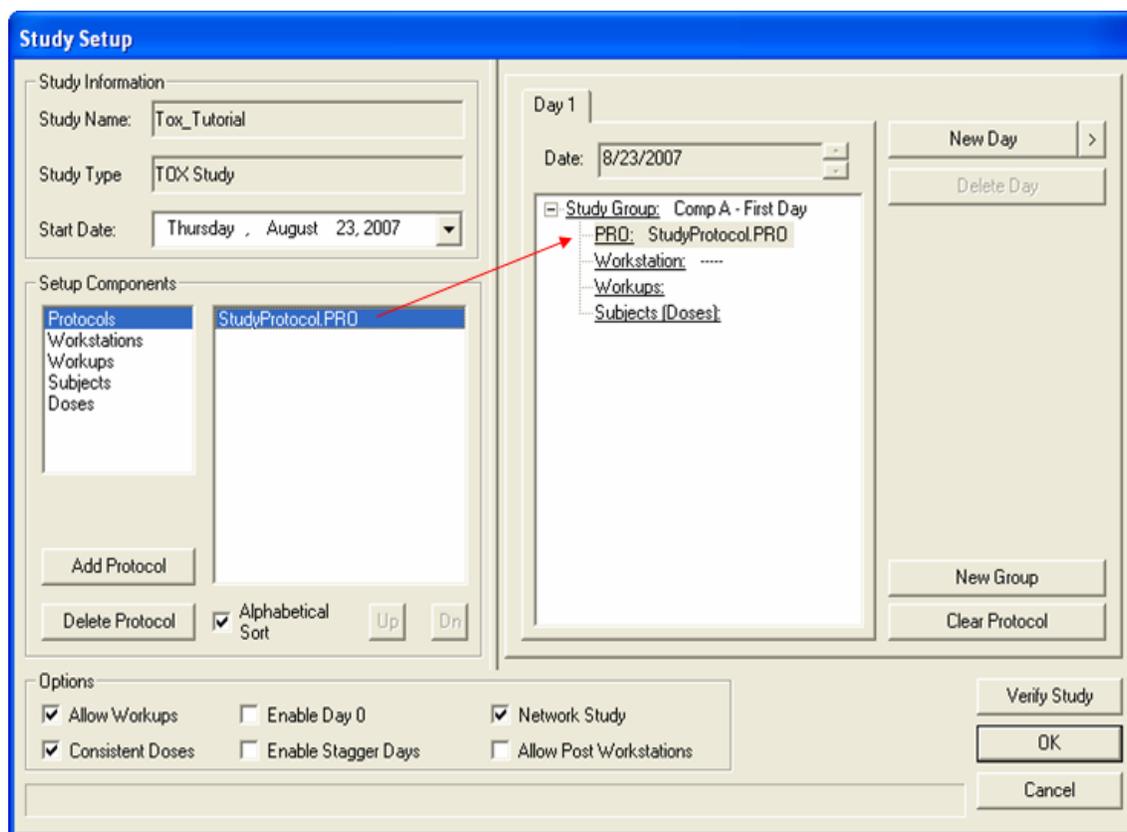


The first item to take care of is to set up the groups that will be used. This is done by clicking on the **New Group** button. In this case, five groups need to be added. Groups can be configured for multiple reasons. In this case multiple P3 Plus workstations are being used, and to show which subjects are associated with which P3 Plus workstation, multiple groups are used. Also, since Stagger Days will be used, multiple groups for each P3 Plus workstation will be used. Other reasons that multiple groups may be used would include the use of multiple protocols.

When a new group is added the user has the capability of modifying the name of the study group. Since this study is using multiple computers and stagger days, the study group name will be entered to identify this information. The modification of the study group name can be done at any time prior to running an acquisition. The user can change the study group name later by left clicking on the study group name.

**NOTE: The Study Group Name should only be configured up to 20 characters.**

After the groups are added, the setup components can be added to the study structure. This is done by clicking and dragging the items from the setup components to the study structure.

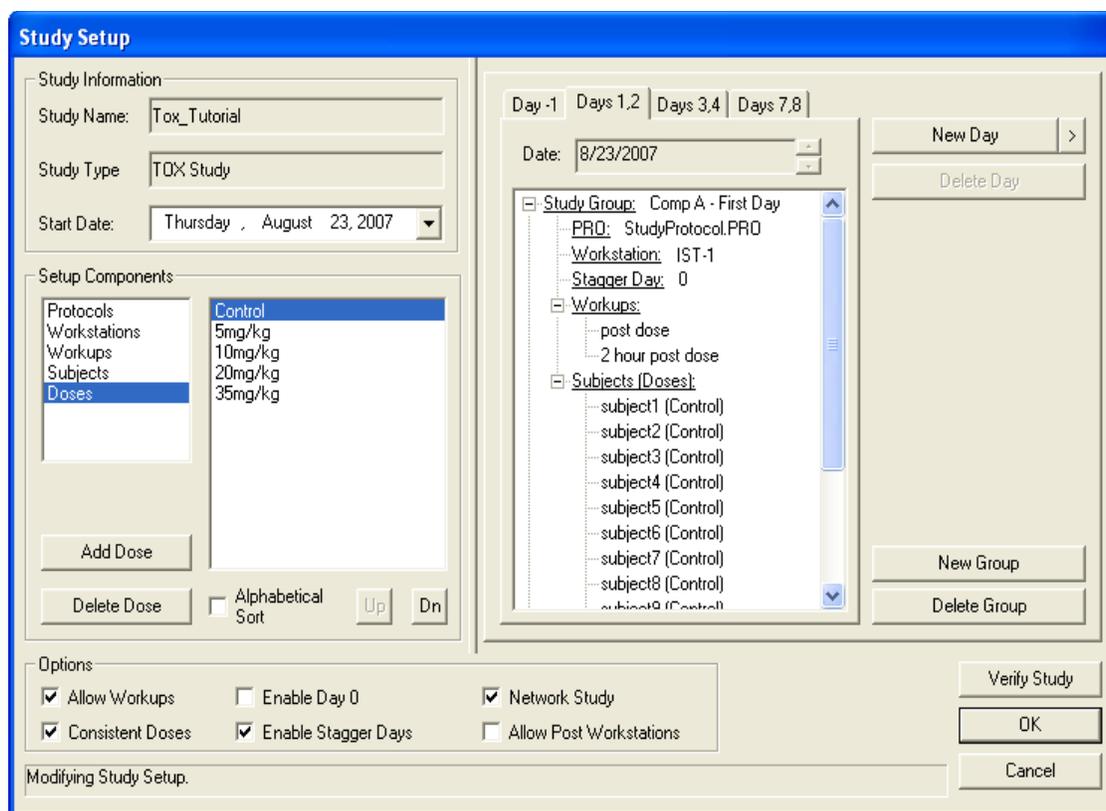


In the above screen capture the protocol **StudyProtocol.PRO** has been dragged and dropped from the Setup Components to the study structure. For each Study Group configured, only one protocol can be added. This is also true for Workstations, if workstations are used.

If the component can be added to the study structure, the cursor will change to either a pointer with a curved arrow or a pointer with a plus sign. If the component cannot be added to the study structure, the mouse will change to a **NO** sign.

Repeat the above process for each of the Setup Components that need to be added. Multiple workups and subject/dose combinations can be added.

Below is a screen capture of a basic setup showing study groups configured. The Workstation component will not be listed when running on one P3 Plus workstation.



If Stagger Days are required, the **Enable Stagger Days** check box can be checked (enabled). This will allow the user to acquire data across multiple days but keep the structure of the study simple. In this tutorial it will be needed. The Stagger Days are used so that multiple study groups can be configured to look as if they need to be run on the same day but time constraints do not allow the acquisitions to be performed on that day.

After the **Enable Stagger Days** check box is enabled, another option within each group appears, coming up as **Stagger Day**. For the groups in question that need to be modified, select **Stagger Day**, and then click on the + key to increase the day that needs to be used. In this case the second and fourth groups will have a **Stagger Day** of **1**. When stagger days have been configured, the day listed at top will change to indicate all of the days that are configured.

**NOTE:** Even though the Days tab has a 1 and 2 displayed, the data collected on Day 2 will still have a dose day of 1. This just allows the staggering of the Study Groups.

Below is a screen capture of how the tab will look.



Each study group has 9 subjects configured. The user can configure study groups in any way that they need.

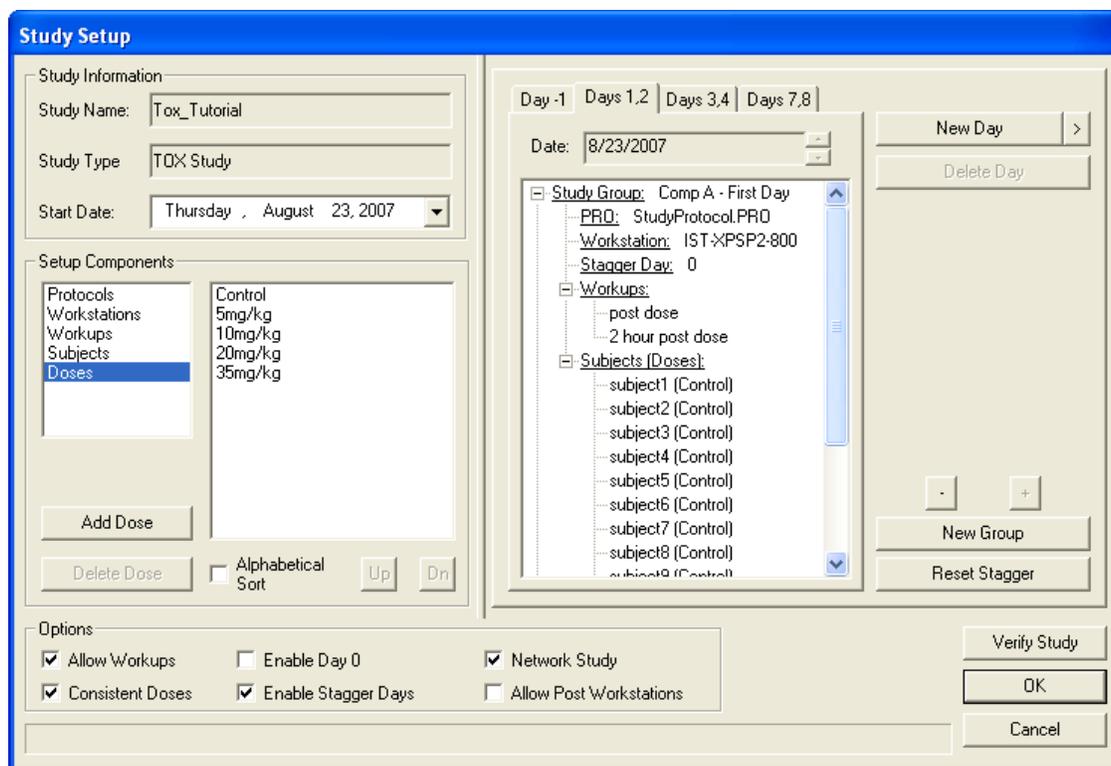
After the study group information is configured, the days can be configured. Since the days that are configured for this tutorial include a Day 1, the **Enable Day 0** option should be deselected. The **Enable Day 0** option only changes how the first post dose day is shown. It does not affect anything within the study. The days that will be configured for this tutorial are -3, 1, 3, and 7.

To add a new day, click on the **New Day** button. This will add a new day one day after the currently selected day. If the **New Day** button is selected in the case above, **Days 3, 4** will be added. When the new post dose day is added, all of the study group information will be copied. If Days 3, 4 are not the days that needs to be configured, the up and down arrows next to the Date can be selected to change the date of that day. See the Study Manual for other options in changing the day used.

Repeat the above process for all of the days needed. When the pre dose days are added, no study group information is added. This allows the user to configure any type of pre dose day configuration that is needed. Also, since it is a pre dose day, doses cannot be added to the subjects.

