

Center for Drug Evaluation and Research

Rockville, Maryland 20857

Presents...

NDA Electronic Data Analysis Training

NEDAT

Contents

INTRODUCTION	1
Prerequisites	1
LESSON 1 – NEDAT PRESENTATION	3
LESSON 2 - ACCESSING ELECTRONIC DATA	9
Electronic Document Room (EDR)	10
Associating Files	13
About The SAS System Viewer	14
Installing The SAS System Viewer	15
Launching The SAS System Viewer	15
Navigating SAS Transport Files	16
Selecting Cells	17
Sorting Datasets.....	17
Sorting Using Query Language	18
Searching (Find) Text.....	19
Map a Network Drive.....	20
Copying Files or Folders to Your Computer.....	21
Review	25
LESSON 3 - CONVERSION AND ANALYSIS TOOLS	27
About StatTransfer V5	28
Launching StatTransfer	28
StatTransfer Dialog Boxes	29
MS Excel Conversion.....	29
About Microsoft Excel	31

Open MS Excel Worksheet	31
MS Excel Features	32
Microsoft Access Conversion.....	33
About Microsoft Access	34
MS Access Features	36
Review	39
LESSON 4 – JMP FEATURES	41
About JMP.....	42
Launch JMP.....	42
Import a SAS Transport File	43
Navigating a JMP Dataset.....	45
Selecting Cells	45
Move and Hide Columns	46
Column Headers	48
Saving a JMP File.....	49
Review	51
LESSON 5 – JMP TOOLS	53
Sort Command	54
Select Rows "Where..."	54
Subset	55
Search Command.....	56
Group Summary	57
Distribution of Y	58
Exclude/Include.....	59
Adding a Computed Column.....	61
Fit Y by X.....	62
Exporting to Excel and Word	65

Review	69
LESSON 6 – SUPPORT.....	71
Classes and Documentation	72
Additional Training	73
Help Menus	74
OIT Support.....	74
Peer Support	74

Introduction

CDER has provided guidance to industry for sponsors to send case report form tabulations and individual animal line listings as datasets. To help Center review staff use these electronic datasets, the Office of Information Technology, in conjunction with review staff, has developed NDA Electronic Data Analysis Training (NEDAT).

NEDAT provides the information necessary to get you started on reviewing electronic datasets. The course includes instructions on how to access the data via the Electronic Document Room (EDR) and convert the files to formats that can be used with a variety of software packages, including MS Excel and Access. The course also offers an introduction in The SAS System Viewer and JMP to open datasets and perform some basic data analyses. Instruction is provided for exporting statistical information to other applications for Word processing and additional analytical review.

The NEDAT program does not end with in-class instruction. The final lesson includes support options for reviewers who have taken the class, but require access to additional technical support. NEDAT incorporates the use of an extensive classroom manual, desktop reference guides, and software online guides for on-hand desktop support. The course also instructs reviewers how to access support via OIT and peers within the Center and provides a glossary of NEDAT terms.

Prerequisites

Before beginning these lessons, you should have a working knowledge of Windows 95 and its conventions. In particular, you should know how to do the following:

- Use a mouse and standard Windows or Macintosh menus and commands.
- Open, save, and close files.
- Resize and position application and document windows on the screen.

For help with any of these techniques, please see your Windows 95 documentation or the CDER OIT Help Desk. Classes in Windows 95 are offered by OIT.

Windows 95 System requirements:

- Windows 95
- 486 or higher processor with VGA or higher monitor
- 191 MB available disk space for software
- 12 MB RAM

Windows NT 4.0 and later:

- Version 4.0 or higher
- 486 or higher processor with VGA or higher monitor
- 191 MB available disk space for software
- 16 MB RAM

Lesson 1 – NEDAT Presentation

Please use the blank lines to take notes during the presentation.

This lesson will take approximately 10 minutes to complete.

Slide 1

NDA Electronic Data Analysis Training (NEDAT)

CDER/OIT Training

Please Sign-In Before Seating and Make Sure to Logon with Your Username

Slide 2

NEDAT Overview

- Review of "Providing Regulatory Submissions in Electronic Format - NDAs" Guidance
- SAS Transport
- Blueprint of Guidance
- NEDAT Objectives

Slide 3

CDER ERSR Goals for 2002

- All submissions can be received and archived electronically
- All electronic submissions, reviews, and other related data can be accessed by the reviewer through a desktop computer
- **Data analysis**
- Publicly available information is on the Internet


Slide 4

SAS Transport File (STX)

- Flexible format - compatible with multiple formats (SAS, JMP, Access, etc.)
- Archivable
- defacto Standard
- Free viewer (The SAS System Viewer)
- User-friendly navigation

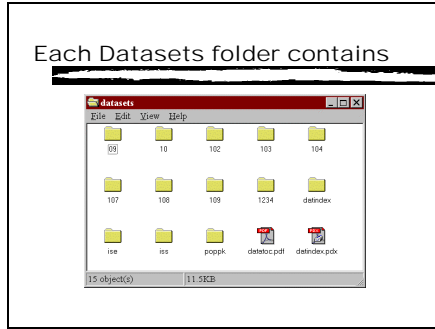
Slide 5

NDA Discipline Folder:

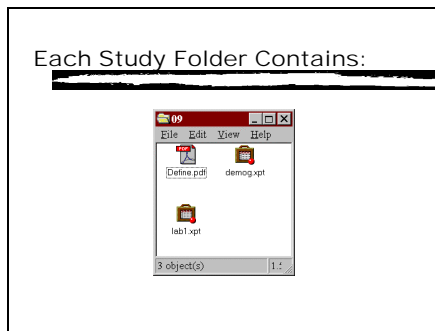


The screenshot shows a Windows Explorer window with a menu bar (File, Edit, View, Help) and a toolbar. The main area displays a folder view with three subfolders: 'datasets', 'domain', and 'profile', and one file: 'crtoc.pdf'. The status bar at the bottom indicates '4 object(s)' and '5.5'.

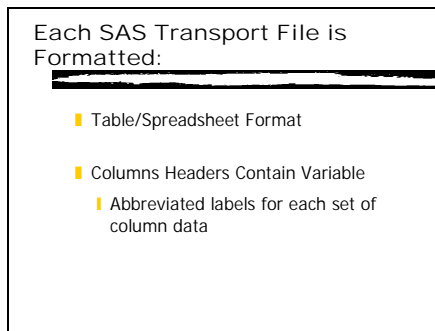
Slide 6



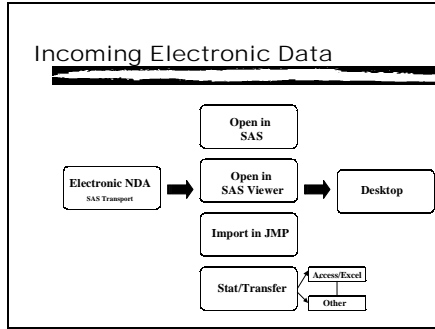
Slide 7



Slide 8



Slide 9



Slide 10

- ### NEDAT Objectives
- NDAs accessed via EDR
 - The SAS System Viewer to open, navigate, sort, and search SAS Transport files
 - Use Stat/Transfer to convert files to MS Excel and Access
 - JMP to import, navigate, search, and perform basic statistical analysis
 - Support Options

Slide 11

NDA Electronic Data Analysis Training (NEDAT)

Let's begin the NDA Electronic Data Analysis Training.....

Lesson 2 - Accessing Electronic Data

Electronic data, currently in SAS Transport file format, submitted to CDER's Central Document Room (CDR) is placed on the CDER network for access and review by CDER staff. Before these datasets can be reviewed, staff must first be able to access an NDA folder via the Electronic Document Room (EDR) and save a drive path (map) to the submission folder. This lesson will cover how to search for a specific NDA via the EDR Intranet site. Once the drive path to the NDA data folder is found on the network, The SAS System Viewer is used to open, view, and perform basic analysis on the data. The path to the folder can then be saved and assigned a drive letter (mapping), where the datasets can then accessed or converted to a software package most conducive to review staff needs.

Windows 95 file management tools, Microsoft's Internet Explorer, Adobe Acrobat, and The SAS System Viewer are used to complete the tasks in this chapter.

This lesson will take about 30 minutes to complete.

Electronic Document Room (EDR)

Once an NDA, Amendment, or Supplement has been placed on the CDER network, the location of the datasets can be found via the Electronic Document Room (EDR). The EDR is a Web based tool on the CDER network that contains search capabilities for NDAs and their associated Amendments and Supplements. Once you have an NDA number, use the EDR to find the location of the submission files.

To access the EDR:

- ☞ Start MS Internet Explorer by double-clicking the icon on the Win95 desktop
- ☞ In the Address field, type **EDR** and press [ENTER]

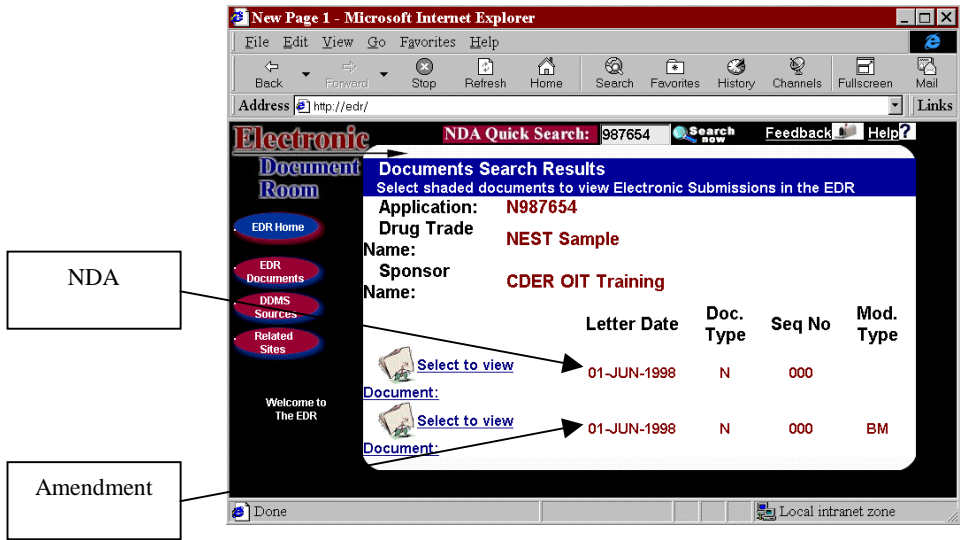
The Electronic Document Room Web page will appear.

- ☞ In the NDA Quick Search field, remove the 0, enter the sample classroom NDA number, **123456** (Actual NDAs begin with 0) and press the Search button

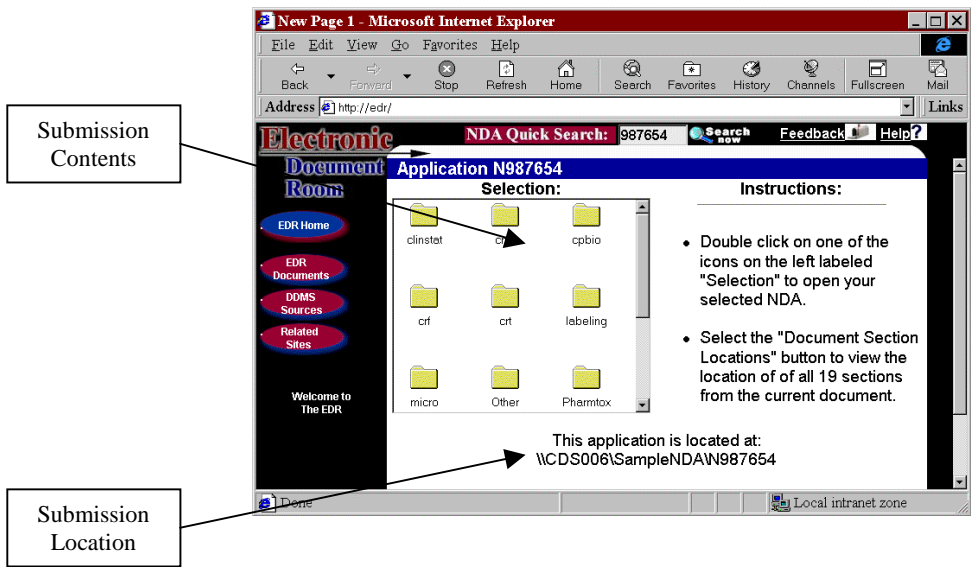


If the NDA number is valid, the NDA Application #, Trade Name, and Company Name will appear for each submission. Type, Sequence #, Sup. Mod. Type, Stamp Date, Application Drive Path (location on the network), and Comments will appear for the NDA and any associated Amendments or Supplements. Note the sample NDA drive path (\\cds006\samp1enda\n123456), as it will be used in the next section.

NOTE: NDA, Amendment, and Supplement folders may look identical on the network. Use the EDR to distinguish between them.

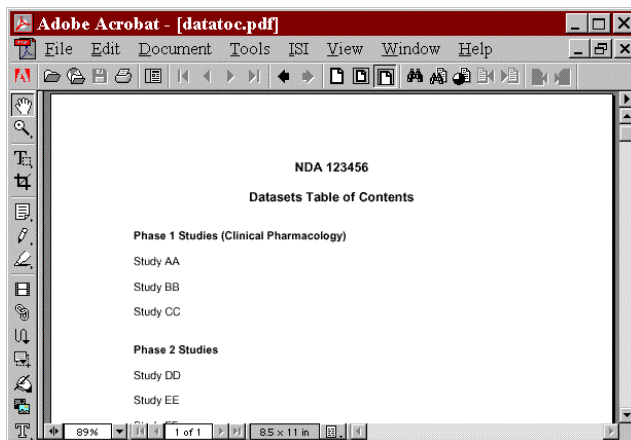


To access and display the contents of the main NDA folder, click on [Select to view Document](#) for the respective NDA, Amendment or Supplement. The next window will display a list of folders and files contained in the electronic NDA.



Double-click the *crt* folder. The datasets are contained in the folder *datasets*.

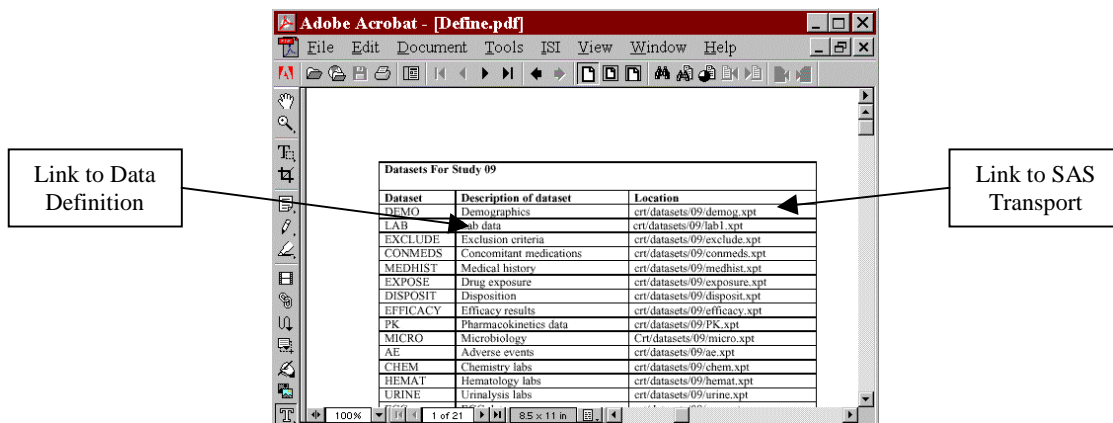
In the *datasets* folder, there is a file *datatoc.pdf*. This file is a table of contents for all of the data in the *crt* folder. To access the dataset table of the contents, double-click directly on the *datatoc.pdf* file in the EDR window.



If installed, Adobe Acrobat or Reader will launch with the *datatoc.pdf* in the main window. The PDF file lists all of the folders that contain datasets for this sample submission. The datasets used in NEDAT are located in **Phase 3 Controlled Studies**, in the Study number, **09**, folder.

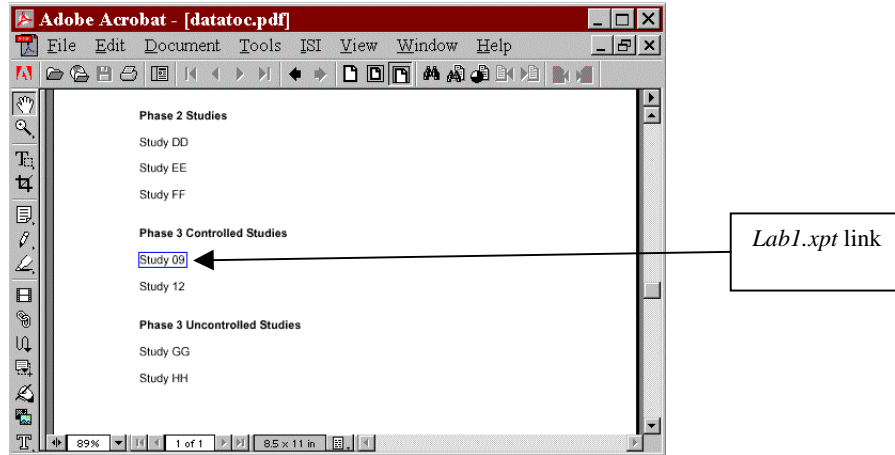
To access these files, click on the Study 09 link in *datatoc.pdf*. This link points to a file, *define.pdf*, in the Study 09 folder that file contains a list of all the datasets in the study.

The first page of the file is the table of contents. Links are established in the table that will allow you to open the file or the data definition table for each dataset by clicking on the corresponding links.



To get a better idea of how the variables appear in column header, go back to the first page of the PDF file. As stated, the dataset table of contents contains links to the actual datasets.

☞ Click on the link for the *lab1.xpt* file



Adobe Acrobat will prompt you to confirm that **The SAS System Viewer** will launch when you click on this link.

☞ Click the **Yes** button to open the dataset. If you do not receive this message, perform the steps listed in **Associating File Types**.

Associating Files

Windows 95 gives you the ability to launch applications by opening an associated file from one of the Windows file management screens. In order to perform this, Windows 95 must have a relationship, or **association**, established between a file type and an application. For example, after installing MS Word, Windows is setup to open Word by clicking on any file that ends in a .DOC extension.

If you click on a file and are prompted by Win95 with an **Open With** window, then the association of that file type with an application has not been setup in Windows. If this situation happens after installing The SAS System Viewer, perform the following procedure:

Note: Not all file types can be associated. Make sure you are using the correct software before performing these steps

1. If the **Open With** window appears when clicking on files
 - Click on **The SAS System Viewer** icon, labeled **SV**, from the list of programs
 - If the icon does not appear, click the **Other** button and navigate to `C:\PROGRAM FILES\SAS SYSTEM VIEWER\SV.EXE`
 - Click the **OK** button. The SAS System Viewer This will open automatically when you click on an associated file

2. Associating Files from My Computer¹

- Double-click `My Computer`
- On the `View` menu, click `Options`, and then click the `File Types` tab
- To create a new file type, click `New Type`. To modify the settings for an existing file type, click the type, and then click `Edit`
- Specify a description for the file type and the filename extension associated with this type of file
- Click `New` to define an action for this file type. If you are modifying an existing type, you can click the command in the `Action` box that you want to modify, and then click `Edit`
- Specify the action that you want to define, such as `Open` or `Print`, and the command that should run to complete this action
- Repeat the previous two steps for as many actions as you want to define for this file type

Once the file type `.XPT` has been associated with The SAS System Viewer, you can proceed to the next section of this lesson

About The SAS System Viewer

The SAS System Viewer is a free statistical software application that allows viewing files created by the SAS System. The SAS System Viewer displays datasets in a grid format.

The SAS System Viewer has the following capabilities (NEDAT topics in **bold**):

- **View SAS Datasets**
- Print Datasets
- View multiple file types
- Subset the data
- **Perform Text Searches**
- Create new SAS program and text files
- Launch the SAS System (if installed)
- **Sort by column**
- **Resize columns and rows**
- Launch by *right*-clicking on Dataset icons

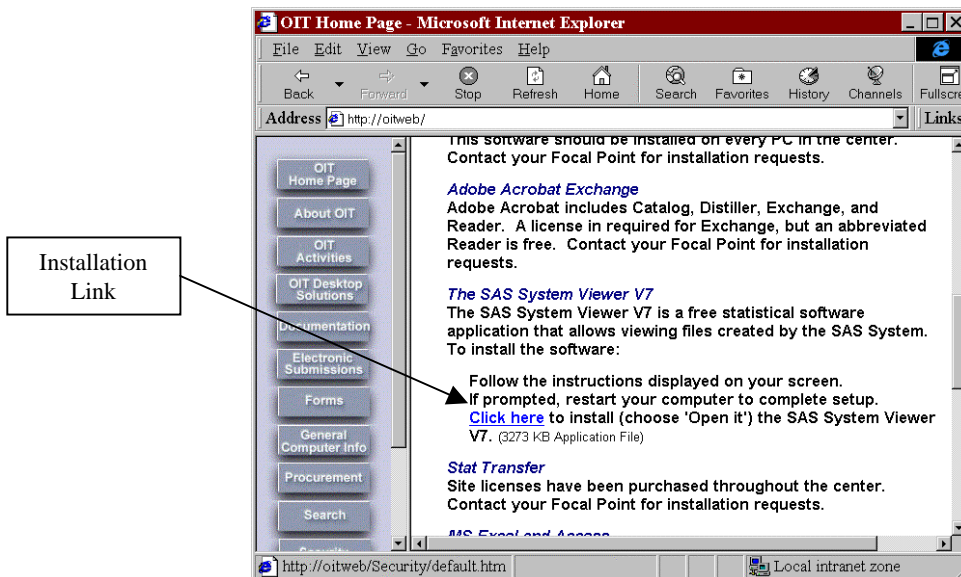
¹ From Microsoft Windows 95 Help Topics Menu (`Start | Help`)

Installing The SAS System Viewer

Since The SAS System Viewer is a free software package, you do not need to purchase a license to receive the software. OIT has placed a copy of the installation file on the OIT Intranet Home Page.

To install The SAS System Viewer from the OIT web:

- Start MS Internet Explorer by double-clicking the icon on the Win95 desktop
- In the Address field, type **OITWEB** and press [ENTER]
- Under the training section, go to the course catalog and click on the NEDAT link
- A page will appear listing the software packages incorporated with NEDAT training. Under The SAS System Viewer, click the [Click Here](#) link and follow the onscreen instructions to install the software.

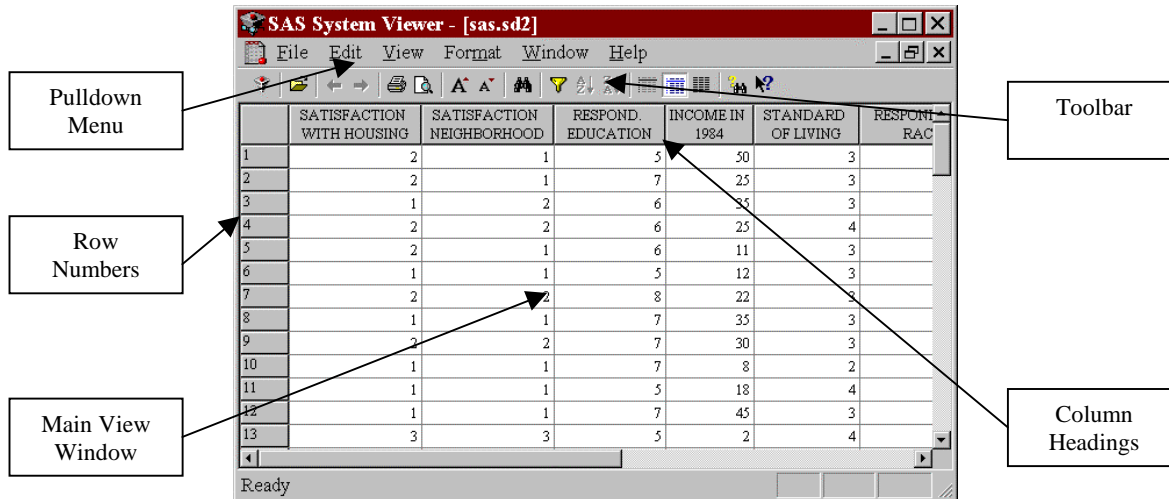


CDER Note: Contact the Help Desk if you experience difficulty in downloading the software

Launching The SAS System Viewer

If you have not launched The SAS System Viewer by double-clicking on a SAS Transport file, open the software by going to Start | Programs | The SAS System | The SAS System Viewer V7

The SAS System Viewer is a Windows based application. The features from the software can be accessed via the pulldown menu at the top of the screen. Shortcut buttons to common pulldown menu features are also available on the Toolbar.



- ☞ If you have not opened *define.pdf* as of yet, go to File | Open and navigate to the Z:\N123456\CRT\DATASETS\09 folder

Note: The SAS System Viewer has the ability to open several different dataset types. Consult the software's Help for a complete listing.

When the *lab1.xpt* file was clicked, the file opens in the main window. The column headings, row numbers, and cells appear within the window. Note that the column headers, or **variables**, are completely defined. To view the variable name:

- ☞ On the pull-down menu, go to View and uncheck the Labels option

The variable names now appear in the column header. Set this Label view to your preference.

Navigating SAS Transport Files

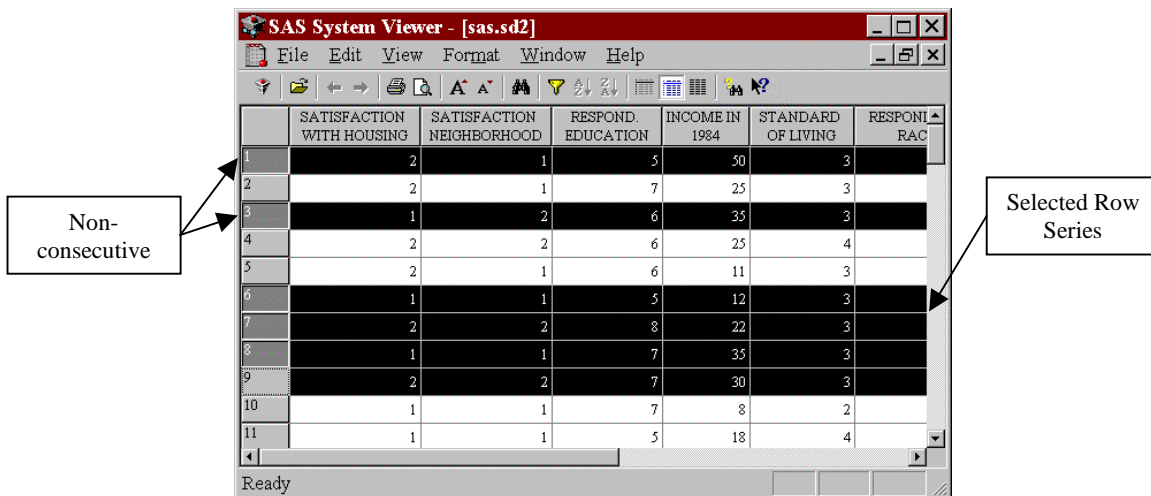
To select a cell, click directly on top on the cell and a box will surround the selected cell. This box indicates the active cell. You can also use the mouse to scroll up/down or side/side by clicking or dragging the scroll bars. Use the following tables to navigate the dataset using the keyboard:

Action	Result
← or → keys	Move one cell left/right
↑ or ↓ keys	Move one cell up/down
[CTRL] + ← or [CTRL] + →	Move to beginning/end of row
[CTRL] + ↑ or [CTRL] + ↓	Move to beginning/end of column
[CTRL] + [Home] or [CTRL] + [End]	Move to first/last cell in Dataset
[Page Up] or [Page Down]	Scroll up/down one screen

Selecting Cells

Before performing any action, you will first need to select the cells involved in the action. As we have already seen, clicking once on a cell selects that active cell. To select an entire row, click on the row number to the left of the cells. The selected rows will be highlighted. Click a Column Header to select an entire column.



Consecutive rows can be selected by clicking on a row number, holding down the mouse button and dragging up/down. Let go of the mouse to finish selecting rows. Non-consecutive rows can be selected by clicking on a row number, holding down [CTRL], and clicking on another row number. Use [SHIFT] in the same manner to select a series of rows.



Use the same functions to select consecutive, non-consecutive, or a series of columns. Selecting all of the rows or columns will select all of the cells in the dataset. You can also click the button above the row numbers/left of the column headers or go to **Edit | Select All** on the pulldown menu to select the entire table.

Sorting Datasets

These datasets can be sorted alphabetically in ascending or descending order. To sort by column:

- ☞ Select the column that will control the sort
- ☞ Click the Ascending, , or Descending, , button on the toolbar to sort alphabetically. The relationship among will remain constant among the other cells in each row.