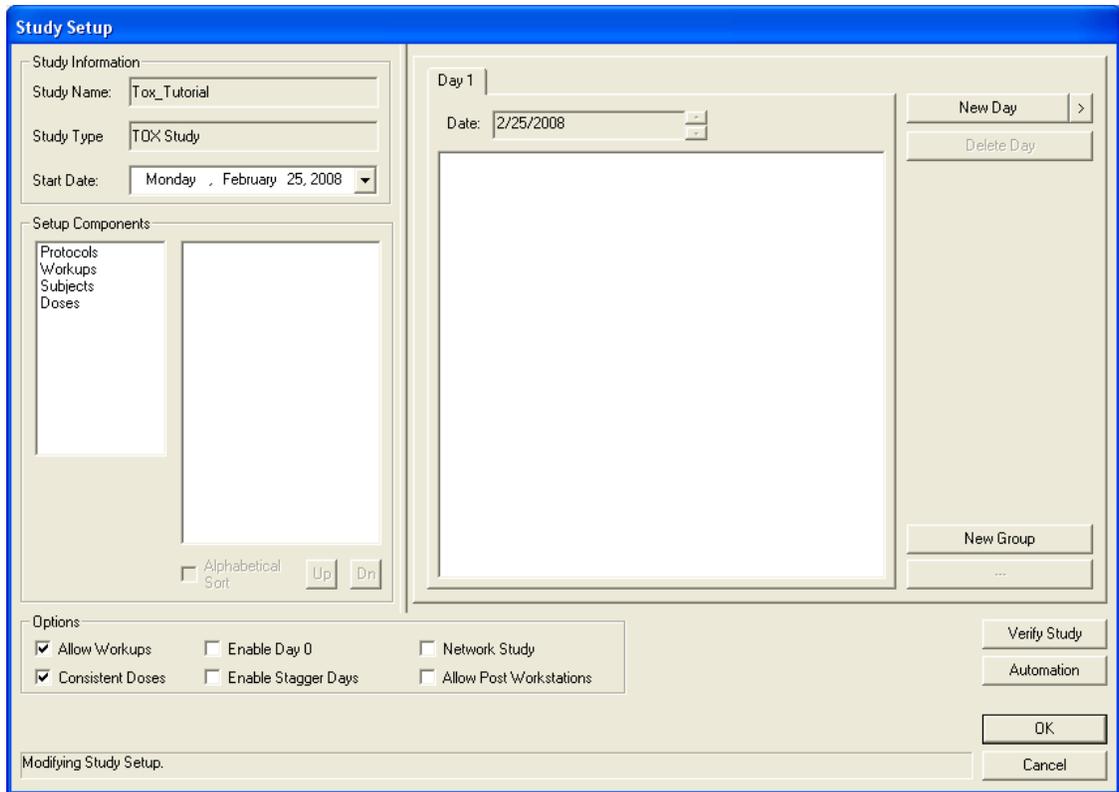
If the same configuration that is used for post dose days will be used for pre dose days, the user can add a new post dose day, and then change the date with the down arrow button to the correct pre dose day required.

The screen capture below shows the completed study.

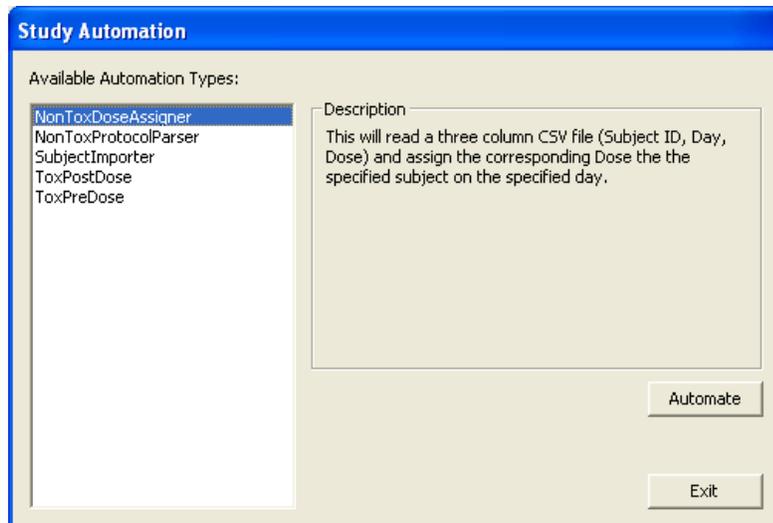


## Study Automation

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. This feature can be accessed by clicking on the Automation button.



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 for the Tox Study:

- 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
- 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.

## Study Automation: CSV File Format

The tables below outline example formats for the CSV files generated by the third party software which will be used by the Study Automation feature.

### ToxPredose.csv

```
Subject001, M
Subject002, M
Subject003, M
Subject004, M
Subject005, M
Subject006, F
Subject007, F
Subject008, F
Subject009, F
Subject010, F
```

### ToxPostdose.csv

```
Subject001, NUM147, Dose_A
Subject002, NUM148, Dose_B
Subject003, NUM149, Dose_C
Subject004, NUM150, Dose_D
Subject005, NUM151, Dose_E
Subject006, NUM152, Dose_A
Subject007, NUM153, Dose_B
Subject008, NUM154, Dose_C
Subject009, NUM155, Dose_D
Subject010, NUM156, Dose_E
```

### SubjectImporter.csv

```
Dog1, 11111, Cage1, 56, M
Dog2, 22222, Cage2, 53, M
Dog3, 33333, Cage3, 59, M
Dog4, 44444, Cage4, 63, M
Dog5, 55555, Cage5, 51, F
```

Dog6, 66666, Cage6, 58, F

Dog7, 77777, Cage7, 52, F

Dog8, 88888, Cage8, 59, F

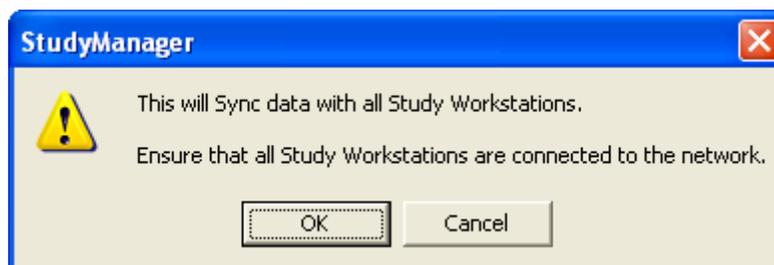
**Note:** The Study Automation scripts expect a very simple CSV format. Double quotes will be automatically stripped from any of the values. Any leading or trailing spaces will be removed. Any comma, whether contained within quotes or not, will be considered to be a delimiter, so including commas within the values will result in unexpected behavior.

---

## Synchronizing the Study to Multiple P3 Plus Workstations (not needed when running on one P3 Plus Workstation)

The next part of the tutorial will be to transfer the study information to the other P3 Plus workstations that will be running the acquisitions. In this tutorial the primary P3 Plus workstation will be used to acquire data as well. Since this study can be run on multiple P3 Plus workstations, the user may want to save the backup file up on the network where the other P3 Plus workstations have access. If this is not the case, the file will need to be copied onto removable media and either transported to the other P3 Plus workstations or synchronized using network study features.

To synchronize the study information, select **Synchronize Study Data** from the **Study** menu. The dialog below appears.



Click on the OK button to synchronize the study information.

**NOTE:** If utilizing the Network Study features, please refer to the Study Protocol Option (MU00162) manual for setup and transfer of information specific to this feature. The specific sections are Network Options and Study Database Utilities.

backup the study information, select **Backup Study** from the **Study** menu. The dialog below appears.

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 ODBC files).

# Running the Acquisitions

The next part of the tutorial will be to run the study acquisitions. This is done by selecting **Run Study** from the **Study** menu. The dialog shown below will appear.

**Run Study: ToxTest\_123**

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 | Subject Info | Date  | Dose    | Workup   | Acq | Rep | Rvw |
|---------|--------------|-------|---------|----------|-----|-----|-----|
| 1       | SDY_300-1    | Day 1 | 0mg/kg  | Predose  | 0   | 0   | 0   |
| 1       | SDY_300-1    | Day 1 | 0mg/kg  | Postdose | 0   | 0   | 0   |
| 2       | SDY_300-2    | Day 1 | 20mg/kg | Predose  | 0   | 0   | 0   |
| 2       | SDY_300-2    | Day 1 | 20mg/kg | Postdose | 0   | 0   | 0   |
| 3       | SDY_300-3    | Day 1 | 40mg/kg | Predose  | 0   | 0   | 0   |
| 3       | SDY_300-3    | Day 1 | 40mg/kg | Postdose | 0   | 0   | 0   |
| 4       | SDY_300-4    | Day 1 | 0mg/kg  | Predose  | 0   | 0   | 0   |
| 4       | SDY_300-4    | Day 1 | 0mg/kg  | Postdose | 0   | 0   | 0   |

Hardware > Acquire > Load Ext Data

Previous Runs

| Run ID | Type | Date - Time | User | Note | Report |
|--------|------|-------------|------|------|--------|
|--------|------|-------------|------|------|--------|

Replay Review

Status: No Run Performed. Save PRO

If running on multiple workstations, each P3 Plus workstation that is running acquisitions can narrow down the study acquisitions by selecting the appropriate P3 Plus workstation from the **Workstation** filter. This allows the user to only list the study acquisitions for the P3 Plus workstation being used. The options available from the **Workstation** filter are **All** and **This Workstation**. Study will automatically compare the current P3 Plus workstations name to the study acquisitions that need to be run on that P3 Plus workstation.

Dependent on the hardware being used, a calibration may need to be performed prior to the acquisition starting. To accomplish this, select the study acquisition to be performed, select the **Hardware** button and select the appropriate option button.

After the calibration has been completed, the study acquisition can be acquired. This is done by selecting the **Acquire** button. If a scheduled acquisition is to be performed, select the advanced acquisition button next to the **Acquire** button. This is the right arrow next to the **Acquire** button. From here a menu appears with the selections **Acquire** and **Sched. Acq**.

If the scheduled acquisition is selected, the **Scheduler Setup** dialog appears so that modifications can be made to account for the difference between the initial setup of the protocol to the time that the scheduled acquisition is performed.

Repeat the above process for all of the study acquisitions that need to be performed on each of the P3 Plus workstations.

## Reviewing Data from

A review is performed from the Run Study menu by clicking on a previously acquired acquisition in the Previous Runs panel.

As Reviews are performed and Marks sections saved, these newly created Runs will be listed in the Previous Runs panel.

| Subject | Subject Info | Date  | Dose    | Workup   | Acq | Rep | Rvw |
|---------|--------------|-------|---------|----------|-----|-----|-----|
| 1       |              | Day 1 | 0mg/kg  | Predose  | 5   | 0   | 0   |
| 1       |              | Day 1 | 0mg/kg  | Postdose | 0   | 0   | 0   |
| 2       |              | Day 1 | 20mg/kg | Predose  | 3   | 0   | 0   |
| 2       |              | Day 1 | 20mg/kg | Postdose | 0   | 0   | 0   |
| 3       |              | Day 1 | 40mg/kg | Predose  | 0   | 0   | 0   |
| 3       |              | Day 1 | 40mg/kg | Postdose | 0   | 0   | 0   |
| 4       |              | Day 1 | 0mg/kg  | Predose  | 1   | 0   | 0   |
| 4       |              | Day 1 | 0mg/kg  | Postdose | 0   | 0   | 0   |

| Run ID   | Type | Date - Time           | User | Note                 | Report   |
|----------|------|-----------------------|------|----------------------|----------|
| 80510002 | Acq  | 9/27/2007 9:57:44 AM  | mjub | .....                |          |
| 80510003 | Acq  | 10/11/2007 3:22:12 PM | mjub | .....                |          |
| 80510004 | Acq  | 10/11/2007 3:22:30 PM | mjub | Semifinal review     |          |
| 80510005 | Acq  | 10/11/2007 3:22:54 PM | mjub | Day 1 and 7 reviewed |          |
| 80510006 | Acq  | 10/11/2007 3:23:05 PM | mjub | Final Review         | Selected |

Notes may be added to Runs in the Previous Runs panel by right clicking the mouse on the desired run. A selection for Modify Note appears. Selecting this function will provide the following dialog and allow a note to be entered or modified at any time.

Note for Run: 80510006

Final Review

OK Cancel

This is useful to annotate various runs to track changes between them. The default name for a Note will be the last saved Marks Section name. Additionally, using the right mouse click will provide the option to select the report run (this will be used to mark data for the DSI Reporting Option).

---

## 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.

---

## Checklist for Configuring Tox Study

- Create Protocol
  - Enable the appropriate number of channels under Channel Input Setup
  - Select the same derived parameters for all channels
  - Enable and configure Data Reduction information under Data Reduction Setup
  - Enable appropriate number of traces and presentations under Graph Setup
  - Configure Study Specific parameters under Settings
  - Save Protocol
- Create Study
  - Select New Study from Study menu, enter name and select appropriate type of study
  - Configure Protocols, Workups, Subjects, Doses, and Workstations under Setup Components (Sort components - used for DSI Reporting )
  - Configure Study Groups and Study Days (pre and post days)
  - Drag and drop Setup Components to Study Structure
  - Configure Options like Enable Day 0 and Stagger days if needed
- Synchronize the Study to Multiple P3 Plus workstations (not needed when running on one workstation)
- Select Synchronize Study Run Acquisitions
  - Select Run Study from Study menu
  - Select appropriate filters (such as Workstation and Day)
  - Select appropriate study acquisition, calibrate, and acquire data
- Synchronize Study to all P3 Plus workstation (not needed when running on one P3 Plus workstation)
- A back up of the database should be performed on the completed study only. It is not recommended for studies involving multiple acquisition PCs.

# Tutorial for Non Tox Study

---

## Introduction

This section will run through creating a non tox study. The general outline will include:

- Creation of a protocol file
- Creation of the study
- Synchronizing the setup to multiple P3 Plus workstations (not needed when running on one P3 Plus workstation)
- Running the acquisitions
- Synchronizing the entire study data to all P3 Plus workstation (not needed when running on one P3 Plus workstation)

This non tox study will be configured for 16 subjects, 2 study groups, and 3 days. Each study group will have 8 subjects.

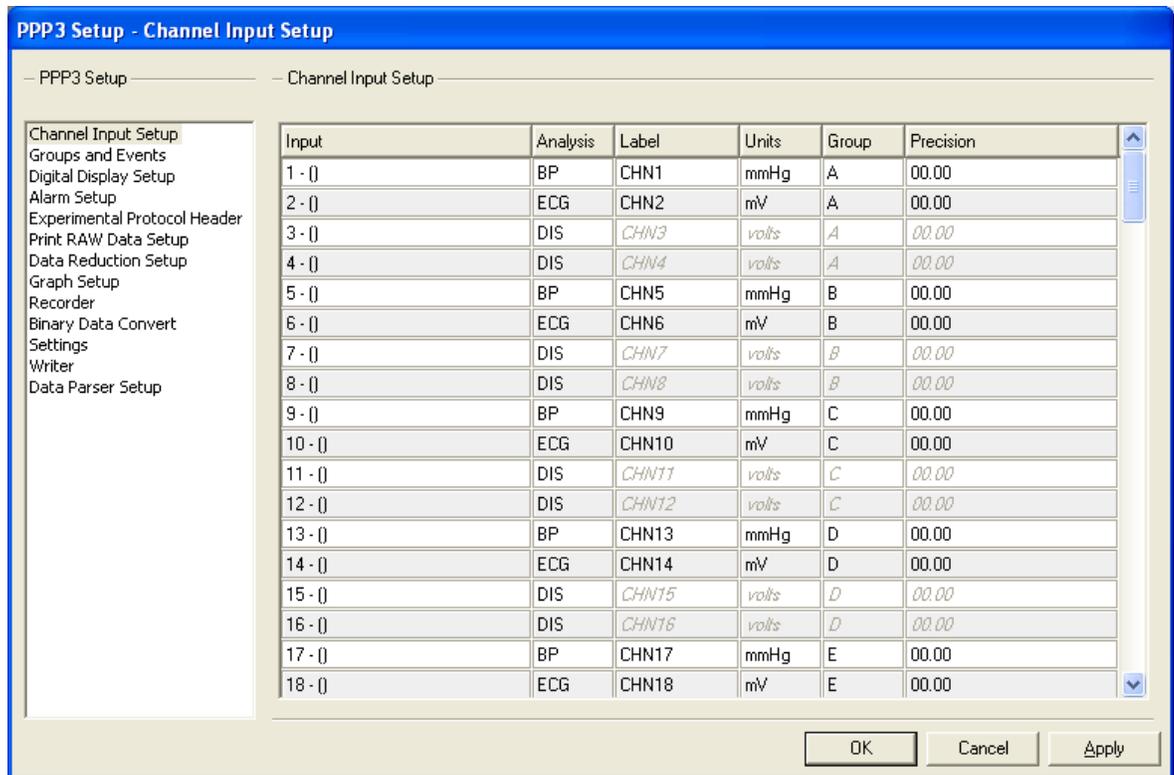
---

## Creation of a Protocol File

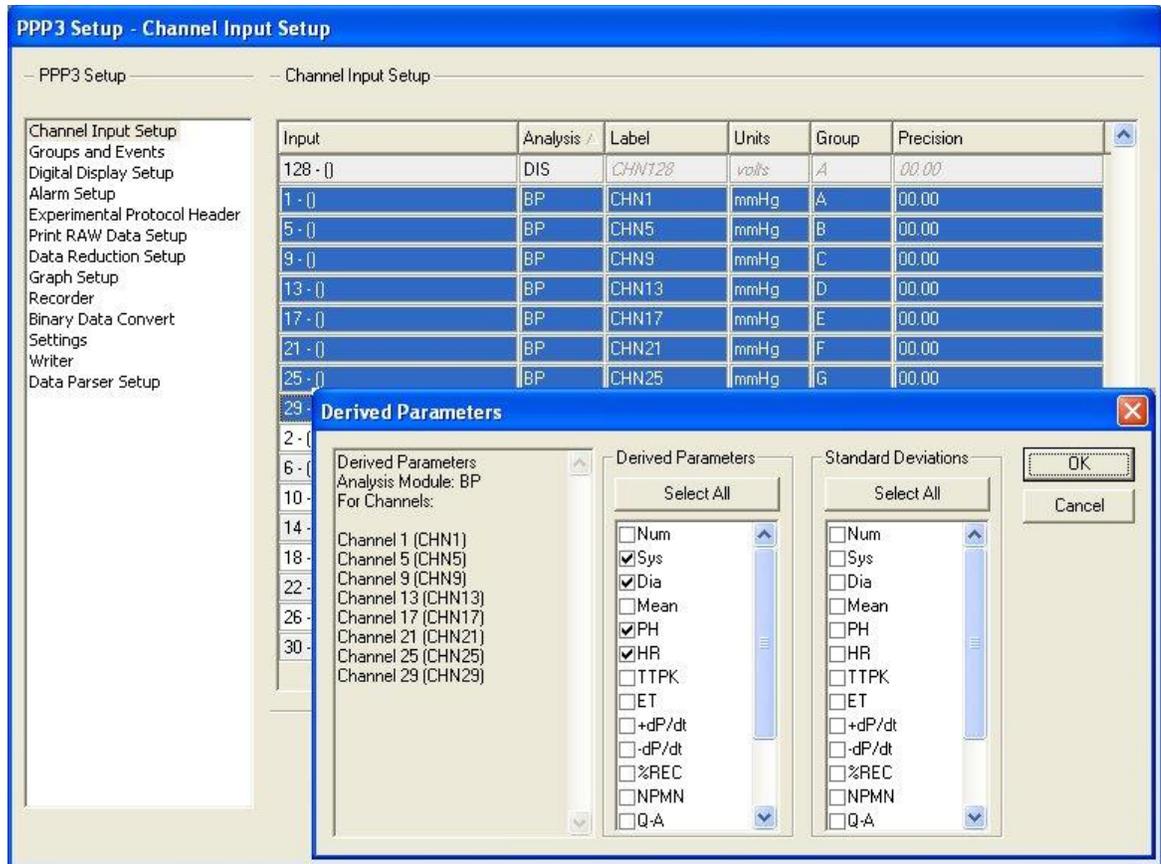
The first part of the tutorial will be to create the protocol file used. Once P3 Plus is started, open the **PPP3 Setup** dialog and select the **Channel Input Setup** configuration.

For this configuration, the user needs to set up the channels that will be used. In this case, one BP channel and one ECG channel per subject will be set up. Groups A through H will be used.

**NOTE: When using BP with OpenART, Digital, or JET an Ambient Pressure Reference (APR-1) is used to obtain gauge pressure from the devices. The APR-1 will be added to the Channel Input Setup as the last channel. This channel should be defined to the BARO analysis module and be included as part of the last group. In this example, the last group is H, so the APR-1 should be set to BARO and defined to Group H.**



From here the derived parameters that are needed can be set up. Select the channels with the same analysis (ex. BP), right click on one of the selected channels, and select **Derived Parameters**. Select the required derived parameters. The user has the ability to sort within the **Channel Input Setup** configuration. By clicking on the column headers, the user can sort each column. In the screen capture below, the **Analysis** column has been sorted so that all of the same analyses are next to each other.

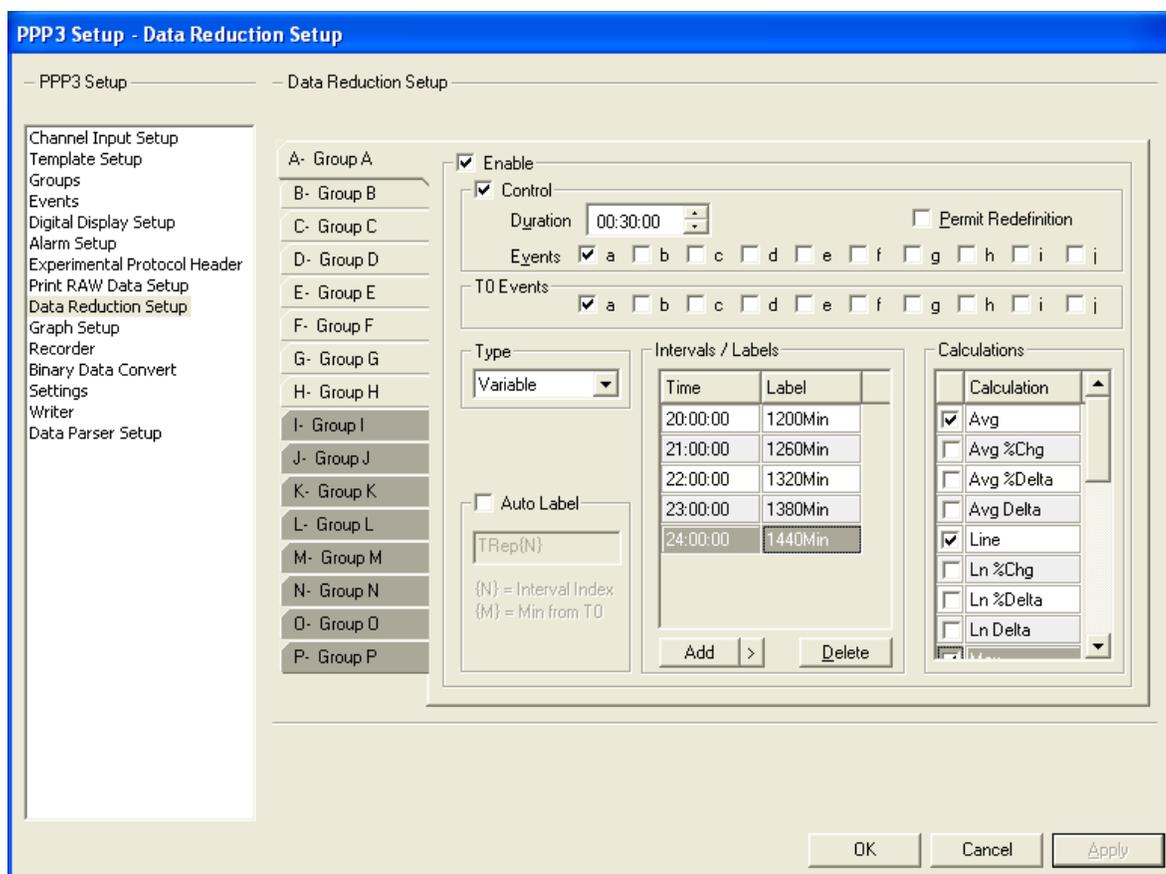


It is required to set up all similar channels with the same derived parameters. If the derived parameters are not the same from one group to another, problems will occur when the **Run Study** dialog is opened and when DSI Reporting is used.