SAS System Viewer - [sas.sd2]


File Edit View Format Window Help

	SATISFACTION WITH HOUSING	SATISFACTION NEIGHBORHOOD	RECOND. EDUCATION	INCOME IN 1984	STANDARD OF LIVING	RESPON RAC
1	2	1	5	50	3	
2	2	1	7	25	3	
3	1	2	6	35	3	
4	2	2	6	25	4	
5	2	1	6	11	3	
6	1	1	5	12	3	
7	2	2	8	22	3	
8	1	1	7	35	3	
9	2	2	7	30	3	
10	1	1	7	8	2	
11	1	1	5	18	4	

Ready

Sorting Using Query Language

A query is a string expression that utilizes mathematical and Boolean expressions. It is necessary to have variables setup for the dataset to use query language. To use query language to filter data:

- ☛ Click the Filter button, .
- ☛ Enter the following SQL string: **Where Age > 50**

Filter

Where Clause: Where Age > 50

Filter

Cancel

Order By

Ascending

Descending

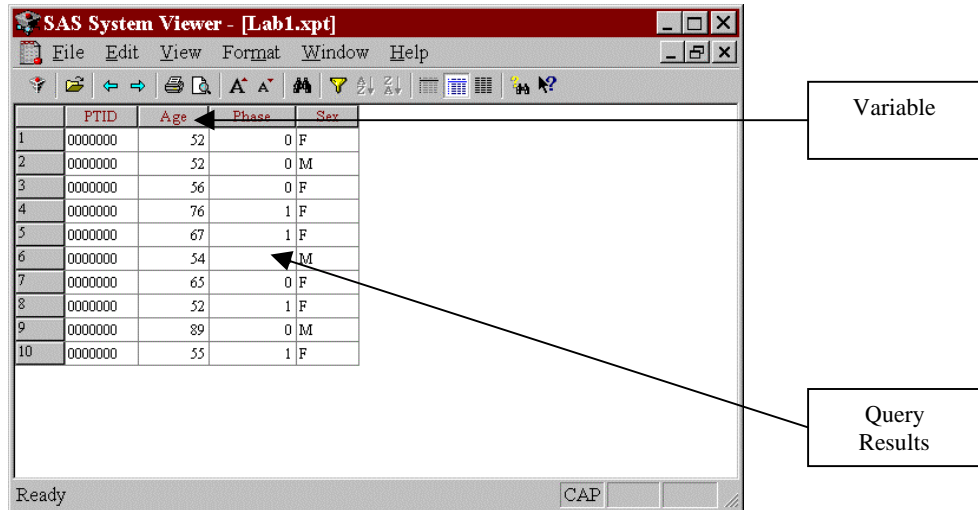
Column: 1

Starting Row: 1

Number of Rows: 1000

Text Color: █

The Boolean expression is WHERE. The variable is Age, followed by the mathematical formula. The above example will display all rows that contain a value above 50 in the Age column.




Currently, to remove the filtering:

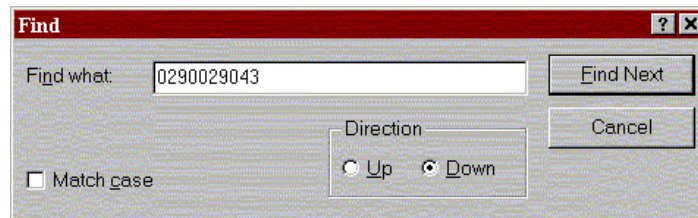
- Click the Where button
- Leave the SQL string filed blank
- Click OK

CDER Note: Consult the Help feature on the pulldown menu for additional information on Query Language, toolbars, and toolbar options in present and future releases of the software.

Searching (Find) Text

Instead of sorting by an entire variable, you may wish to find just one instance of text. To perform a text search in The SAS System Viewer:

- Click the Find Button, 
- Enter the text you wish to find. Look for patient **0290029043**
- Click the Find Next Button



The SAS System Viewer will find the next instance for patient 0290029043. To search for the next instance of the patient ID number, click the Find button again.

While The SAS System Viewer is a user-friendly tool for data analysis, the system may not be able to handle some large datasets or perform graphing, solver, advanced searches, advanced queries, or sorting features that are available in Microsoft Excel and Access. StatTransfer will be used in the next lesson to convert the SAS Transport Files to MS Excel and Access formats.

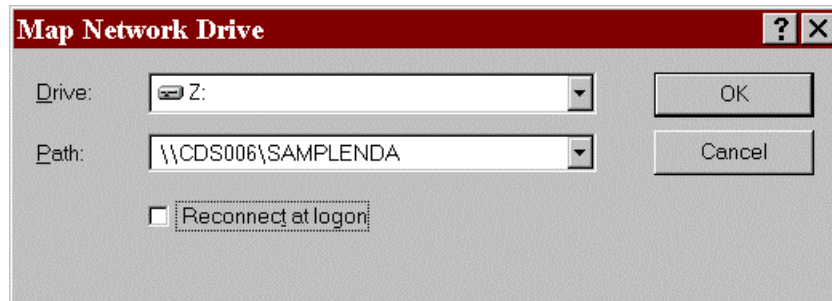
Before these files can be accessed from StatTransfer, a path must be saved to the shared area found via the EDR.

Map a Network Drive

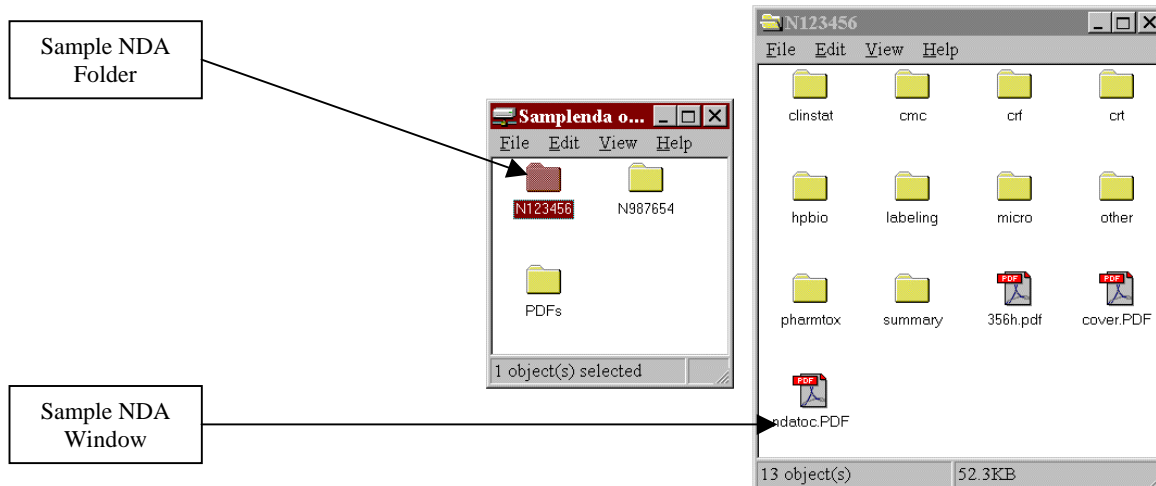
Once you have obtained the drive path of the sample NDA, you can access (map) this path on your desktop. Mapping will create a drive letter on your desktop, which allows easy access to the NDA shared area from applications used in the review process.

To map to a network drive:

- ☞ Minimize any open applications
- ☞ Right-click on My Computer and click Map Network Drive
- ☞ Select Z as the Drive letter and enter \\cfs006\samplenda in the Path: field
- ☞ Make sure the Reconnect at logon box is not checked (You may wish to check the box in order to repeat this process with every logon to your Office PC)
- ☞ Click the OK button (you should now be mapped to the Sample shared area)



Once you have mapped to the network drive, a window will open displaying the contents of the shared area. Double-click on the *N123456* folder to reveal the contents of our sample NDA.

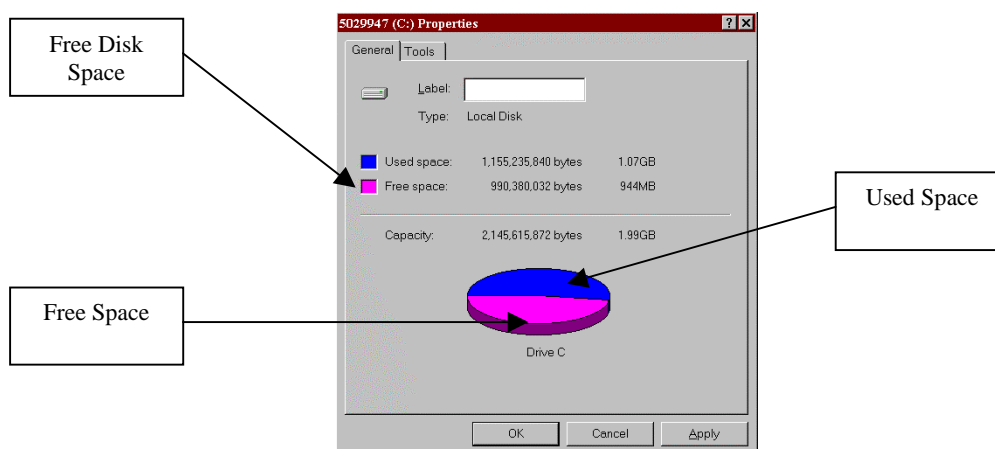


As you can see, this window is identical to the EDR. You can now access these files within your Windows 95 applications. You can also copy specific files or folders related to your discipline directly to your PC.

Copying Files or Folders to Your Computer

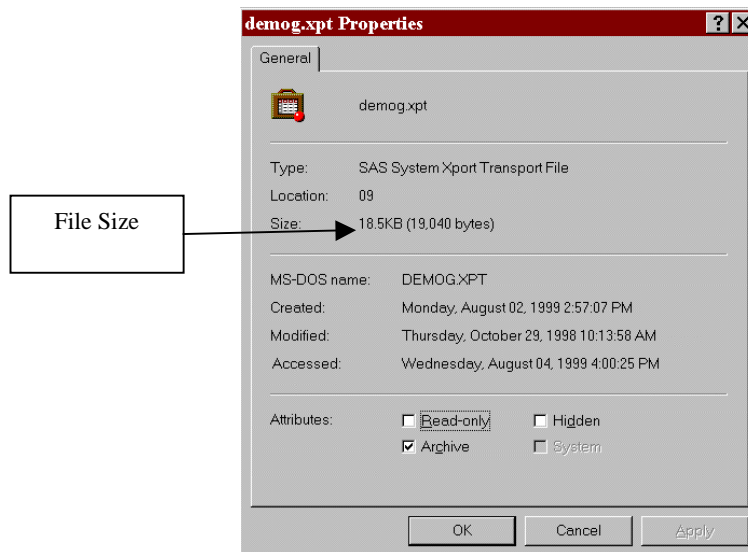
You can copy dataset files directly to your hard drive. This will allow you to convert datasets without accessing the network. Before you copy a folder or file, you need to make sure you have available disk space:

- ☞ Open My Computer and *right-click* on the C : drive icon
- ☞ Choose *Properties* on the pulldown menu. Note the free disk space on the C : drive and click OK.



To check the size of the file/folder:

- ☞ Double-click on the *crt* folder in the N123456 window
- ☞ Double-click on the *datasets* folder
- ☞ Double-click on the *09* folder
- ☞ Right-click on the *demog.xpt* file
- ☞ Select Properties from the pulldown menu



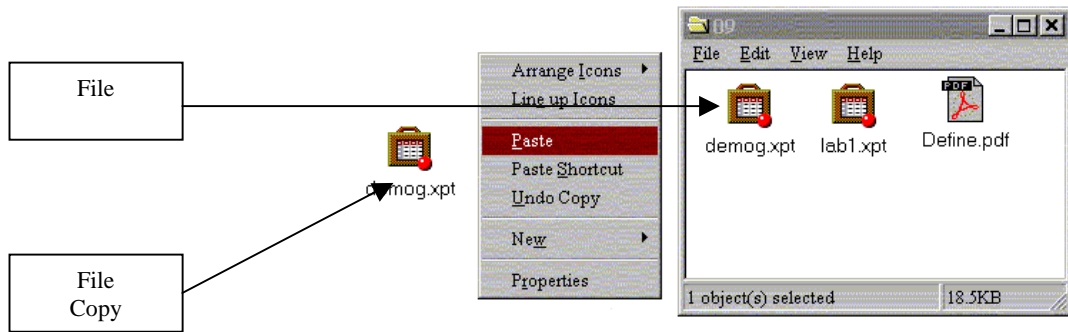
If the size of the file you are copying is less than the space available on your C : drive, continue to the next step. If the file is larger, you will not be able to copy the file to your C : drive.

- ☞ Click OK

CDER Note: It is recommended that you always keep at least 50mb available space on your hard drive for optimum PC performance.

To copy the file to your C : drive:

- ☞ Right-click on the *demog.xpt* file:
- ☞ From the pulldown menu, select Copy
- ☞ Move your pointer onto the desktop and right-click. A pulldown menu will appear.
- ☞ Highlight and click Paste



The file now appears on your desktop!

- ☞ To finish this lesson, close My Computer, any shortcut windows, The SAS System Viewer, Adobe Acrobat, and MS Internet Explorer.

NOTE: These directions for copying files apply to Amendments and Supplements as well. Make sure when creating a shortcut or copying a folder to note on your desktop whether that shortcut points to an Amendment, Supplement, or NDA.

Review

This lesson introduced you to accessing NDA, Amendment, and Supplement datasets via the Electronic Document Room (EDR). The SAS System Viewer was then used to open, navigate, sort and filter data in SAS Transport files. In order to convert the transport files to other formats, you learned how to map and save the drive path on your desktop for access by StatTransfer.

The following lesson will cover using StatTransfer to convert the SAS Transport files to file types compatible with MS Excel, and MS Access. To test your knowledge of the topics covered in lesson 1, answer the following questions:

- How do you access the Electronic Document Room (EDR)?
- How do you find the location of and NDA or Review using the EDR?
- What is the name of the table of contents file for the *crt* folder?
- What information is displayed in the column header?
- How do you find additional information on The SAS System Viewer?
- What is a Boolean expression?
- How much available hard drive space is recommended for optimum PC performance?
- What process is used to copy NDA folders?

Lesson 3 - Conversion and Analysis Tools

In this lesson, you will learn the following:

- About StatTransfer
- How to launch StatTransfer
- Convert SAS Transport Files to MS Excel and MS Access formats
- Use MS Excel and discuss enhanced analysis
- Become familiar with relational data analysis in MS Access

This lesson will take about 25 minutes to complete.

About StatTransfer V5

Data created by one program may be needed for analysis within another application. Not only must the data be transferred, but any supplemental information, such as variable names, missing values and variable labels must also remain associated with the data in proper format.

StatTransfer is a Windows based tool that allows fast, reliable conversion of data among multiple formats.

Using a Windows interface, StatTransfer automatically reads data from one program and transfers the data to the internal format of another supported application. StatTransfer supports the following formats (NEDAT formats in **bold**):

- 1-2-3
- **Access**
- ASCII – Delimited
- DBASE and compatible formats
- Epi Info
- **Excel**
- FoxPro
- Gauss
- **JMP**
- LIMDEP
- Matlab
- Mineset
- Minitab
- ODBC
- OSIRIS
- Paradox
- Quattro Pro
- SAS Datasets
- **SAS Transport Files**
- S-Plus
- SPSS Data
- SPSS Portable
- Stata
- Stata Version 6
- Statistica
- SYSTAT

Consult the HELP button on the Transfer tab in StatTransfer for additional information.

CDER Note: Contact your Focal Point for a licensed StatTransfer installation.