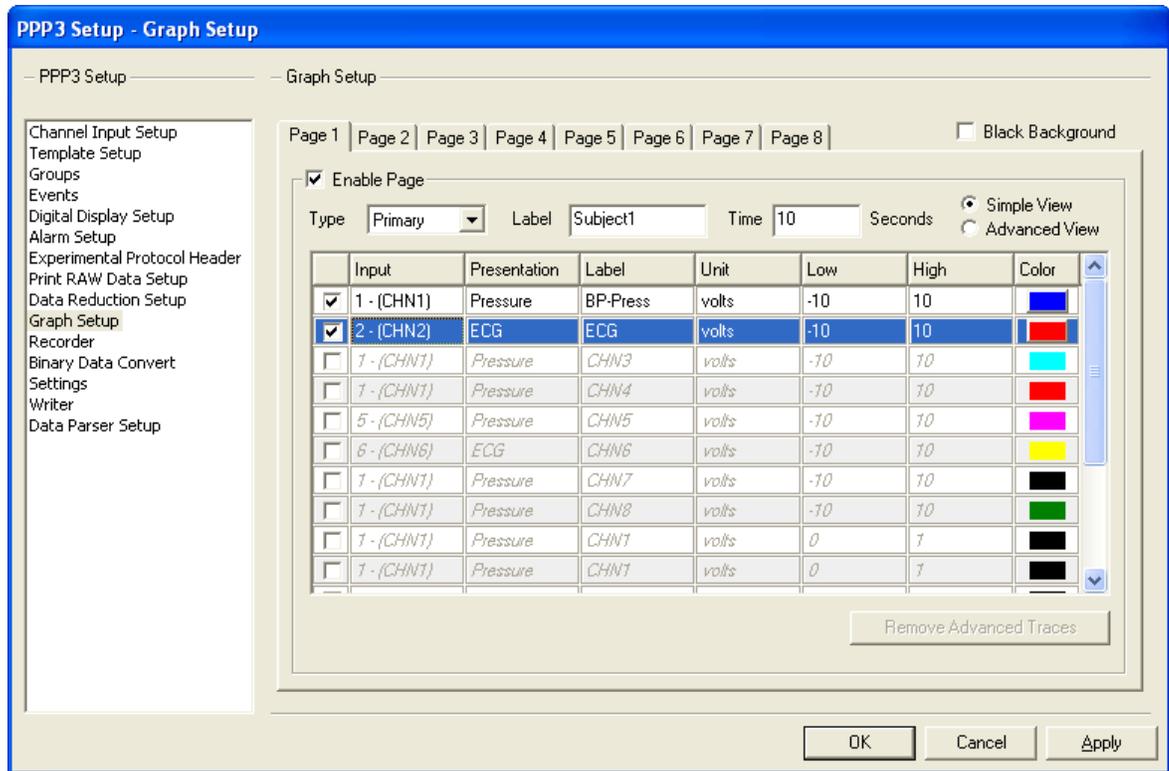
Repeat the above process for each type of analysis.

**NOTE: Once data has been collected in a Study, the Channel Input Setup and the Derived Parameters cannot be changed.**

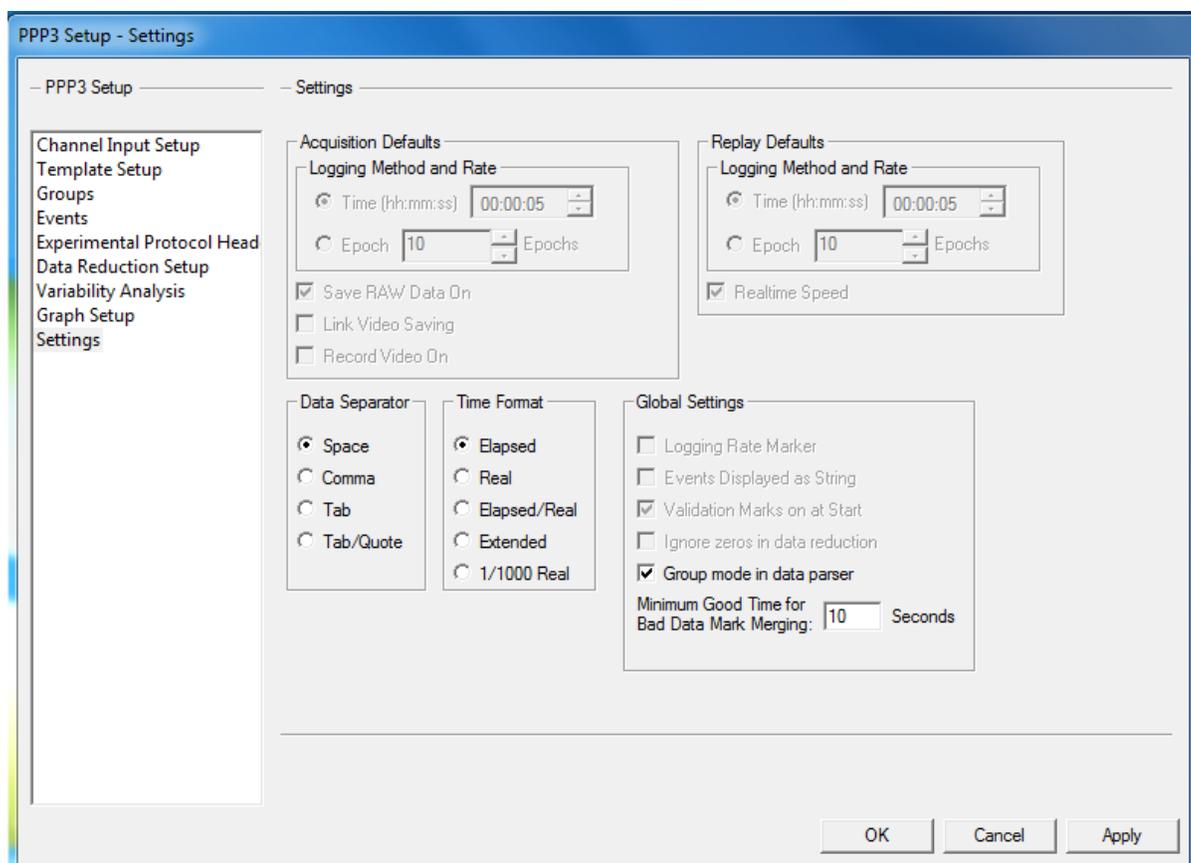
Now the user will need to configure Data Reduction. Select the **Data Reduction Setup** configuration. Select all of the group tabs that will be used. Each group must be set the same. Selecting all of the group tabs will accomplish this. Shown below is a typical Data Reduction configuration. Note that Group A through Group H have been selected.



The graph pages can now be configured. Select the **Graph Setup** configuration. Configure the graph page(s) as needed. Note that the labels from the inputs are not copied to the graph pages. They will need to be reentered. Shown below is an example of a typical configuration for one of the graphs.



Once the graphs have been configured, the basic settings can be configured, as shown below. View the P3 Plus Manual for details on configuring basic settings.



Close the **PPP3 Setup** dialog by clicking on the **OK** button.

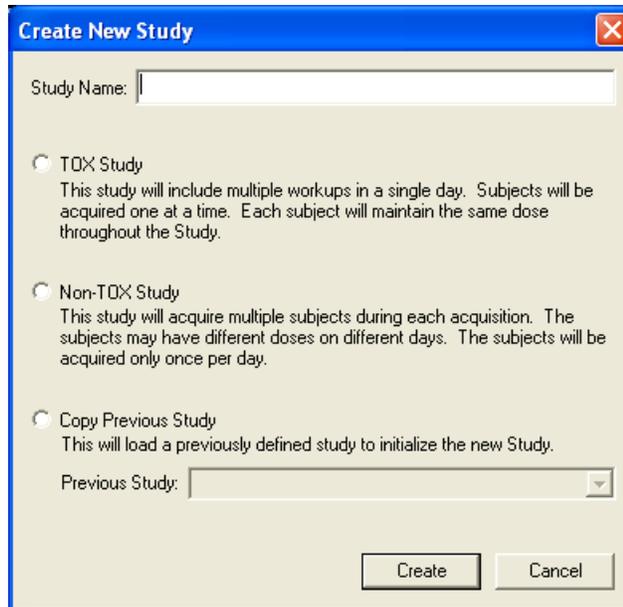
Other options, such as acquisition sample rate and the ODBC Interface can be configured now as well.

Save the protocol by selecting **Save As** from the **File** menu (the name NonTox.PRO has been used for this tutorial), type in a specific name, and click on the **Save** button. The protocol has now been configured.

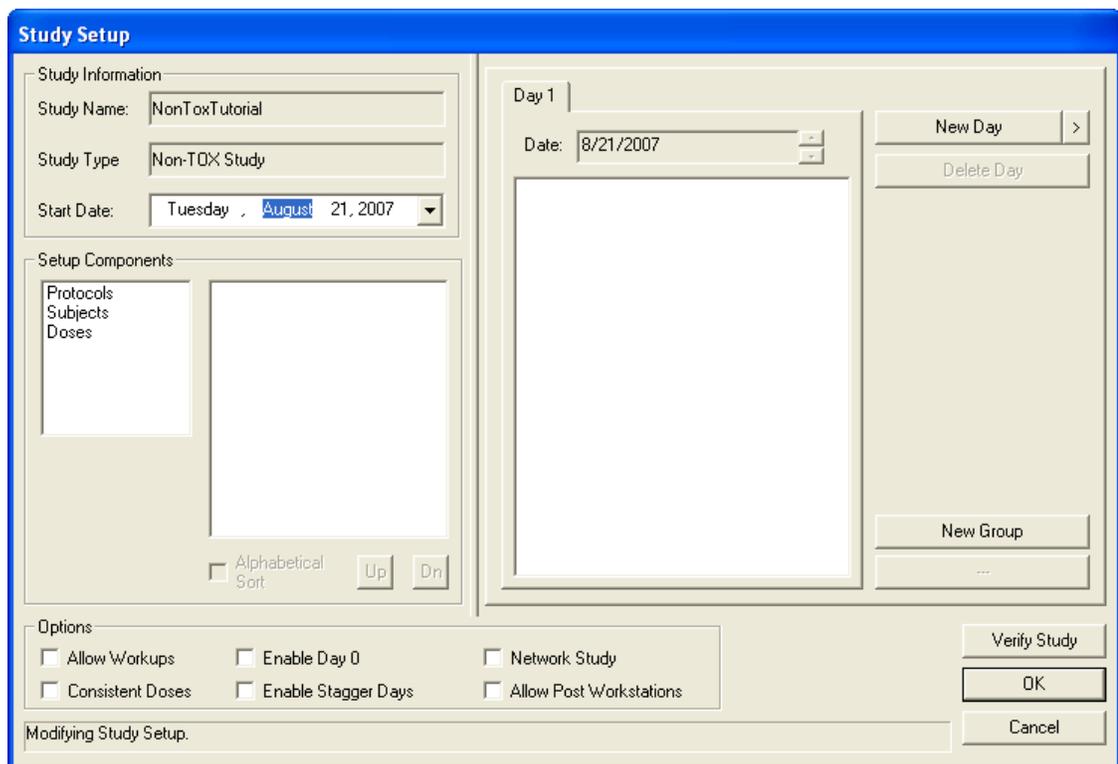
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## Creation of the Study

The next part of the tutorial will be to create the study. Select **New Study** from the **Study** menu. The dialog below will appear.



Type in a Study Name, select **Non-TOX Study** and click on the **Create** button. The **Study Setup** dialog will appear as shown below.



## Setup Components

There is no specific order in which the Setup Components need to be configured. The only requirement is that the setup components are configured prior to configuring the study structure.

## Protocols

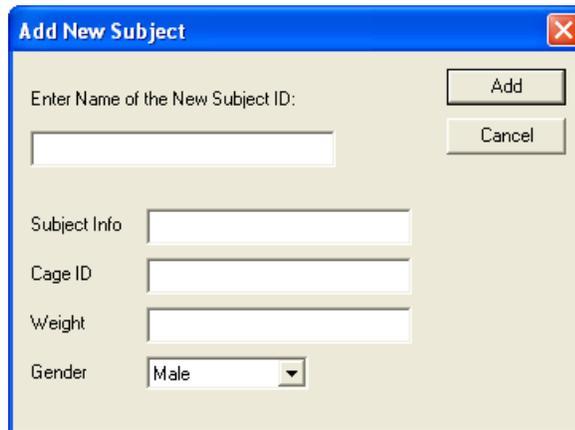
Double click on the **Protocols** to open a common dialog to select the protocol(s) that will be needed. The user can also select **Protocols** from the list and click on the **Add Protocol** button. This is the case for all of the different **Setup Components**. For the tutorial, the protocol NonTox.PRO will be selected. When configuring the in-house study, select all of the protocol files that will be used. If different animals require specific attributes, multiple protocol files will need to be used. Select the protocol and click on the **Open** button.

When a protocol is added, the amount of subjects for that study group will be listed. This is based off of the protocol groups that were configured. In this case 8 subjects will be listed.

**NOTE:** For a typical DSI telemetry setup, a P3 Plus protocol (and a DSI setup file) needs to be generated for each study group to assure that the correct DSI calibration factors are used for that study group.

## Subjects

The subjects can now be entered into the study. Double click on the **Subjects** setup component. The dialog shown below will appear.



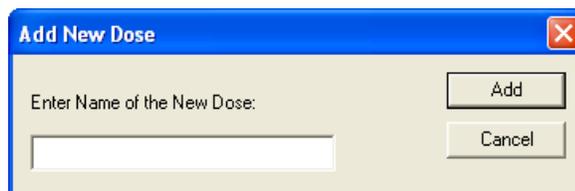
Enter the name of the subject, any subject information, cage ID, weight of the subject, and the subjects gender. Repeat this for all of the subjects in the study. The Cage ID and Gender are used as filters on the **Run Study** and **Backup** dialogs. The Subject Info and Weight are used for documentation only.