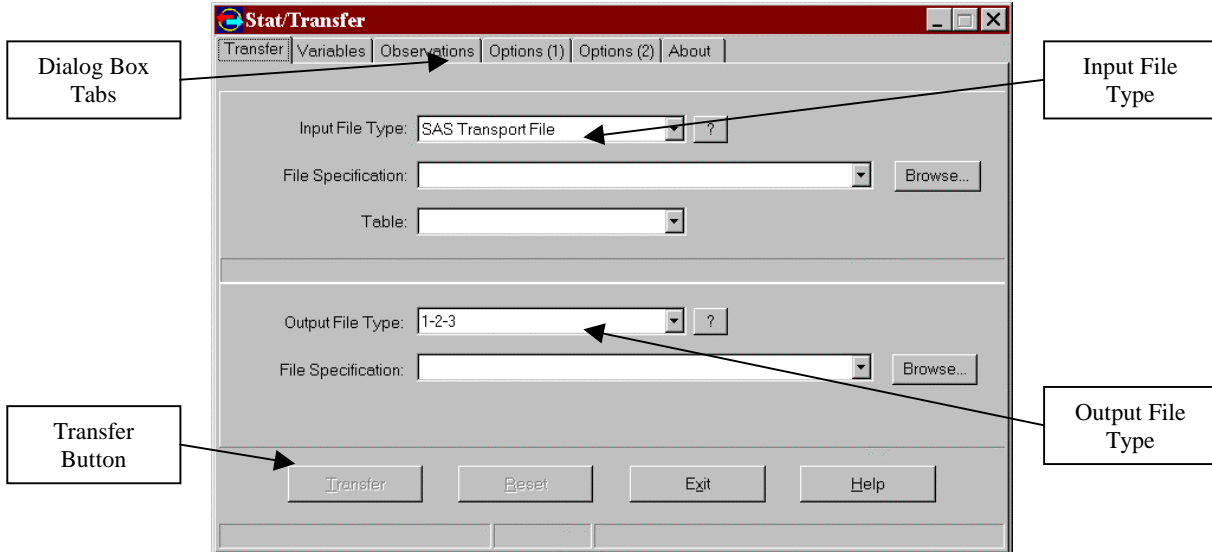
Launching StatTransfer

Electronic NDA datasets arrive in SAS Transport (.xpt) format. The format was chosen based on the ability to archive and the format's flexibility. Some statistical/spreadsheet programs are not able to open these datasets in their native format. Therefore, StatTransfer must be used to convert the .xpt files to formats used by some data analysis programs.

To Launch StatTransfer:

On the Win95 taskbar, go to Start | Programs | StatTransfer 5 | StatTransfer

StatTransfer will appear on the Win95 desktop



StatTransfer Dialog Boxes

The StatTransfer work area consists of five dialog boxes. To access these features, click the tab at the top of the window. When transferring all of the cases and variables from one format to another, you can immediately use the **Transfer** dialog box. The Transfer dialog box is used to simply choose the input and output file types and locations and will open automatically when launching StatTransfer.

If you want to select only some of the variables in the input dataset, click on the **Variables** tab at the top of the Transfer dialog box. You will be able to select/deselect the variables before performing the conversion. The **Observation** tab feature will allow you to select specific records and cases from your input dataset.

After you have achieved a familiarity with data conversion, you may find the need to change some of the **Options** with StatTransfer. The Options dialog box gives you access to changing the advanced formatting options within the software. Basic Information about the software can be found in the **About** dialog box.

Consult the HELP button in the Transfer dialog box for additional information.

MS Excel Conversion

As stated, SAS Transport files are not readily compatible with statistical software used within the Center. Use StatTransfer to convert these files to formats conducive with Center software.

To convert SAS Transport files:

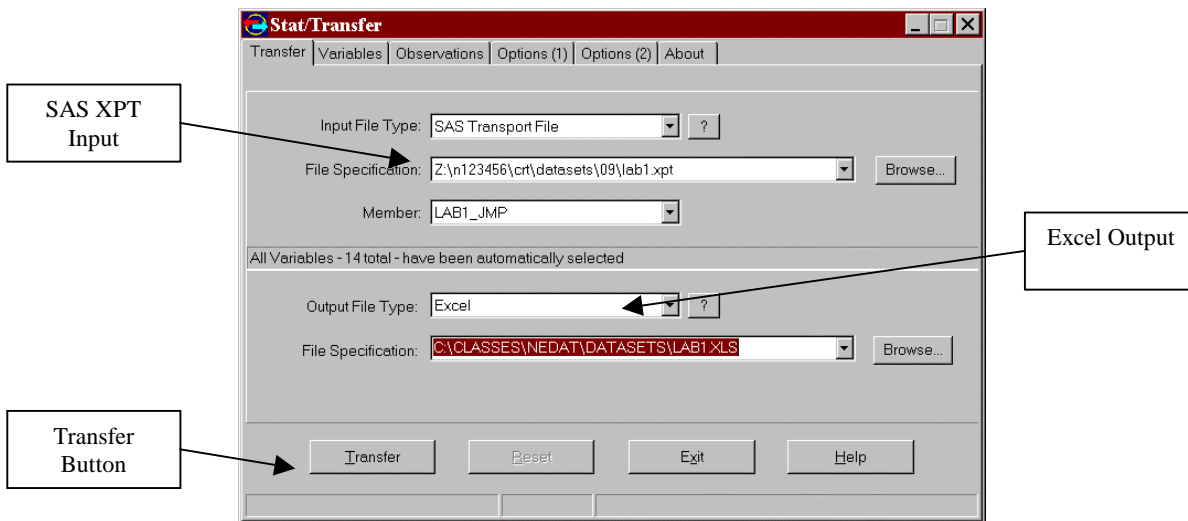
1. Choose the Input file type and location:

- ☞ Use the pulldown arrow in the Input File Type: field to choose the SAS Transport File option
- ☞ Click the Browse button next to the File Specification: field
- ☞ Navigate to the folder path, Z:\N123456\CRT\DATASET\09\ that was created in the second lesson
- ☞ From the File Name: field, select lab1.xpt
- ☞ Click OK

When the input file has been selected, a message, the Variable Selection Indicator, will appear displaying that all of the variables in the dataset have been selected.

2. Select the Output file type and location

- ☞ In the Output File Type: field, use the pulldown arrow to select the first format discussed, Excel
- ☞ Click the Browse button next to the File Specification: field and navigate to the folder C:\CLASSES\NEDAT\DATASETS
- ☞ Rename the file lab1.xls
- ☞ Click OK in the Save As window



- ☞ Click the Transfer button. (If you need to stop the conversion, the Transfer button is now labeled Stop. Press the button if you wish to halt the transfer)

- ☞ Once the conversion is complete, click the OK button to complete the transfer. The total number of transferred cases will appear at the bottom of the Transfer dialog box.

MS Excel can now be used to analyze the newly created SAS Dataset.

About Microsoft Excel

Microsoft Excel is the Windows based spreadsheet program of Microsoft Office. Excel uses formula creation, as well as natural language formulas that let you build equations using your own terminology. Charting options in Excel allow you to present data in chart types such as pie-of-pie and bubble charts. Since Excel is part of the Microsoft Office suite, you have the ability in Excel to build hyperlinks and import/export information to/from other Microsoft Office documents.

Open MS Excel Worksheet

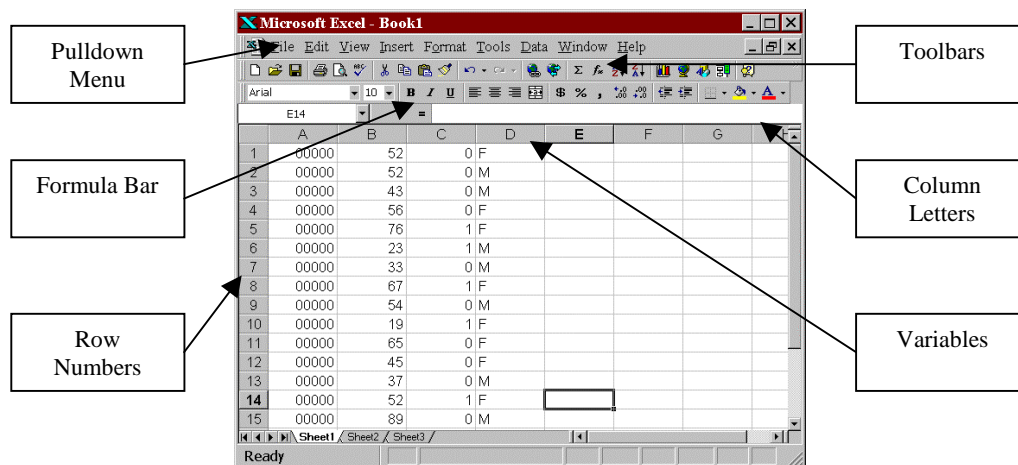
To open Microsoft Excel:

- ☞ On the Win95 taskbar, go to Start | Programs | Microsoft Excel

The MS Excel window is similar to The SAS System Viewer window. There is a pulldown menu at the top of the screen, with several toolbar options available.

To open the newly created Electronic Submission worksheet:

- ☞ On the pulldown menu, go to File | Open
- ☞ Navigate to the C:\CLASSES\NEDAT\DATASET folder
- ☞ Open the LAB1.XLS file



Several noticeable differences exist between the MS Excel and The SAS System Viewer windows. The Variables that were the Column Headers in The SAS System Viewer have been

converted to cells. Also, there is a Formula bar that allows new data entry and formula calculations.

MS Excel Features

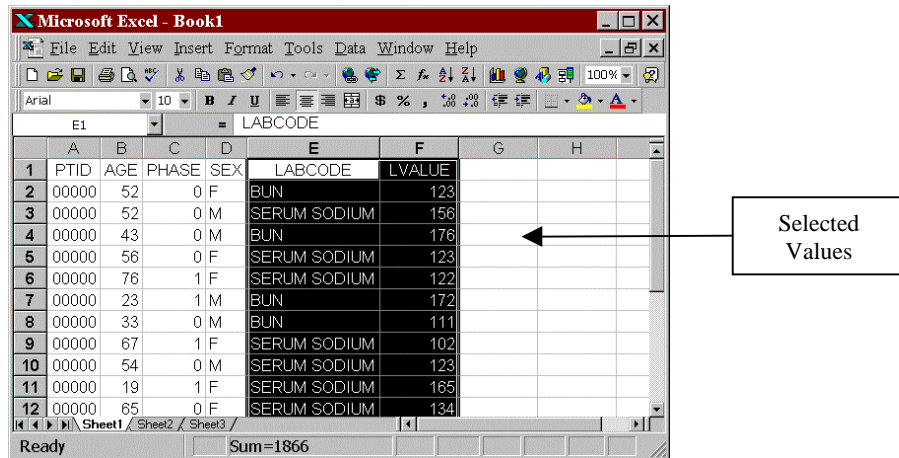
While The SAS System Viewer allows for basic sorting and text searches, Microsoft Excel has the capabilities to perform the following advanced features (NEDAT in **bold**):

- Advanced Sorting
- Auditing
- Formula Calculations
- Conversion to other formats
- **Graphing**
- Links to other MS Office Applications
- Editing and revision tools
- AutoFilter


In order to sample the one of the power analytical tools in MS Excel, perform a quick graphing of the newly converted data.

Using the Excel graphing features, compare the lab values at baseline and after drug for the first patient, 0290019584:

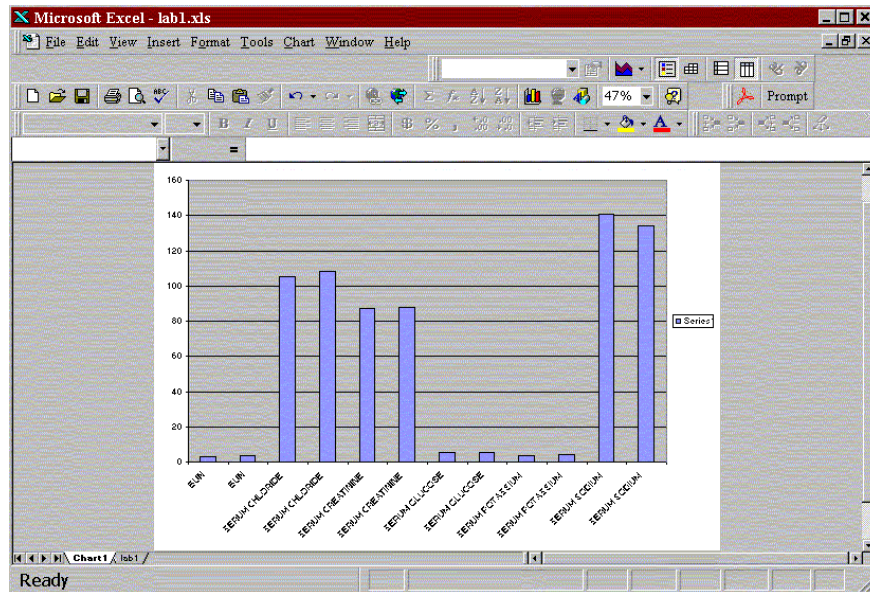
- ☞ In the LADCODE column, click in the first cell of row 2.
- ☞ Hold down the mouse and drag down to the last LADCODE value for the patient (row 13 - SERUM SODIUM)



- ☞ Hold down [CTRL] and select all the lab values (LVALUE column) for the patient

- ☞ On the standard toolbar, click on the Chart Wizard, 

- ☞ Since the values were selected, click the Next button three consecutive times until you get to the last Chart Wizard window
- ☞ Since some of the text in the LABCODE column is large, check the As new sheet button to create a new worksheet with the table
- ☞ Click Finish



A new worksheet has been created that shows the baseline value of the lab next to the value after treatment. As the chart illustrates, there was a slight increase in chloride and a slight decrease in sodium.

This exercise is a basic example of the charting tools available in MS Excel. Consult the Help option on the pulldown menu for specific information about these analytical, and additional, features available in MS Excel.

CDER note: OIT offers an Introduction to Microsoft Excel course. Consult the OIT Home page ([HTTP://OITWEB/OIT](http://oitweb/oit)) for dates and registration.

While MS Excel offers these advanced analytical features, you may have a need to perform advanced relational queries and reports. MS Office also have a relational database application, MS Access, that is compatible with SAS Transport files and Stat Transfer.

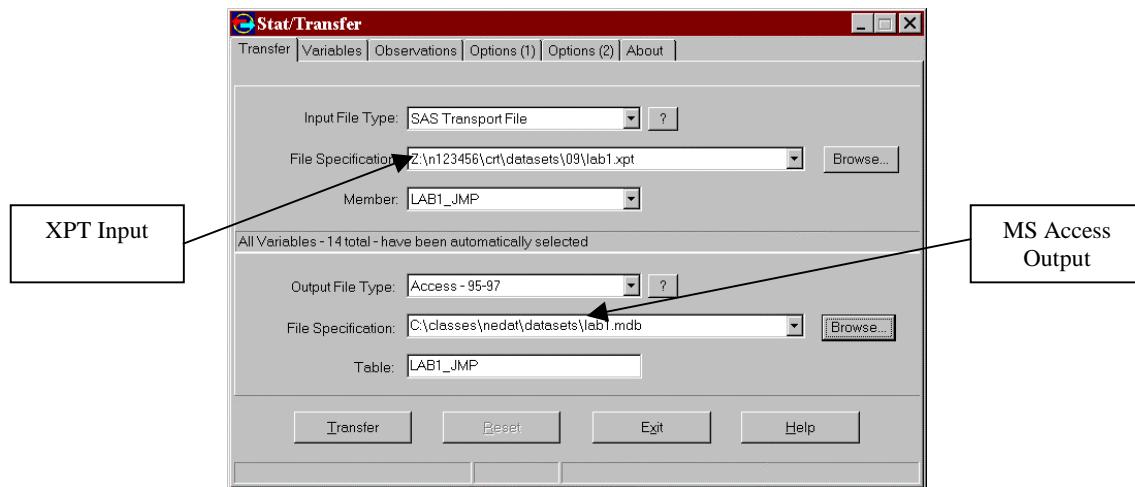
You can close MS Excel at this point in the training.