If the user is using the 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.

**NOTE:** Once the Study has data, the Subject ID cannot be changed.

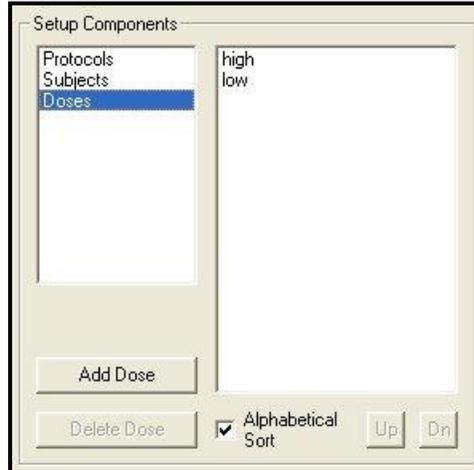
## Doses

The doses can now be entered into the study. Double click on the **Doses** setup component. The dialog shown below will appear.

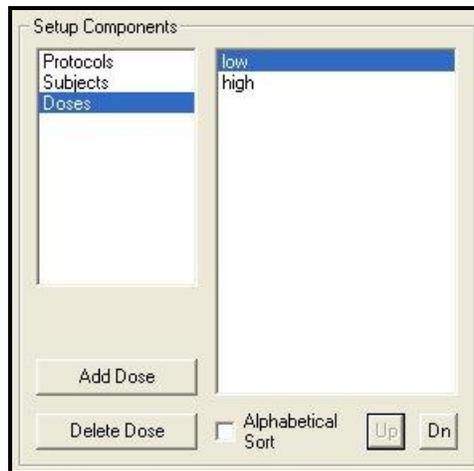


Enter a dose and click on the **Add** button. Repeat this for the other doses. In this case the doses used will be low and high.

If the user views the list of doses that were added, it can be seen that the doses are out of chronological order. Later, when DSI Reporting is used (view the DSI Reporting Manual), the order that the Study is saved will be the order that DSI Reporting will report data. The sort option initially lists data in alphabetical order.



To change this, disable the **Alphabetical Sort** check box. Once this is done, select the dose **low** and click on the **Up** button located next to the **Alphabetical Sort** check box. This will move the selected dose. The doses should now be configured like the picture below.

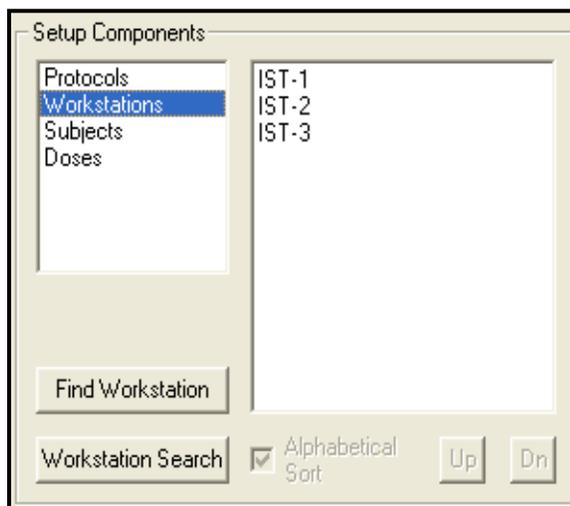


### ***Workstations (not needed when running on one P3 Plus workstation)***

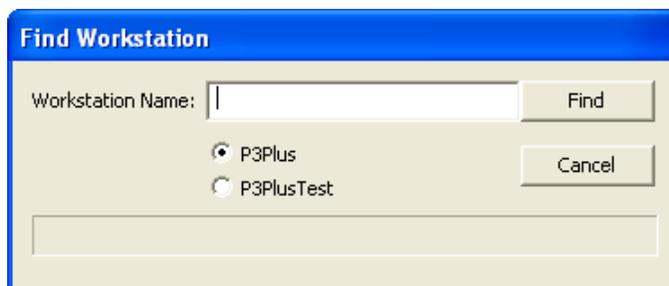
Since this study will be run on multiple P3 Plus workstations, the **Network Study** check box must be enabled in the **Options** section at the bottom of the **Study Setup** dialog, shown below.



Once the **Network Study** option is disabled, the **Workstations** setup component will become visible. See below.



By default P3 Plus searches for all available workstations connected to the network that have the same P3 Plus version. When the **Workstations** option is selected, a list of these workstations will appear. See the Study Manual for the specifics on workstation configuration. To search for a workstation that is currently not listed or one that has just been turned on, click on the **Find Workstation** button. A dialog like the one below will appear.

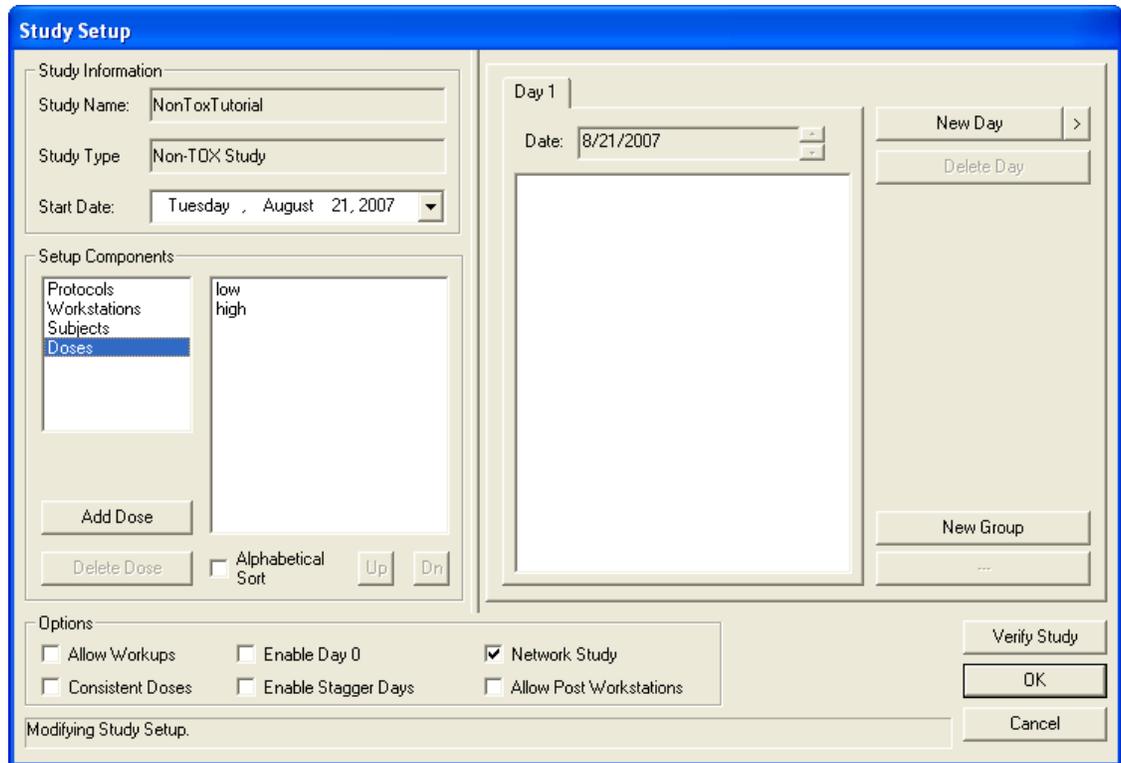


Enter the name of the workstation, select which instance of the data being used and click the **Find** button.

If workstations are enabled, the filter selection **Workstation**, located on the **Run Study** dialog can be used. . The filter selections are covered in the **Running the Acquisitions** section on Page 39.

## Study Structure

After all of the study components have been added, the study structure can be configured. This is done in the right hand section of the **Study Setup** dialog.

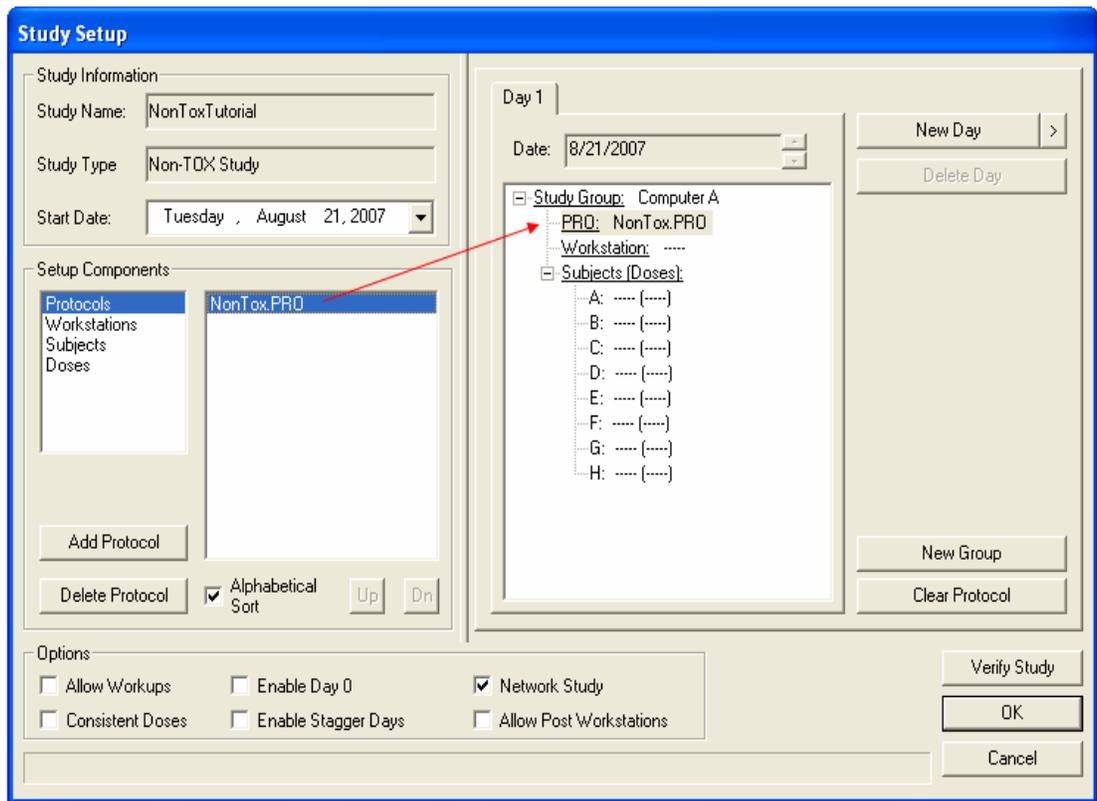


The first item to take care of is to set up the groups that will be used. This is done by clicking on the **New Group** button. In this case 2 groups need to be added. Groups can be configured for multiple reasons. In this case multiple P3 Plus workstations are used, and to show which subjects are associated with which P3 Plus workstation, multiple groups are used. Other reasons that multiple groups may be used would include multiple protocols or stagger days that need to be used.

When a new group is added the user has the capability of modifying the name of the study group. Since this study is using multiple computers, the study group name will be entered to identify this information. The modification of the study group name can be done at any time prior to running an acquisition. The user can change the study group name later by left clicking on the study group name.

**NOTE: The Study Group Name should only be configured up to 20 characters.**

After the groups are added, the setup components can be added to the study structure. This is done by clicking and dragging the items from the setup components to the study structure.