Microsoft Access Conversion

In order to convert the network copies of the SAS Transport file to MS Access, we need to go back to the Stat Transfer software.

To convert the dataset to MS Access:

- ☞ On the Win95 taskbar, click on the Stat Transfer button
- ☞ Click the Reset Button at the bottom of the Stat Transfer window
- ☞ Repeat Step 1 under the MS Excel Conversion section of this lesson
- ☞ Make sure to choose Access 95-97 in the Output File Type field
- ☞ In the Save As window, navigate to C:\CLASSES\NEDAT\DATASETS and click on the filename lab1.mdb (A sample database was created. StatTransfer will add the converted table to the database)
- ☞ Click the Transfer button



- ☞ Click the Reset button
- ☞ Repeat the previous conversion steps, this time converting the file Z:\N123456\CRT\DATASETS\09\DEMOG.xpt

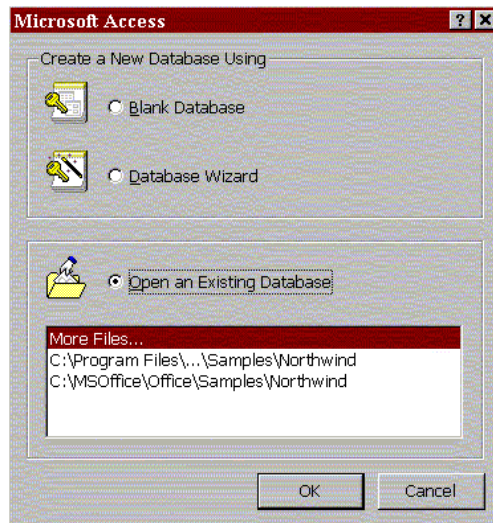
After converting the second table, click the **Exit** button on StatTransfer.

About Microsoft Access

Microsoft Access is a relational database management application that integrates and organizes information from spreadsheets and other databases. Multiple datasets from an Electronic NDA can be converted to multiple MS Access tables, where advanced query functions can be utilized.

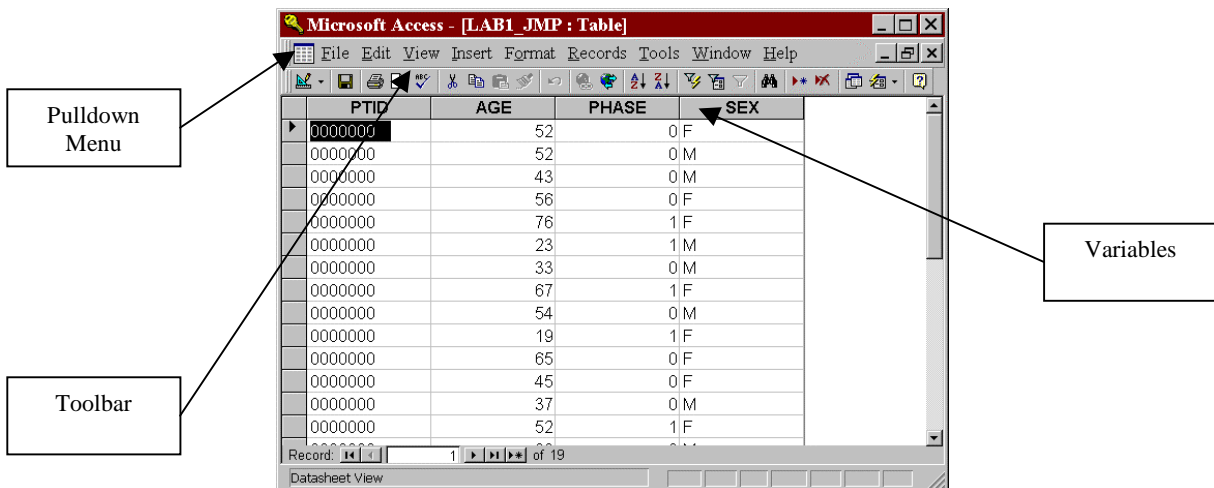
To open MS Access:

- ☞ On the Win95 taskbar, go to Start | Programs | Microsoft Access.
- ☞ When Access is launched, a window appears with several options:



- ☞ Make sure the Open an Existing Database radio button is checked and choose the More Files... option
- ☞ Open the C:\CLASSES\NEDAT\DATASET\LAB1.MDB file

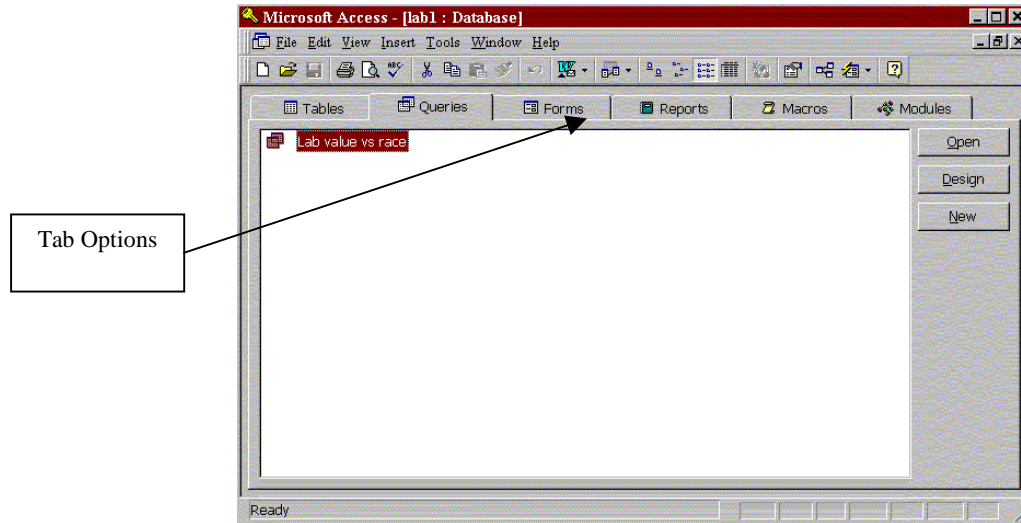
The datasets we converted are now displayed as icons in the Tables tab of MS Access. To open a table, *double-click* the *lab1_jmp* icon on the Tables tab.



As you can see, MS Access maintains the variables as column headings. The Access table is similar to the Excel Spreadsheet and the two applications share many of the same toolbar functions.

MS Access Features

When you close the Access table, you will be taken back to the main Access window. From here, you can access the features of MS Access by clicking on the related tab. Click on the **Queries** tab in the MS Access window.



Tables

Similar to the data we have been viewing in The SAS System Viewer and MS Excel, the table feature is used to provide the data used in the additional MS Access Features.

Queries

Like to SQL string in The SAS System Viewer, queries are used to view, change, and analyze data in various formats. You can also use them as the source of data for **Forms** and **Reports**.

Forms

A form is a customized, visual interface that allows you to access/add to your data in a variety of ways.

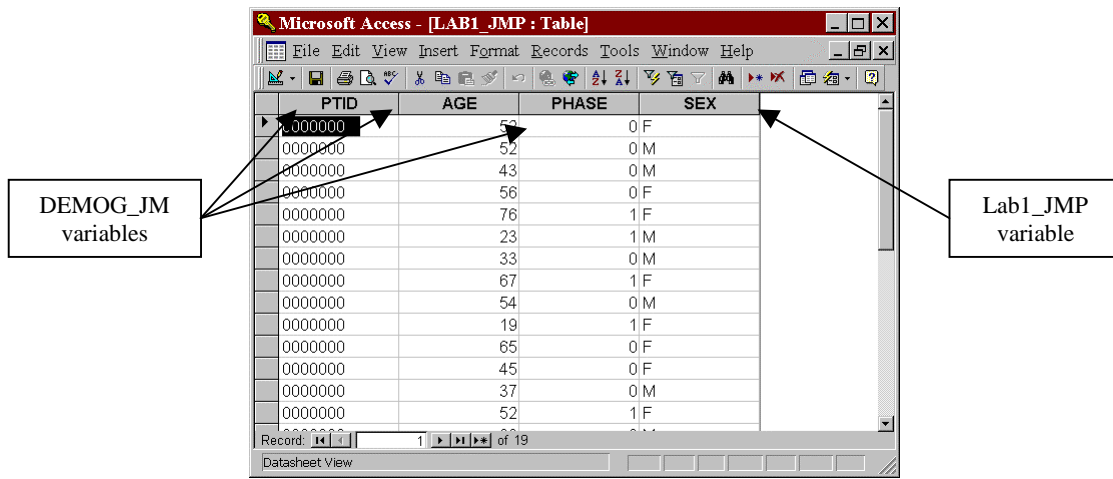
Reports

A report is an effective way to customize the appearance of your data in a your desired output format (e.g., printed.) Because you have control over the layout of a report, you can tailor the information specific to your discipline.

In order to sample one of the powerful relational tools available within MS Access; let's take a look at a sample Query that was previously created, *lab1.mdb*.

Use the query functions of Access to find any lab values above 140. Display the patient's age, sex, race and patient ID number:

- Click on the Lab value vs race query that has been created
- Click on the Open button in the Query window.



The query was set up to first sort the DEMOG_JM table by the PTID, AGE, SEX, and RACE variables. However, the LVALUE was listed in the LAB1_JMP table. Because the variable PTID was constant in both tables, the query was able to join the two tables at that variable and query the last field from the LAB1_JMP table in order to display all LVALUES that are above 144.

Consult the Help feature on the pulldown menu to learn more about Macros, Modules as well as all additional features of MS Access.

CDER note: OIT offers several introductory and advanced tables and reports classes in MS Access. See the OIT Home page ([HTTP://OITWEB/OIT](http://oitweb/oit)) for dates and registration information.

- Close MS Access and StatTransfer to complete this lesson.

Review

In the previous lesson, we learned how to perform sorting and query functions on datasets using The SAS System Viewer. This lesson explored how to convert SAS Transport files using StatTransfer to MS Excel and Access to perform advanced analysis and queries. The next lesson will cover using an advanced, but user friendly software package, JMP, to consolidate all of the functions discussed in the three applications covered in the previous two sections.

To test your knowledge of the concepts and techniques you learned in this lesson, answer the following questions:

- Why do you need StatTransfer to convert NDAs data files?
- In the Open window of StatTransfer, what field do I need to change to open a SAS Transport file?
- What is a Variable?
- How do I find additional information on MS Excel and Access?
- Can I open the SAS Transport files located on the network to perform my analysis?
- Is there additional training offered by OIT for Excel and Access?

Lesson 4 – JMP Features

In this lesson, you'll learn how to do the following:

- Launch JMP
- Import network SAS Transport files into JMP
- Navigate and Select data
- Access the Data Definition Table (*define.pdf*)
- Save a JMP file

This lesson will take about 15 minutes to complete.

About JMP

JMP is a statistical software package developed by the SAS Institute. It provides a graphical interface to display and analyze data. JMP includes:

- a spreadsheet for viewing, editing, entering, and manipulating data
- a broad range of graphical and statistical methods for data analysis
- options to highlight and display subsets of the data
- tools to sort and combine tables
- a calculator for each table column to compute values
- a facility for grouping data and performing subgroup analyses
- tools for moving analysis results between applications and for printing

This lesson is an introduction to JMP. Basic JMP navigation, cell selection, and column and row manipulations is covered. The next lesson will demonstrate how JMP can be used to review data in much the same way one would use a paper or PDF Case Report Tabulation. In addition, powerful data manipulation and analysis tools available in JMP will be examined.

CDER note: Contact your Focal Point for JMP license and installation.

Launch JMP

When JMP is installed on your PC, a shortcut to the software can be found in the Programs section of the Start menu.

To launch JMP:

☞ On the Win95 taskbar, go to Start | Programs | JMP | JMP

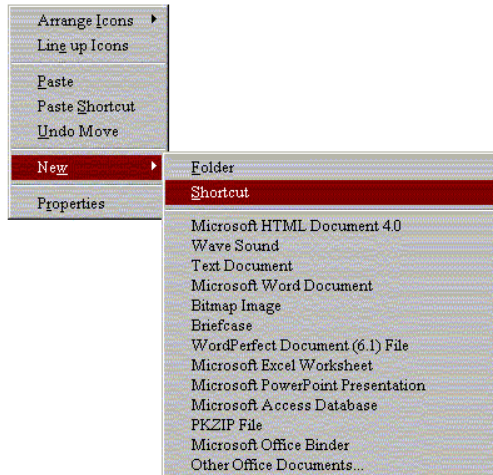
You may also wish to side step this procedure in the future by creating a desktop shortcut to JMP.

To create a desktop shortcut:

☞ Minimize any open windows

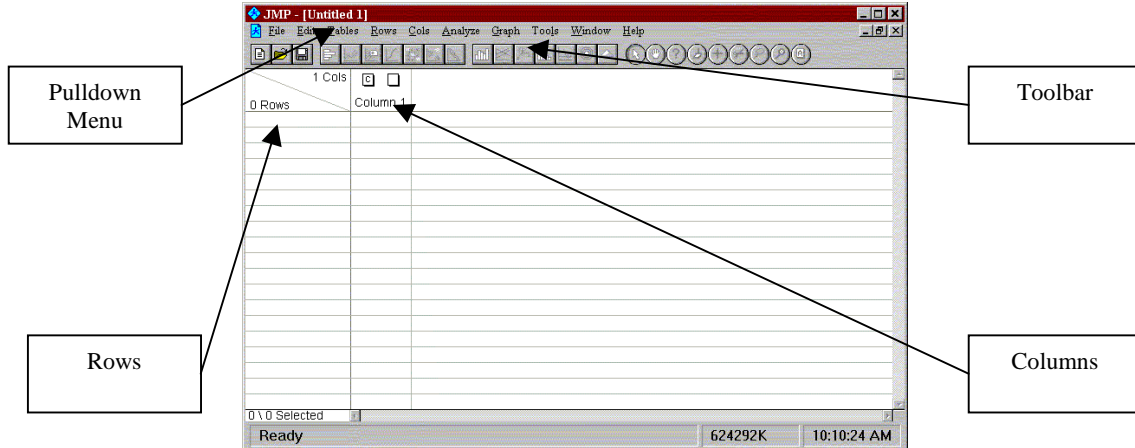
☞ Right-click on the Win95 desktop

☞ From the popup menu, choose New | Shortcut



- ☞ When asked for the command line, enter **C:\JMP\Jmp.exe** (use the browse button if you are not sure of the JMP file location)
- ☞ Change the name of the shortcut to **JMP**
- ☞ Click the Finish button
- ☞ To access JMP in the future, *double-click* the desktop shortcut.