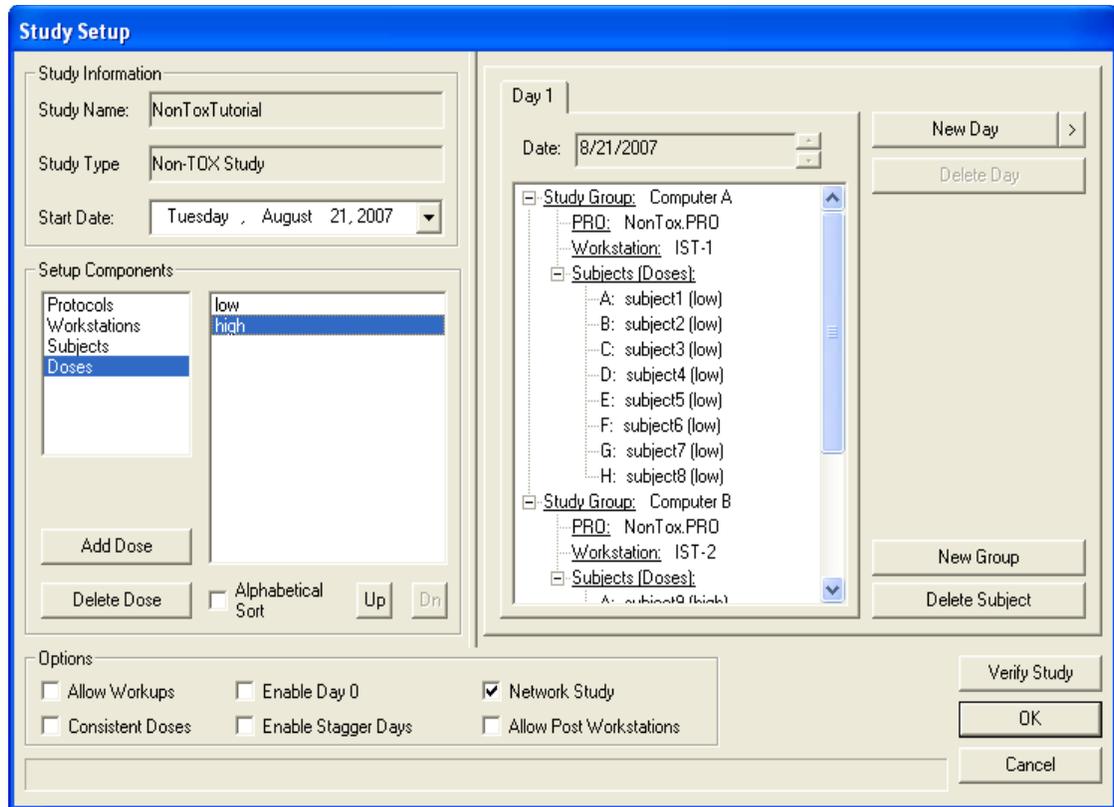


In the above screen capture the protocol **NonTox.PRO** has been dragged and dropped from the Setup Components to the study structure. For each Study Group configured, only one protocol can be added. This is also true for Workstations, if workstations are used.

If the component can be added to the study structure, the cursor will change to either a pointer with a curved arrow or a pointer with a plus sign. If the component cannot be added to the study structure, the cursor will change to a **NO** sign.

Repeat the above process for each of the **Setup Components** that need to be added.

Below is a screen capture of a basic setup showing multiple study groups configured to multiple P3 Plus workstations. The **Workstation** component will not be listed when running on one P3 Plus workstation.



If Stagger Days are required, the **Enable Stagger Days** check box can be checked (enabled). This will allow the user to acquire data across multiple days but keep the structure of the study simple. In this tutorial it will be needed. The Stagger Days are used so that multiple study groups can be configured to look as if they need to be run on the same day but time constraints do not allow the acquisitions to be performed on that day. In this tutorial it will not be needed.

After the study group information is configured, the days can be configured. Since the days that are configured for this tutorial include a Day 1, the **Enable Day 0** option should be deselected. The **Enable Day 0** option only changes how the first post dose day is shown. It does not affect anything within the study.

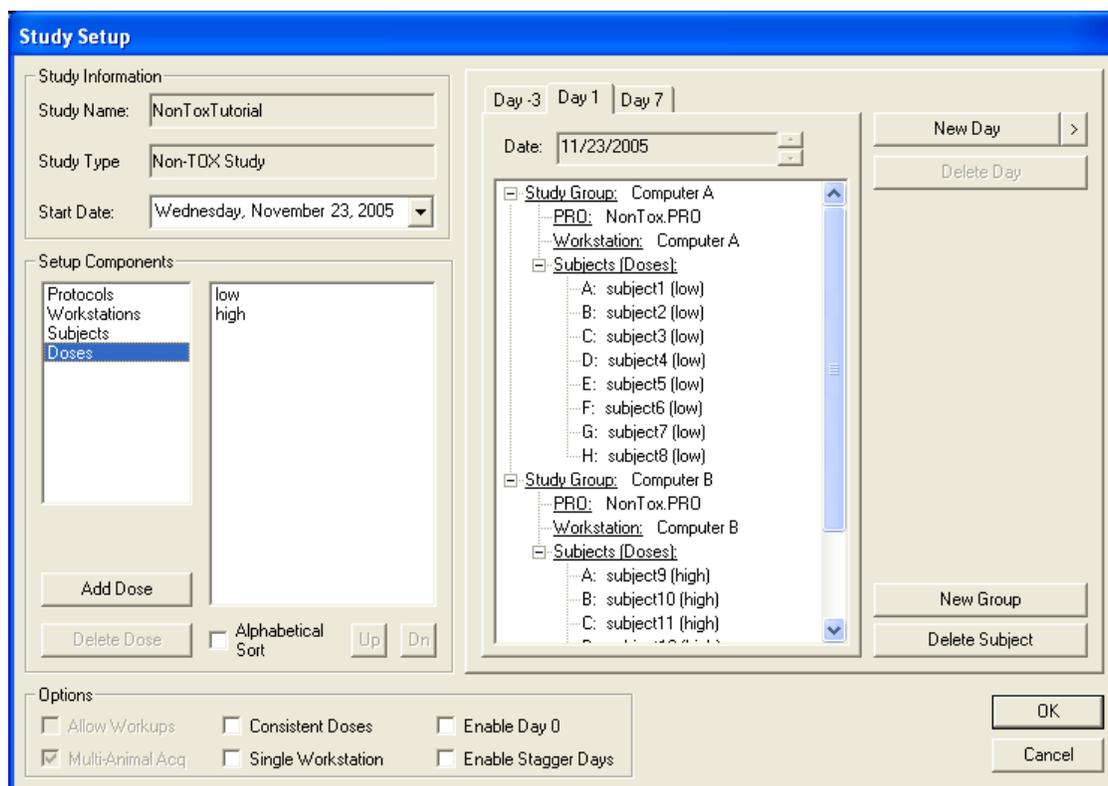
The **Consistent Doses** option will stay disabled for this study. When the option is enabled, the same subjects will receive the same doses on every day.

To add a new day, click on the **New Day** button. This will add a new day one day after the currently selected day. The days that will be configured for this tutorial are -3, 1, and 7. If the **New Day** button is selected in the case above, **Day 2** will be added. When the new post dose day is added, all of the study group information is copied. If Day 2 is not the day that needs to be configured, the up and down arrows next to the Date can be selected to change the date of that day. See the Study Manual for other options in changing the day used.

Repeat the above process for all of the days needed. When the pre dose days are added, no study group information is added. This allows the user to configure any type of pre dose day configuration that is needed. Also, since it is a pre dose day, doses cannot be added to the subjects.

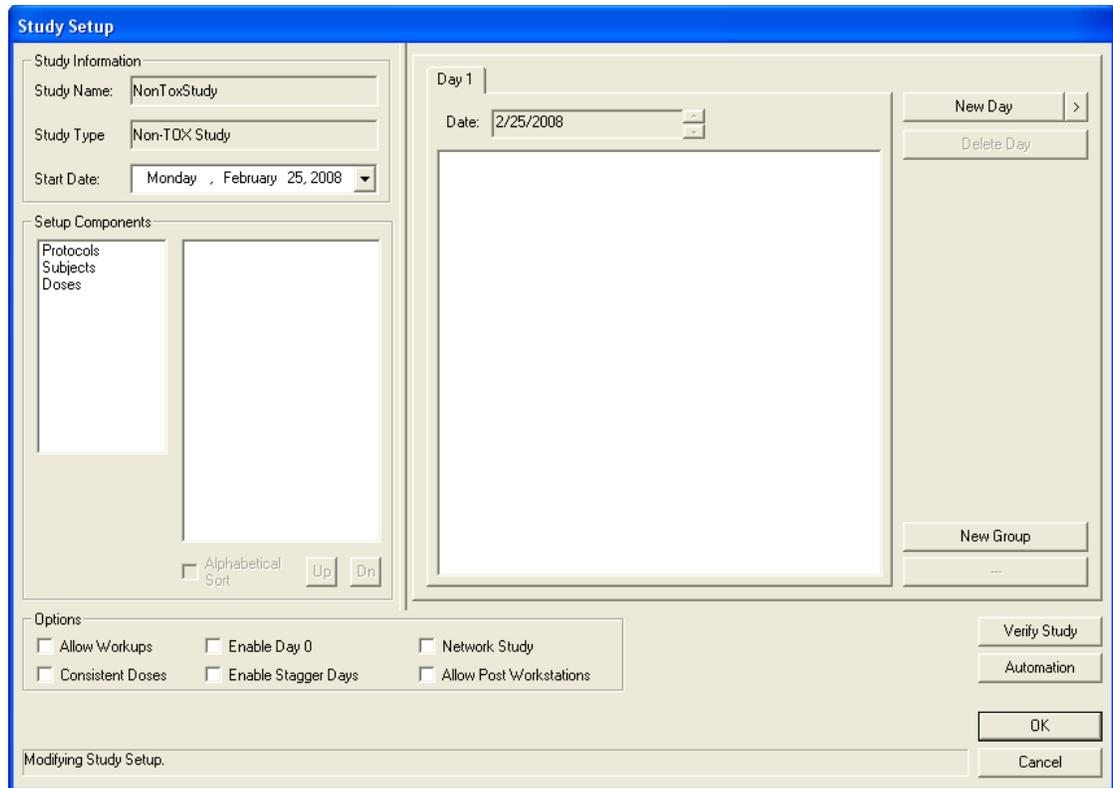
If the same configuration that is used for post dose days will be used for pre dose days, the user can add a new post dose day, and then change the date with the down arrow button to the correct pre dose day required.

The screen capture below shows the completed study.



## Study Automation

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. This feature can be accessed by clicking on the Automation button.



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 for Non Tox Studies:

- Non Tox Protocol Parser – Scans the assigned Protocols and adds the P3 Group Names as subjects to the existing Study Groups (CSV file not required)
- 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.

## Study Automation: CSV File Format

The tables below outline example formats for the CSV files generated by the third party software which will be used by the Study Automation feature.

### NonToxDosesAssigner.csv

```
Group A, 1, None
Group B, 1, Low
Group C, 1, Mid
Group D, 1, High
Group A, 5, Low
Group B, 5, Mid
Group C, 5, High
Group D, 5, None
Group A, 11, Mid
Group B, 11, High
Group C, 11, None
Group D, 11, Low
Group A, 17, High
Group B, 17, None
Group C, 17, Low
Group D, 17, Mid
```

### SubjectImporter.csv

```
Dog1, 11111, Cage1, 56, M
Dog2, 22222, Cage2, 53, M
Dog3, 33333, Cage3, 59, M
Dog4, 44444, Cage4, 63, M
Dog5, 55555, Cage5, 51, F
Dog6, 66666, Cage6, 58, F
Dog7, 77777, Cage7, 52, F
Dog8, 88888, Cage8, 59, F
```

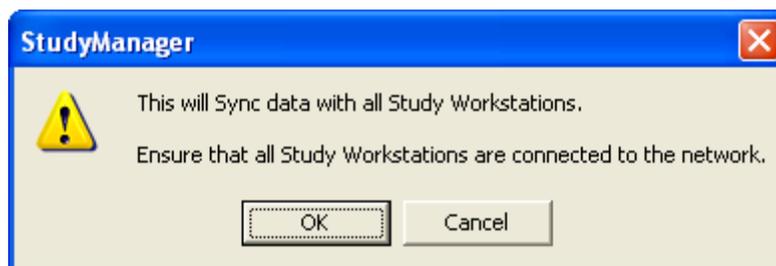
**Note:** The Study Automation scripts expect a very simple CSV format. Double quotes will be automatically stripped from any of the values. Any leading or trailing spaces will be removed. Any comma, whether contained within quotes or not, will be considered to be a delimiter, so including commas within the values will result in unexpected behavior.

---

## Synchronizing the Study to Multiple P3 Plus Workstations (not needed when running on one P3 Plus Workstation)

The next part of the tutorial will be to synchronize the study information to the other P3 Plus workstations that will be running the acquisitions. In this tutorial the primary P3 Plus workstation will be used to acquire data as well. Since this study can be run on multiple P3 Plus workstations, the user may want to save the backup file up on the network where the other P3 Plus workstations have access. If this is not the case, the file will need to be copied onto removable media and either transported to the other P3 Plus workstations or synchronized using network study feature.

To synchronize the study information, select **Synchronize Study Data** from the **Study** menu. The dialog below appears.



Click on the OK button to synchronize the study information.