Either one of these option swill launch JMP and take you to the main JMP screen.

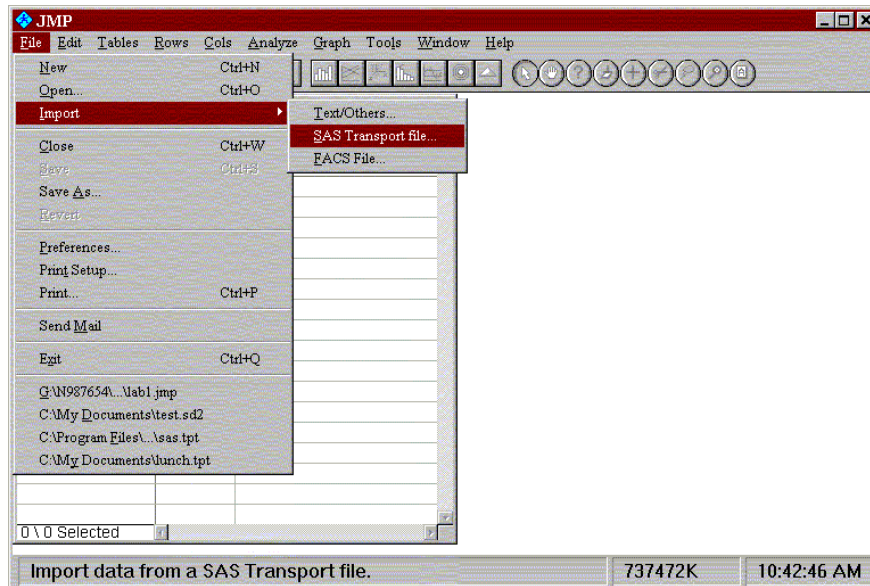


Import a SAS Transport File

In the previous lesson, we used StatTransfer to convert .xpt files to MS Excel Worksheets and Access tables. JMP has the capability built-in to do this conversion from SAS Transport files.

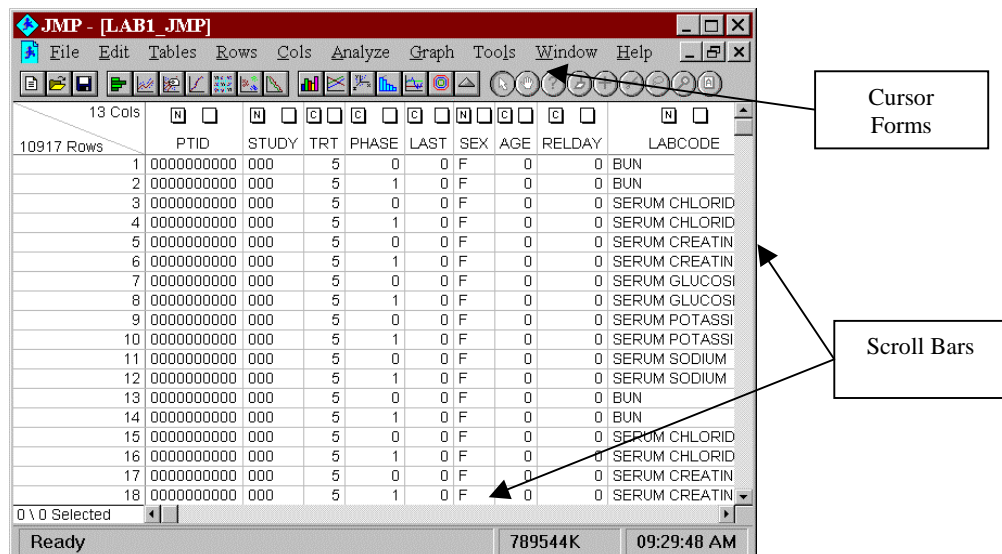
To import a SAS Transport file:

- ☞ On the pulldown menu, go to **File | Import | SAS Transport file...**



- Navigate to Z:\N123456\CRT\DATASETS\09
- Because the .xpt file extension is new, some software versions may not immediately recognize the file extension. Change the Files of type: field in the bottom left hand corner of the import window to All Files (*.*)
- Click on the lab1.xpt icon
- Click Open

The SAS Transport file is now in JMP format.





Navigating a JMP Dataset


Cells are the location where rows and columns intersect. To select a cell, click directly on top on the cell and the cell will be **highlighted**. This highlighting indicates the active cell. You can also use the mouse to scroll up/down or side/side by clicking or clicking and dragging the scroll bars. Use the following tools to navigate the dataset using the keyboard:


Action	Result
← or → keys	Move one cell left/right
↑ or ↓ keys	Move one cell up/down
[CTRL] + ← or [CTRL] + →	Move to beginning/end of visible row
[CTRL] + ↑ or [CTRL] + ↓	Move to beginning/end of visible column
[Home] or [End]	Move to first/last cell in dataset
[Page Up] or [Page Down]	Scroll up/down one screen


Cursor Forms

Cursor forms are present and can be selected to do the following functions:

arrow   - the default cursor form, present when you hover over the deselect areas in the upper left hand corner or when hovering over the data modeling type box in the column header

cross  - when over a column header or a data cell, the cross indicates the ability to select text. When you click on the cross cursor, the text highlights and can be edited. The cursor then becomes an I-beam.

I-beam  - this is a vertical blinking bar which allows you to edit text in a column header or data cell

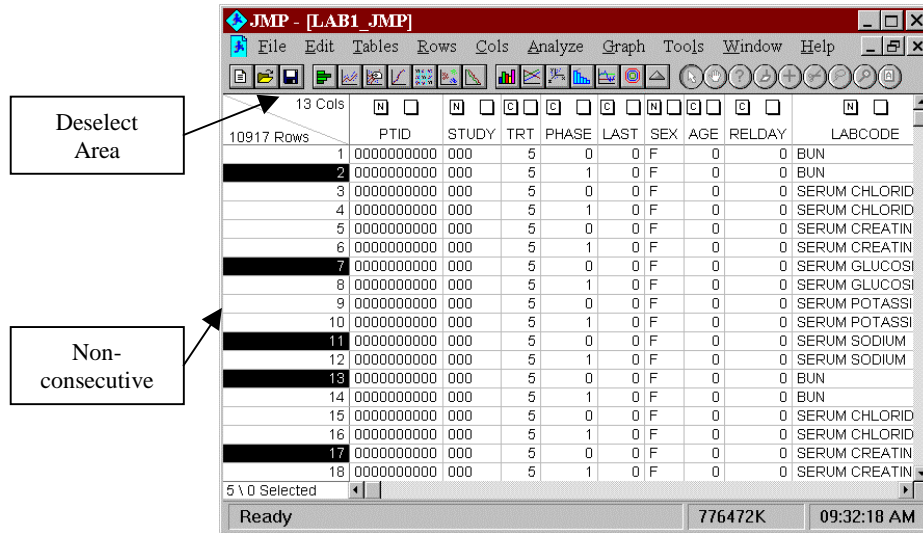
open cross  - is present when you move into a column or row selection area. Use the open cross to select a single row or column. *Double-click*, using the open cross in the column header to get additional column information.

Selecting Cells

Before performing any action, you will first need to select the cells involved in the action. As we have already seen, clicking once on a cell selects that active cell. To select an entire row, click on the row number. The row number will be **highlighted**. Click a Column Header to select an entire column.

Consecutive rows can be selected by clicking on a row number, holding down the mouse button and dragging up/down. Let go of the mouse to finish selecting rows. Non-consecutive rows can

be selected by clicking on a row number, holding down [CTRL], and clicking on another row number. Use [SHIFT] in the same manner to select a series of rows.



Use the same functions to select consecutive, non-consecutive, and a series of columns. Selecting all of the rows or columns will select all of the cells in the Dataset. You can also click the button above the row numbers/left of the column headers or go to **Edit | Select All** on the pulldown menu to select the entire table.

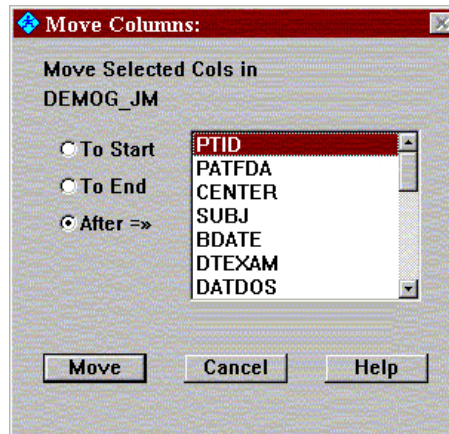
Deselecting Cells

To deselect columns, click in the **Columns** detail area in the top left corner of the dataset. To deselect rows, click in the **Rows** detail area in the top left corner of the dataset.

Move and Hide Columns

To move a column:

- ☞ Select the column Study
- ☞ On the pulldown menu, go to **Cols | Move Columns**
- ☞ Select the **After** radio button
- ☞ Highlight PTID



- ☞ Click the Move button

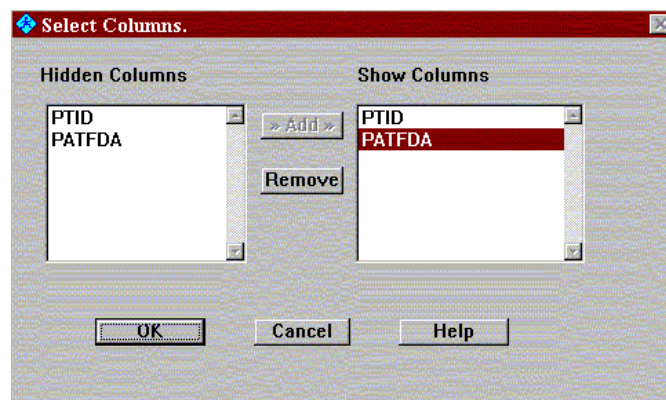
You may also choose a different Move option from the Cols pulldown menu. Repeat the steps to move the column back

To hide a column:

- ☞ Select the PTID and PATFDA columns
- ☞ On the pulldown menu, go to Cols | Hide Columns

Those columns now disappear from the table. To view the columns again:

- ☞ On the pulldown menu, go to Cols | Unhide Columns
- ☞ Select the columns to unhide
- ☞ Click the Add button



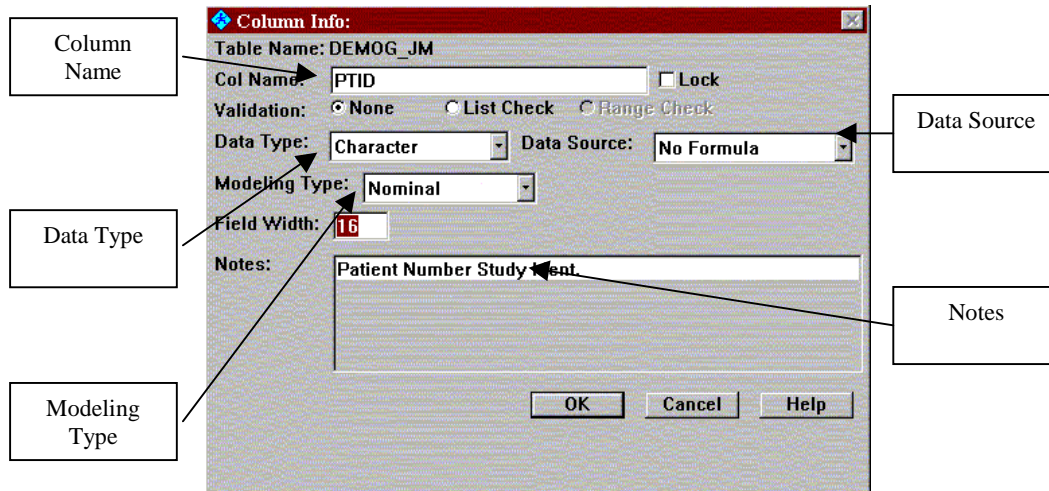
- ☞ Click OK

Column Headers

The Column Headers contain the column's variable name, type, field width, format, modeling type, level, data validation information, and general text notes about the column. If the column is computed, its formula is displayed in the box in the lower left corner of the dialog. The **Notes** field will automatically include the variable label (see Lesson 2.) A note field can also hold up to 29K characters.

To access a column header:

- Double-click on the PTID column header using the open cross



Column Header Fields:

Field	Content
Col Name	Contains the column name
Validation	set up a table of acceptable values
Data Type	Choose numeric or character
Modeling Type	Choose Continuous (numbers), Ordinal (characters or numbers that have an order), or Nominal (characters or numbers with discrete values)
Data Source	Choose Formula or No Formula
Notes	Variable label

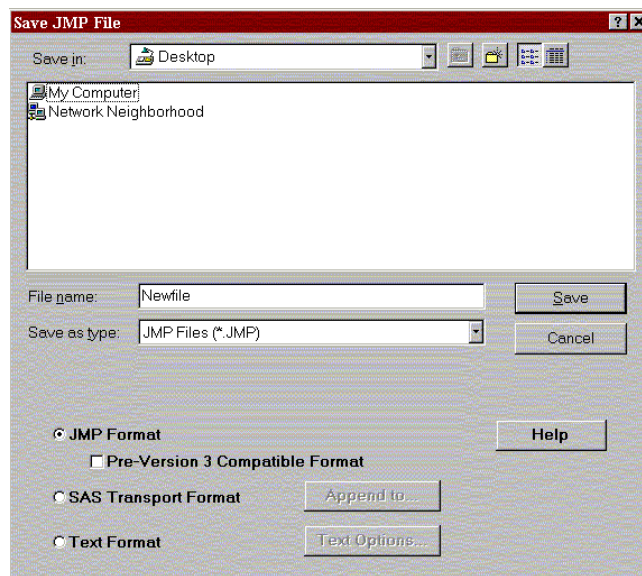
- Click on the OK button to remove the column header.

Saving a JMP File

Since the network datasets cannot be edited, you must save any of your work as a JMP file. If you do not save your changes, all work will be lost and you will have to import the SAS Transport file again.

To Save:

- On the pulldown menu, choose File | Save As
- Navigate to the C:\CLASSES\NEDAT\DATASET folder
- Rename the file DEMOG.JMP
- Click the Save button



Review

In this lesson, you learned the basic features of JMP. The next lesson will discuss the tools needed to perform statistical analysis and export your information to other applications.

To test your knowledge of the concepts and techniques you learned in this lesson, answer the following questions:

- How do you import a SAS Transport file?
- Where do you click to deselect Columns? Rows?
- What is the file name of the Data Definition table?
- Where else can you find a variable definition in JMP?
- How do you navigate to the end of a JMP dataset?
- Can JMP view the SAS Transport NDA data files located on the network?
- Does importing a SAS Transport files automatically save a JMP file?

Lesson 5 – JMP Tools

In this lesson, you'll learn how to use JMP analytical tools. Each tool will contain a brief explanation, as well as exercises in **bold** that apply the topic to NDA data analysis. The following tools are covered in this lesson:

- The Sort Command
- Select Rows "Where..."
- Subset Command
- Search Command
- Group Summary
- Distribution of Y
- Exclude/Include
- Adding a Computed Column
- Fit Y by X
- Exporting to MS Excel and Word

This lesson will take about 40 minutes to complete.

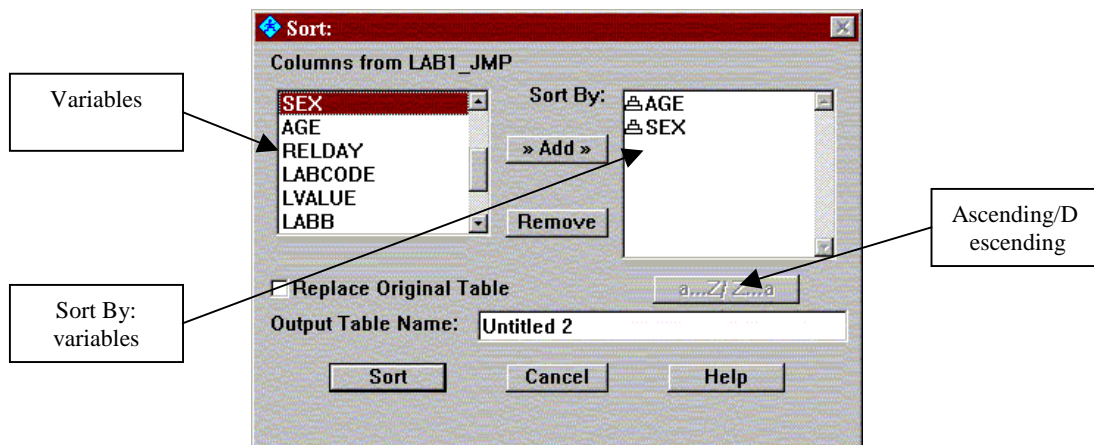
Sort Command


The Sort command sorts a dataset by columns. Use the sort dialog box to add/remove columns as sort fields.

Exercise 1: Use the sort command to sort the table by age and sex, in ascending order.

To sort the table:

- ☞ On the pulldown menu, select Tables | Sort
- ☞ Select AGE as the first sorting variable
- ☞ Click Add
- ☞ Select SEX as the second sorting variable
- ☞ Click the Add button
- ☞ Click the Sort button



You can also sort in ascending/descending sort by clicking on . **Add the variables in order, as procedures in the lesson are order sensitive!**

- ☞ Close the new file, *Untitled2.jmp*, to move on to the next topic.

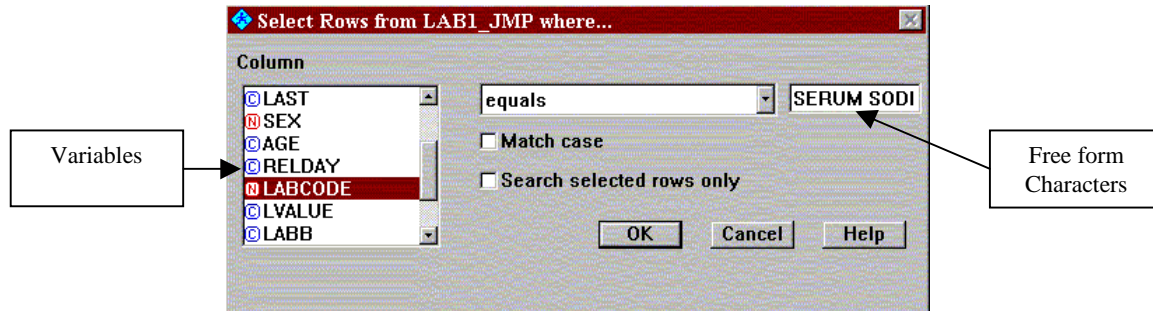
Select Rows "Where..."

When you are only interested in selecting a group of records (rows) that meet a specific criterion, you can use JMP tools to choose these specific rows.

Exercise 2: Display only the data for serum sodium.

- ☞ On the pulldown menu, go to Rows | Select | Where...

- ☞ In the Column area, Click on LABCODE
- ☞ Make sure the equation is Equals
- ☞ In the free form character field, type SERUM SODIUM
- ☞ Click OK



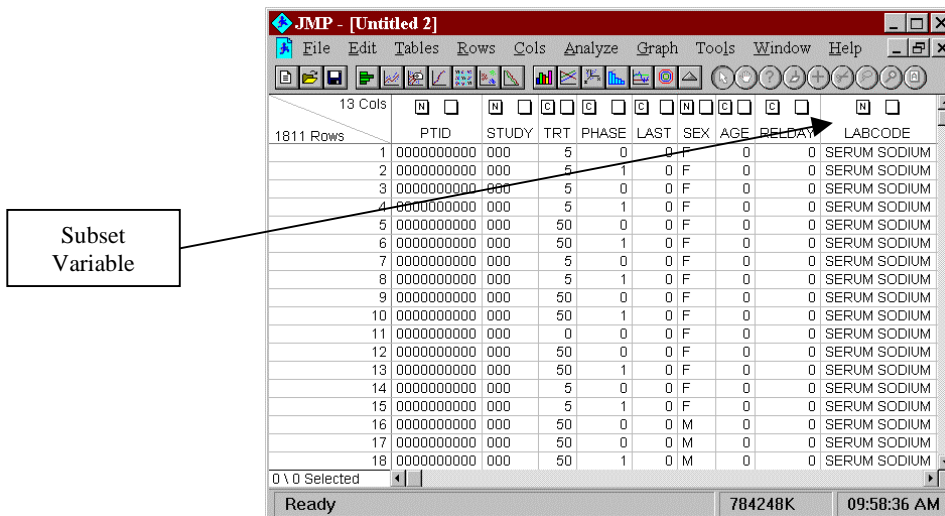
The rows meeting this criterion are highlighted in black.

Subset

Use the Subset command if you wish to pull selected records into a separate, but linked table.

Exercise 3: Subset the selected serum sodium rows of data.

- ☞ On the pulldown menu, go to Tables | Subset



Only those highlighted serum sodium rows and columns appear in the new table.

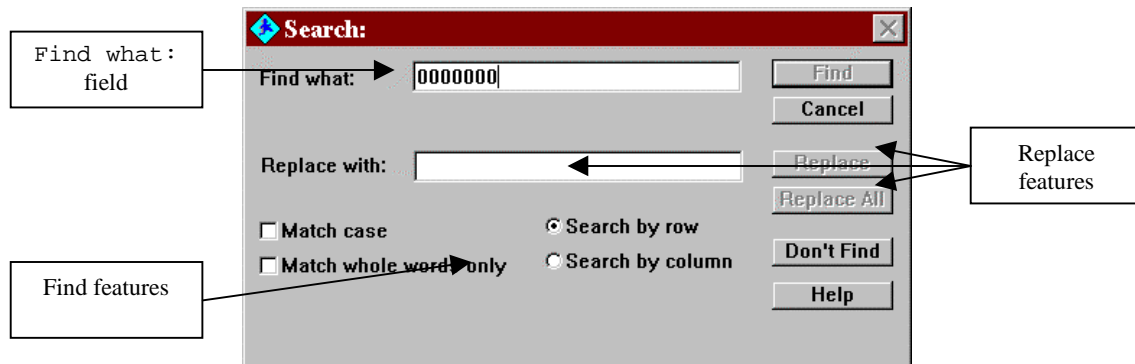
- ☞ Close the newly created *Untitled2.jmp* file and deselect the highlighted serum sodium to move to the next topic.

Search Command

The Search command is used to find and replace text. This command allows you to search for a series of words in a character column, or locate strings with unwanted leading or trailing blanks.

Exercise 4: Search for the patient with ID number, 0000000.

- ☞ On the pulldown menu, go to Edit | Search | Find
- ☞ In the Find what: field, type **0000000**
- ☞ Click the Find button



The first instance of the text, 0000000, is highlighted in the table. To search again, repeat this process. The Find what: field will automatically contain the previous entered text.

Find Features:

Match Case: gives you a case sensitive search

Match whole words only: locates words with at least one leading and one trailing blank

Search by row and Search by column: determine whether the search is performed along rows or columns.

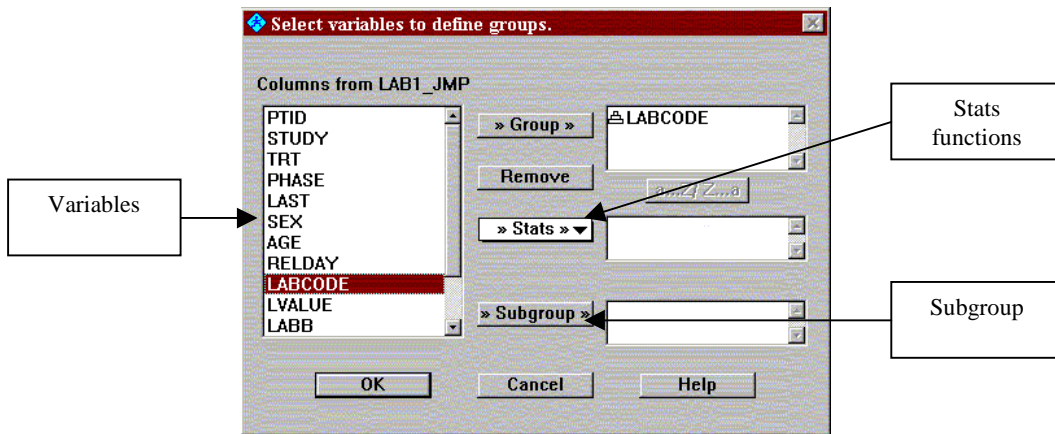
- ☞ Deselect all rows and columns to continue.

Group Summary

The Group/Summary command creates a new JMP table that summarizes columns from the active data table. The summary table has a row for each row or combination of levels of all grouping variables. Up to this point, many reviewers relied on sponsors to do the tasks made available with the Group/Summary command.

Exercise 5: Use the Group/Summary command to find the number of tests per lab test category.

- ☞ On the pulldown menu, go to Tables | Group Summary
- ☞ In the Columns field, select LABCODE
- ☞ Click the Group button
- ☞ Click OK



The new table shows the lab test categories, as well as the number of rows (tests) for each category.

- ☞ Close this new table before moving on to the next example.

You can also group by more than one variable, sub group, and add columns of descriptive statistics to the summary table for any numeric column in the source table. When selecting multiple variables, make sure to add them in the same order you wish the variables to appear in the table.

Exercise 6: Use Group/Summary to find the mean lab value for each test, grouped by treatment assignment, and subgrouped by study period (baseline vs. treatment).

- ☞ On the pulldown menu, go to Tables | Group Summary
- ☞ In the Columns field, select LABCODE
- ☞ Click the Group button
- ☞ In the Columns field, select TRT

- ☞ Click the Group button
- ☞ Select LVALUE
- ☞ Click on the Stats button and choose Mean
- ☞ Select PHASE
- ☞ Click on the Subgroup button
- ☞ Click OK

The new summary table lists the mean lab values by treatment group, and is subgrouped by study period. Take note that in the last few rows, the table displays how the drug affects the serum sodium Values! Save this table, as it will be used later in this lesson:

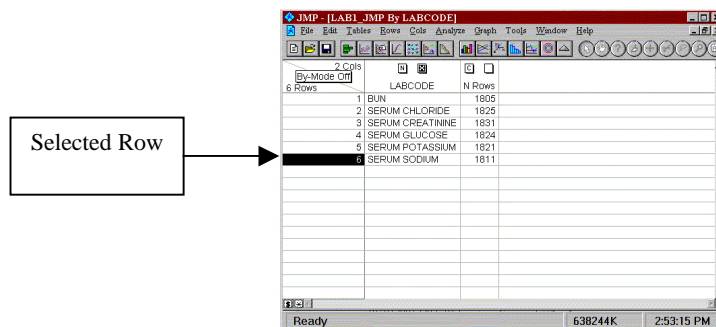
- ☞ On the pulldown menu, go to File | Save As
- ☞ Save the file as C:\CLASSES\NEDAT\DATASET\LABMEANS.JMP
- ☞ Leave the table open and display the original table by going to Window | LAB1_JMP.

Distribution of Y

The Distribution of Y function is used to provide a partitioning of values with histograms, as well as other graphic and text reports.

Exercise 7: Use the Distribution of Y function to find the distribution of post-treatment serum sodium values in this study.

1. Group by the table by LABCODE
 - ☞ On the pulldown menu, go to Tables | Group Summary
 - ☞ In the Columns field, select LABCODE
 - ☞ Click the Group button
 - ☞ Click OK
2. Highlight the serum sodium row in the newly created summary table



3. Select the original table and subset the data to get a table for just serum sodium values.

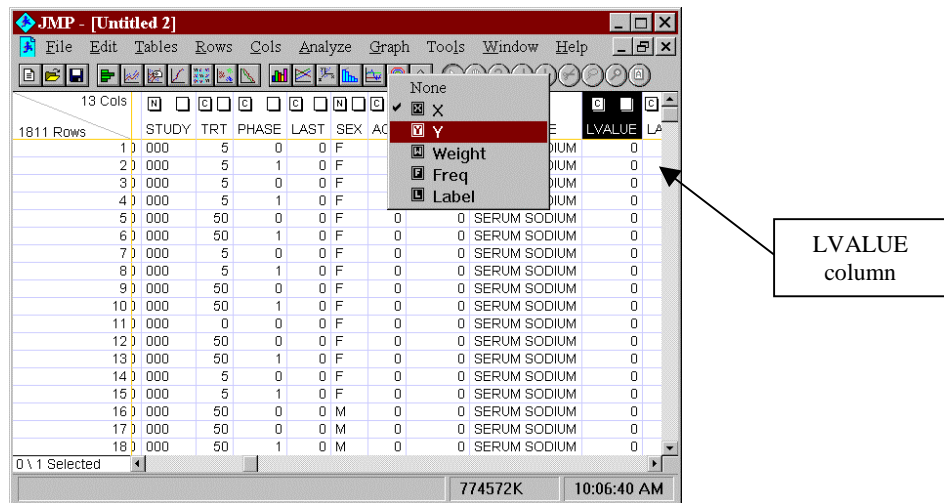
☞ Go to Window | LAB1_JMP


☞ On the pulldown menu, go to Tables | Subset

4. Assign LVALUE as "Y"

☞ Click on the right square above the variable name LVALUE in the column header

☞ Choose Y from the pop up menu



5. On the pulldown menu, select Analyze | Distribution of Y (you can also click  on the toolbar)

The histogram, box plot, quintiles, and statistical moments are displayed. The display can be altered by clicking on the “check” mark that brings up a menu in the lower left of the window.

The graph may not provide the necessary information because the tables used combines baseline and post treatment values. You will want to **exclude** all baseline values before performing a Distribution of Y.

☞ Return to our serum sodium table (Untitled2) to complete the next task.