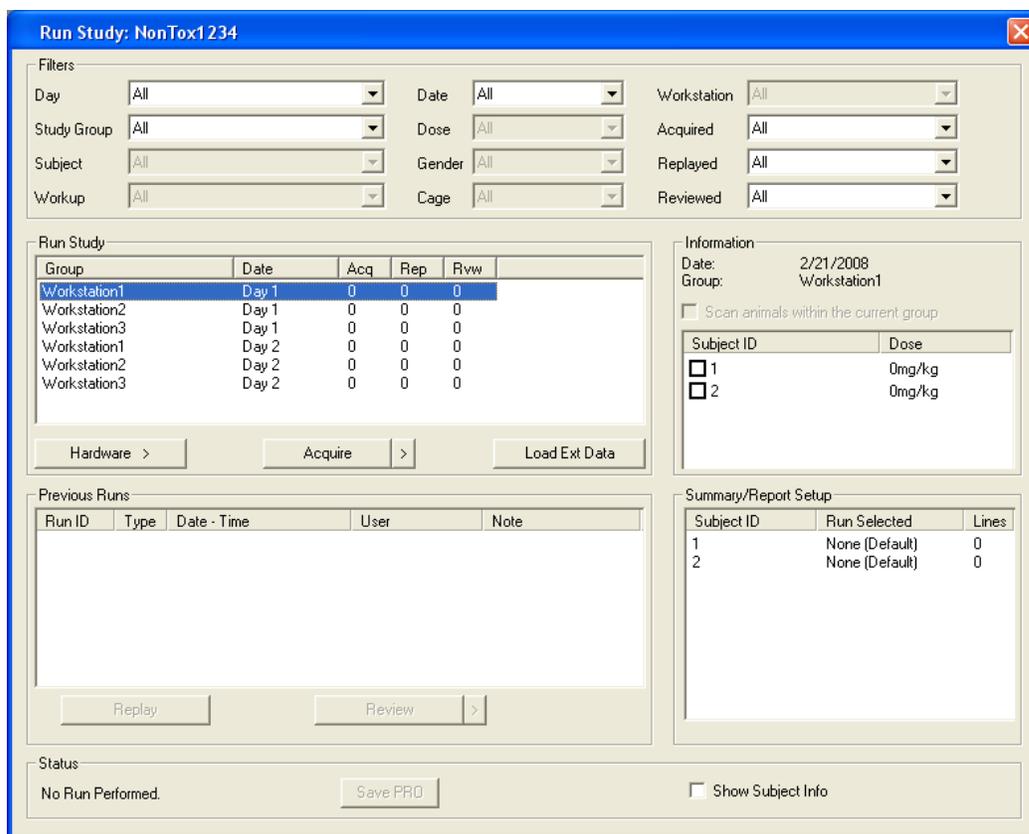
**NOTE:** If utilizing the Network Study features, please refer to the Study Protocol Option (MU00162) manual for setup and transfer of information specific to this feature. The specific sections are Network Options and Study Database Utilities.

To copy the study information, select **Backup Study** from the **Study** menu. The dialog below appears.

---

## Running the Acquisitions

The next part of the tutorial will be to run the study acquisitions. This is done by selecting **Run Study** from the **Study** menu. The dialog shown below will appear.



If running on multiple workstations, each P3 Plus workstation that is running acquisitions can narrow down the study acquisitions by selecting the appropriate P3 Plus workstation from the **Workstation** filter. This allows the user to only list the study acquisitions for the P3 Plus workstation being used. The options available from the **Workstation** filter are **All** and **This Workstation**. Study will automatically compare the current P3 Plus workstations name to the study acquisitions that need to be run on that P3 Plus workstation.

Dependent on the hardware being used, a calibration may need to be performed prior to the acquisition starting. To accomplish this, select the study acquisition to be performed and select the appropriate calibration button.

After the calibration has been completed, the study acquisition can be acquired. This is done by selecting the **Acquire** button. If a scheduled acquisition is to be performed, select the advanced acquisition button next to the **Acquire** button. This is the right arrow next to the **Acquire** button. From here a menu appears with the selections **Acquire** and **Sched. Acq.**

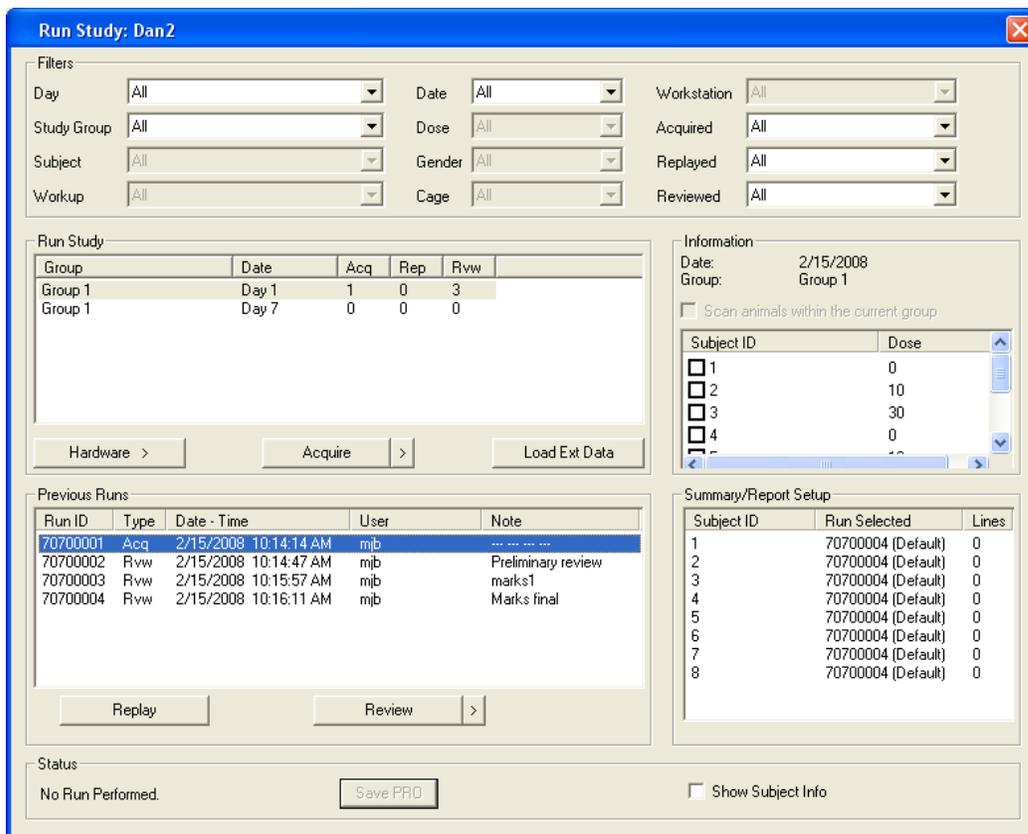
If the scheduled acquisition is selected, the **Scheduler Setup** dialog appears so that modifications can be made to account for the difference between the initial setup of the protocol to the time that the scheduled acquisition is performed.

Repeat the above process for all of the study acquisitions that need to be performed on each of the P3 Plus workstations.

## Reviewing Data from

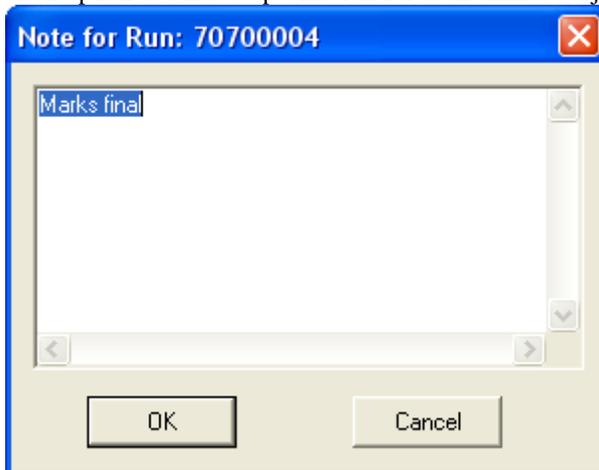
A review is performed from the Run Study menu by clicking on a previously acquired acquisition in the Previous Runs panel. A dialog will be presented prior to opening the file allowing channels to be disabled before entering Review. This option may be used to limit the number of animals (or channels) currently being reviewed. Disabling additional channels will also increase the speed of processing since fewer channels will be used when recalculating data based on attribute or other changes.

As Reviews are performed and Marks sections saved, these newly created Runs will be listed in the Previous Runs panel.



Notes may be added to Runs in the Previous Runs panel by right clicking the mouse on the desired run. A selection for View and Modify Note appears. Selecting this function will provide the following dialog and allow a note to be entered or modified at any time. This is useful to annotate various runs to track changes between them. The default name for a Note will be the last saved Marks Section name. Additionally, using the right mouse click will provide a list of options for selection of the report run (this will be used to mark data for the DSI Reporting Option). The option to select one Run to use for reporting data for all animals is available as well

as an option to select a specific run for each animal/subject.



A Summary Report Setup Panel is displayed to show which run is selected (by Run ID), for summary/report purposes, for each subject and whether Data Reduction values exist. If Data Reduction values exist, these will be listed under Line. This list may also be used to modify the report list for the DSI Reporting Option by right clicking the mouse on a specific Subject ID. 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 and Summary/Report Setup panels.

---

## 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.

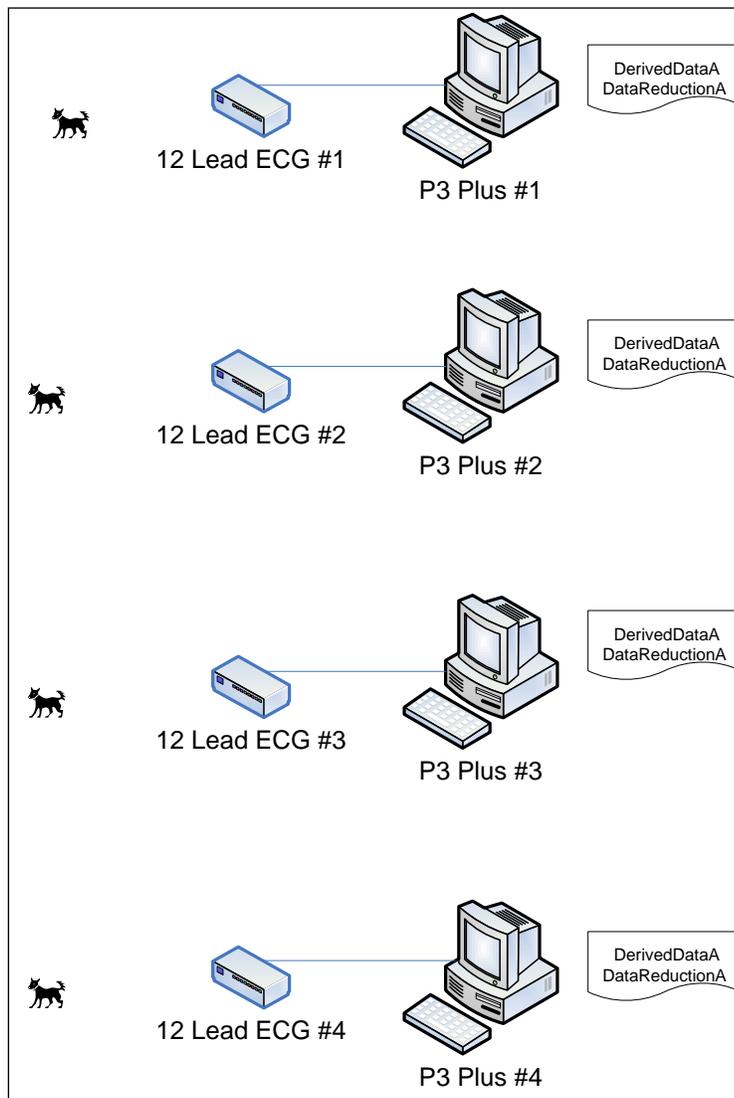
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## Checklist for Configuring Non Tox Study

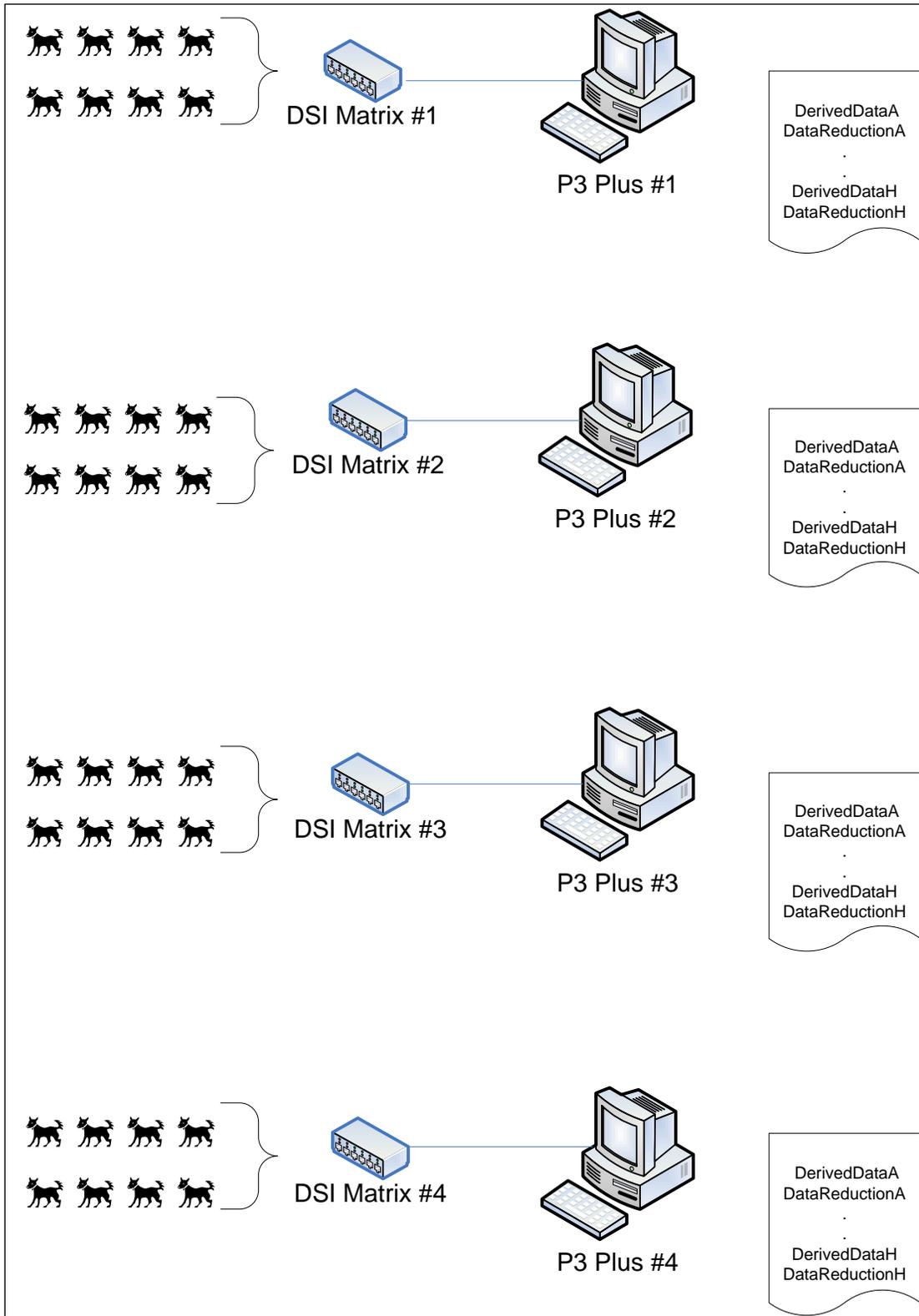
- Create Protocol
  - Enable the appropriate number of channels under Channel Input Setup
  - Select the same derived parameters for all channels
  - Enable and configure Data Reduction information under Data Reduction Setup
  - Enable appropriate number of traces and presentations under Graph Setup
  - Configure Study Specific parameters under Settings
  - Save Protocol
- Create Study
  - Select New Study from Study menu, enter name and select appropriate type of study
  - Configure Protocols, Subjects, Doses, and Workstations under Setup Components (Sort components - used for DSI Reporting)
  - Configure Study Group and Study Days (pre and post days)
  - Drag and drop Setup Components to Study Structure
  - Configure Options like Enable Day 0 and Stagger days if needed
- Synchronize Study to Multiple P3 Plus workstations (not needed when running on one workstation)
  - Select Synchronize Study
- Run Acquisitions
  - Select Run Study from Study menu
  - Select appropriate filters (such as Workstation and Day)
  - Select appropriate study acquisition, calibrate, and acquire data
- Synchronize Entire Study to all P3 Plus workstation (not needed when running on one P3 Plus workstation)
  - Select Synchronize Entire Study from Study menu
- A back up of the database should be performed on the completed study only. It is not recommended for studies involving multiple acquisition PCs.

# Appendix A

## Typical Tox Study Diagram

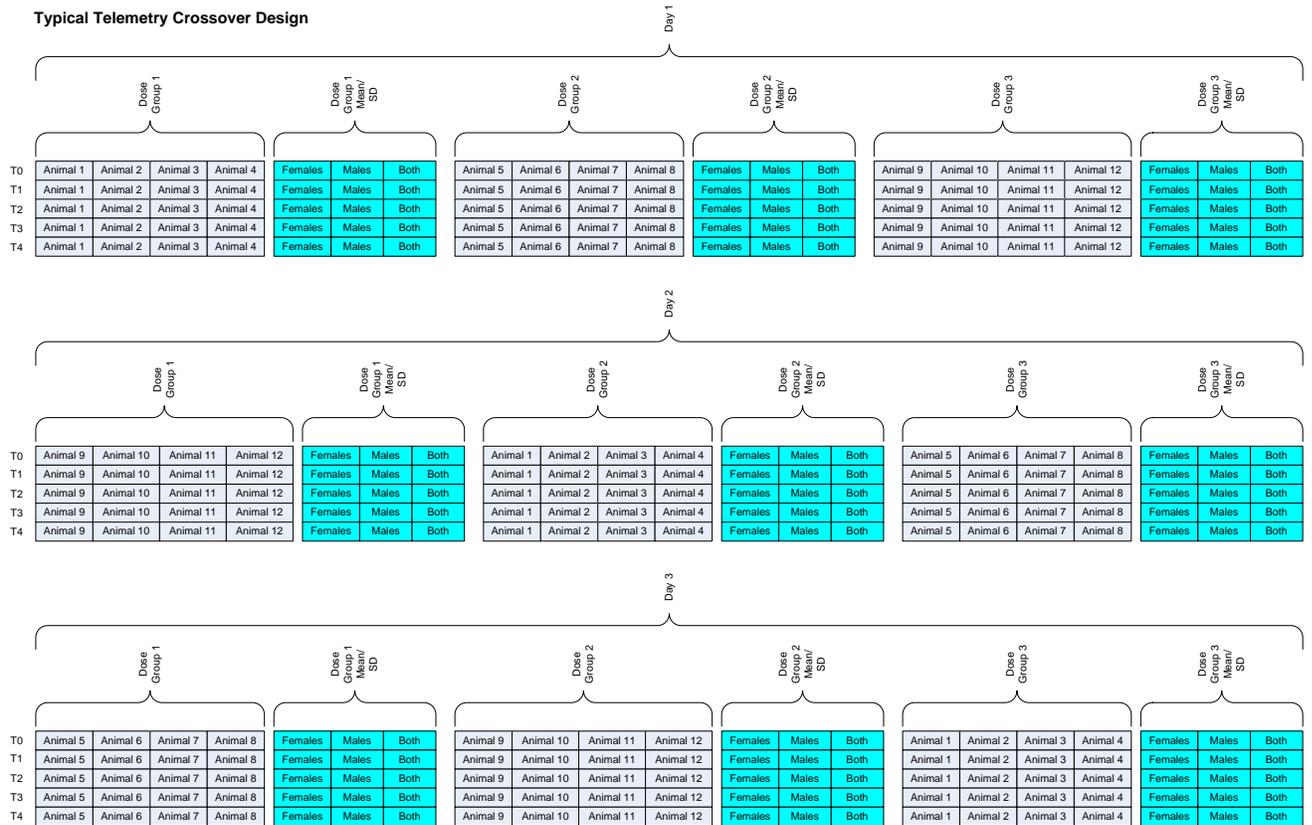


# Typical Non Tox Study Diagram



# 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.

# Appendix B

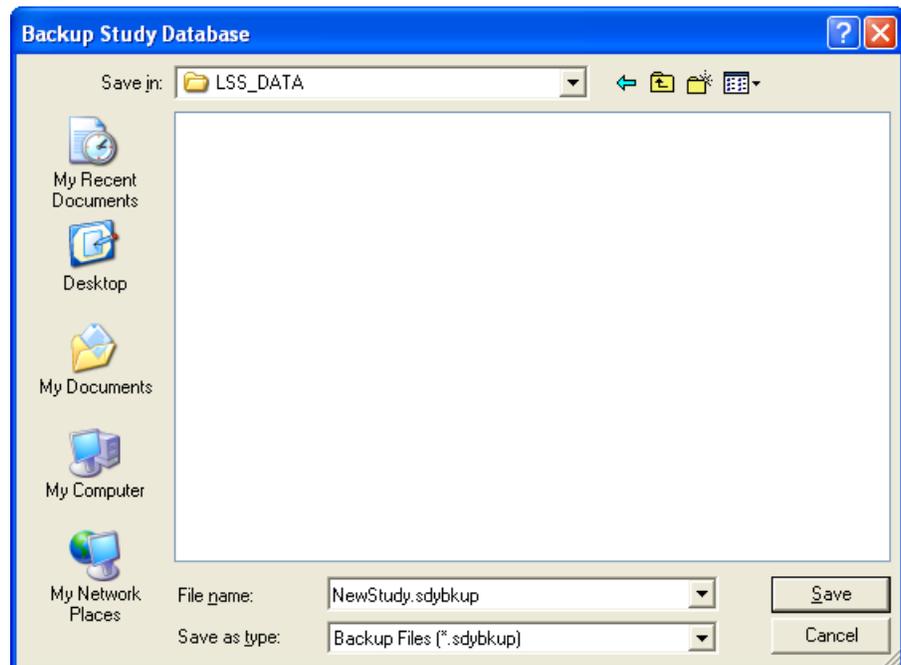
---

## Backup Database

Backup and Restore features are used for archival purposes only and are not to be used to merge data from multiple workstations.

To backup the study information, select **Backup Study** from the **Study** menu. The dialog below appears.

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.

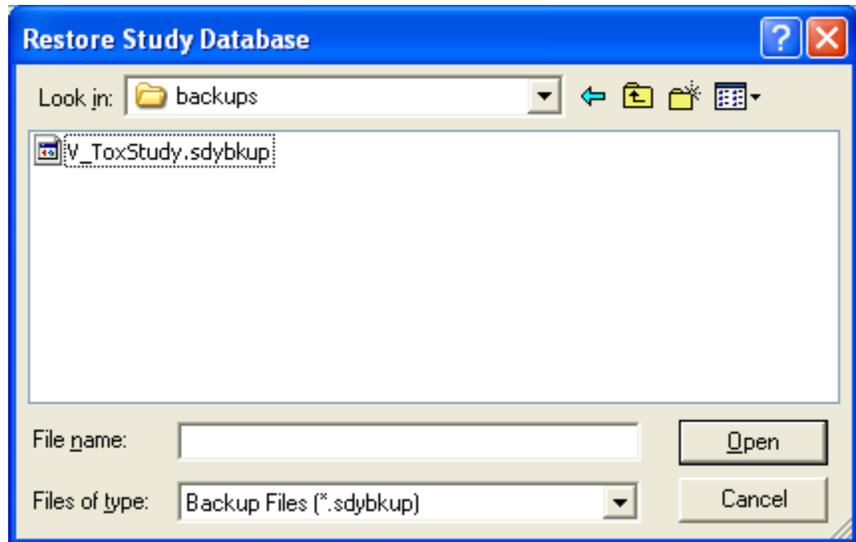


Backing up a study will save the study configuration and all of the data runs that were acquired. Backup will NOT back up binary data (.RAW, .RVW, .EVT, and ODBC files).

---

## Restoring a Database

Once the study has been backed up, it can be restored onto the network or other storage location.



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.

Once this happens, the study is automatically selected as the default study.

**NOTE: When using the restore feature data in the database, it is intended for archiving purposes only for a completed study. If multiple acquisition systems are used, the restore feature does not merge data from multiple workstations. This will overwrite data that was previously restored.**

# Product Issue Report

---

## Product Issue Report Form

|  |                 |
|--|-----------------|
| Sales Person:  | Issue:          |
| Customer Name:   |                 |
| Company:   |                 |
| Address:   |                 |
|  |                 |
| Phone Number:  |                 |
| Email Address:   |                 |
|  |                 |
| P3 Plus Version (including Service Pack):                                  |                 |
| Serial Number:   |                 |
| Priority:  |                 |
| Date:  |                 |
| Hardware:  | Steps to Repeat |
| Status of issue (check one)  |                 |
| <input type="checkbox"/> Unreproduced <input type="checkbox"/> Reproduced  |                 |
| <input type="checkbox"/> Needs repair <input type="checkbox"/> As intended |                 |
|  |                 |
| Computer hardware/software   |                 |
| Brand/Model:   |                 |
| CPU Speed:   |                 |
| RAM:   |                 |
| Operating System (including Service Pack):                                 |                 |
|  |                 |
| Networked  |                 |
| <input type="checkbox"/> Yes <input type="checkbox"/> No                   |                 |