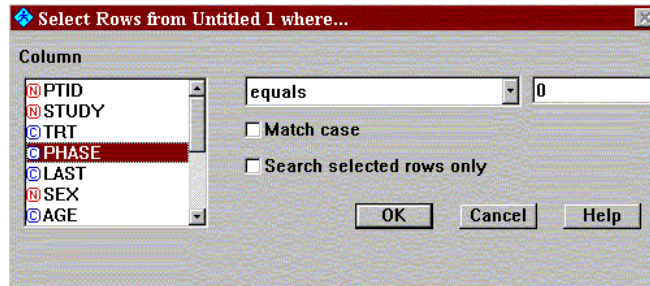
Exclude/Include

The Exclude/Include feature allows you to exclude certain rows from statistical analysis.

Exercise 7 (cont.): Reproduce the previous graph without baseline values.

1. Select the baseline value rows from this table

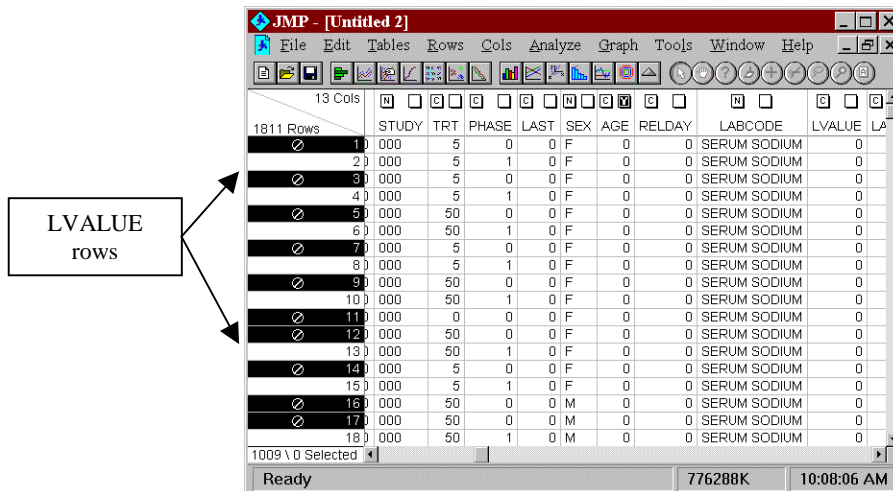
- ☞ On the pulldown menu, go to Rows | Select | Where...
- ☞ In the Column Area, choose PHASE
- ☞ Make sure equals is the equation
- ☞ In the free form character area, type 0
- ☞ Click OK




All of the rows where PHASE equals 0 are now selected.


2. Exclude the selected baseline rows

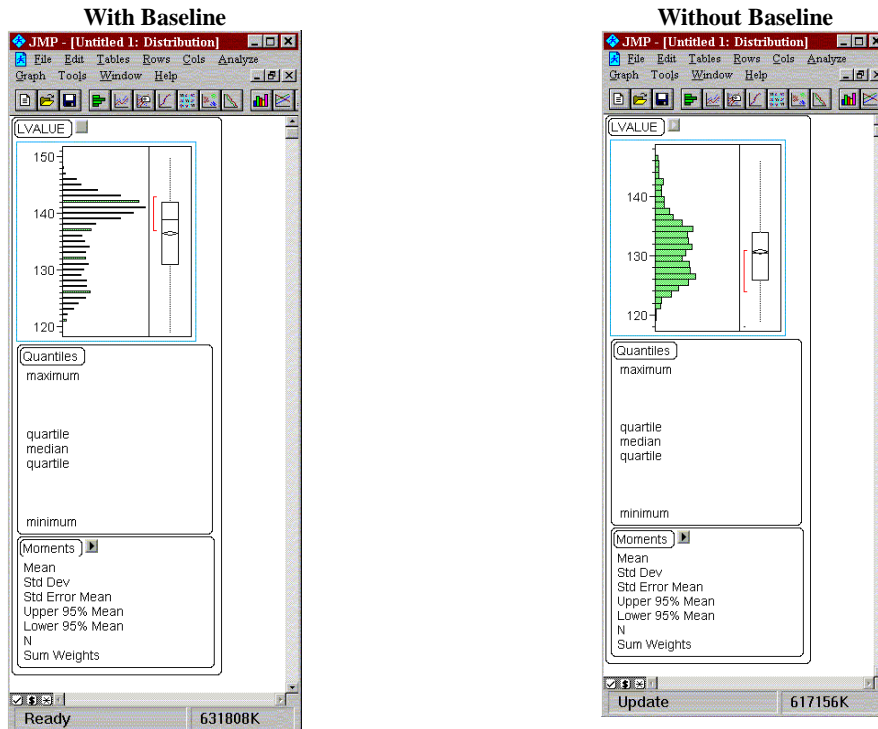
- ☞ On the pulldown menu, go to Rows | Exclude/Include



The excluded rows are marked with . Data will remain excluded until Exclude/Include is chosen again.

3. Distribute by Y

- ☞ On the toolbar, click 
- ☞ Cascade windows to show both charts



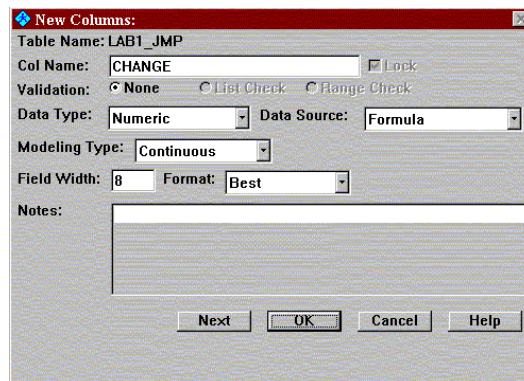
The chart now excludes the baseline values from the analysis.

Adding a Computed Column

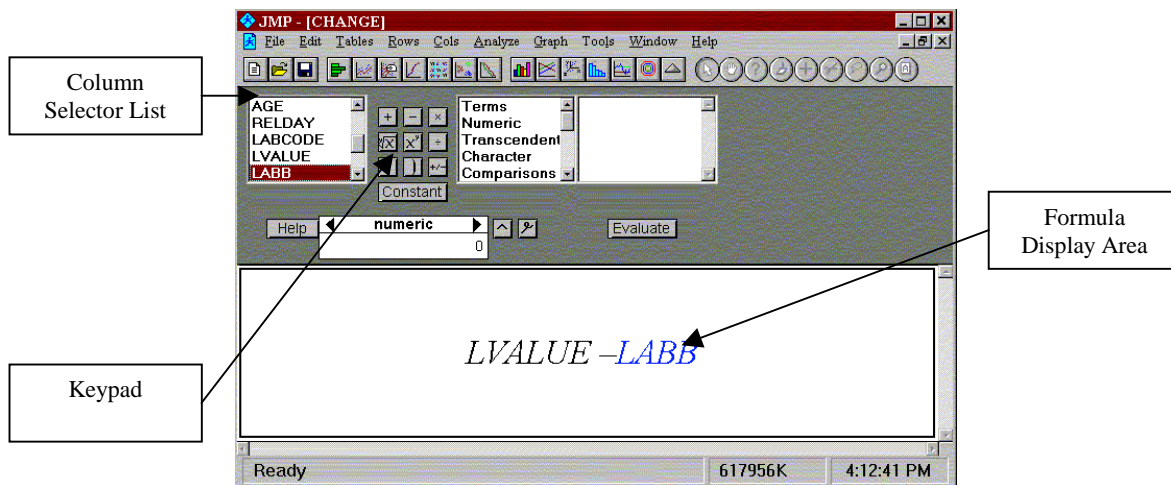
The JMP calculator can be used to create derived variables by adding computed columns.


Exercise 8: Use the JMP Calculator to find the change from baseline for each lab value.

- ☞ On the pulldown menu, go to Window | LAB1_JMP
- ☞ On the pulldown menu, go to Cols | New Column
- ☞ In the Col. Name field, type CHANGE
- ☞ In the Data Source: field select Formula from the drop down selection box



- Click OK. This brings up the calculator window



- Select LVALUE from the Column Selector List
- Click the minus button, , in the Keypad
- Select LABB from the Column Selector List
- Close the Change window

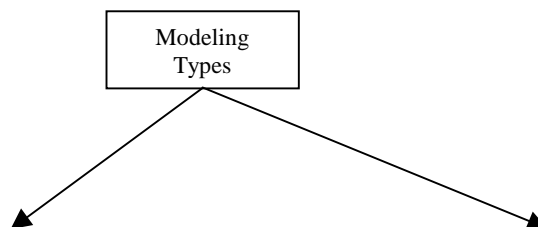
The CHANGE column now displays the change from baseline for each lab value.

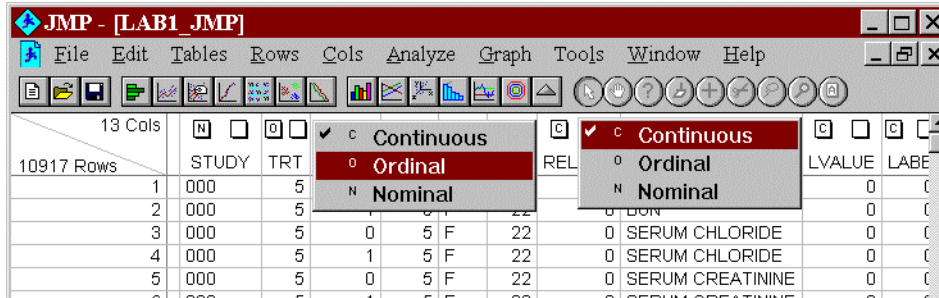
Fit Y by X

This function allows the use of statistical tests such as chi-square, T-tests, and ANOVA.

Exercise 9: Use the Fit by X feature of JMP to find if there is a statistically significant difference in post-treatment serum sodium values across treatment groups.

- Group the table by LABCODE and PHASE
- Make sure that the data modeling type for TRT is Ordinal and LVALUE is Continuous





☞ On the pulldown menu, go to Tables | Group Summary

☞ In the Columns field, select LABCODE

☞ Click the Group button

☞ In the Columns field, select PHASE

☞ Click the Group button

☞ Click OK

2. Subset the data


☞ Highlight the row where LABCODE is equal to Serum Sodium and PHASE is 1 (this is a second way to select out post-treatment serum sodium values, The first way was covered in the distribution of Y - Include/Exclude)

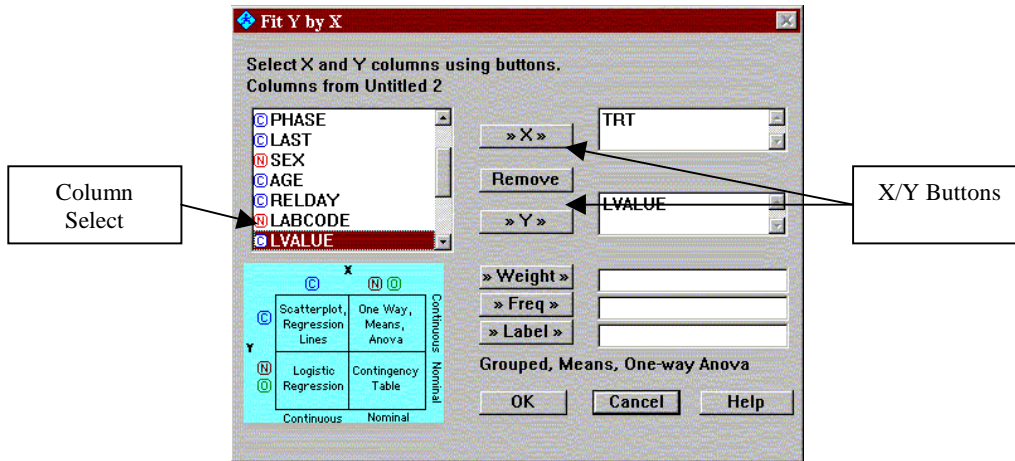
☞ Go to Window | LAB1_JMP

☞ On the pulldown menu, go to Tables | Subset

A new table is created that contains all the rows where LABCODE is equal to Serum Sodium and PHASE is 1

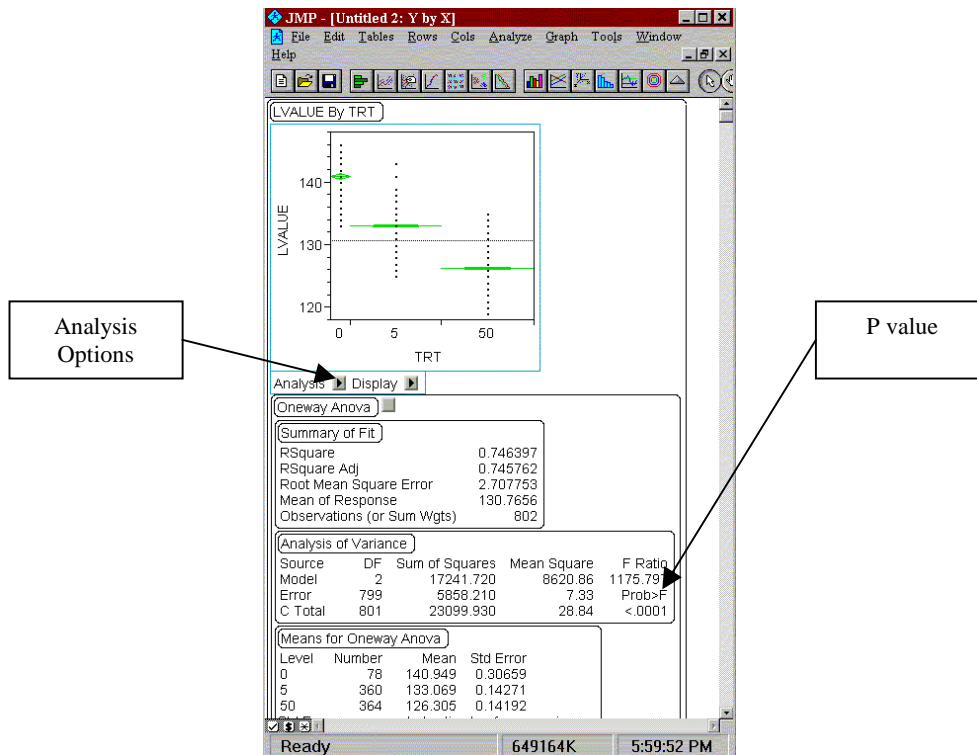
3. Fit Y by X

☞ On the pulldown menu, go to Analyze | Fit Y by X (or press )



Since we have not yet designated our X and Y axis, a JMP window appears asking for the X and Y columns. We need to designate TRT as X and the LVALUE variable as Y:

- Select TRT in the Column Select Area
- Click X button
- Select LVALUE in the Column Select Area
- Click the Y button
- Click OK



JMP creates a scatter plot of serum sodium values according to treatment. Click on the Analysis arrow and select Means/ANOVA/T-test. JMP automatically selects ANOVA as the appropriate statistical test for an ordinal x variable with more than 2 values, and a continuous Y variable. Under Analysis of Variance, the p value is shown in the lower right under “Prob>F” (p<0.0001).


The conclusion is that there is a statistically significant difference in serum sodium values among the 3 treatment groups.

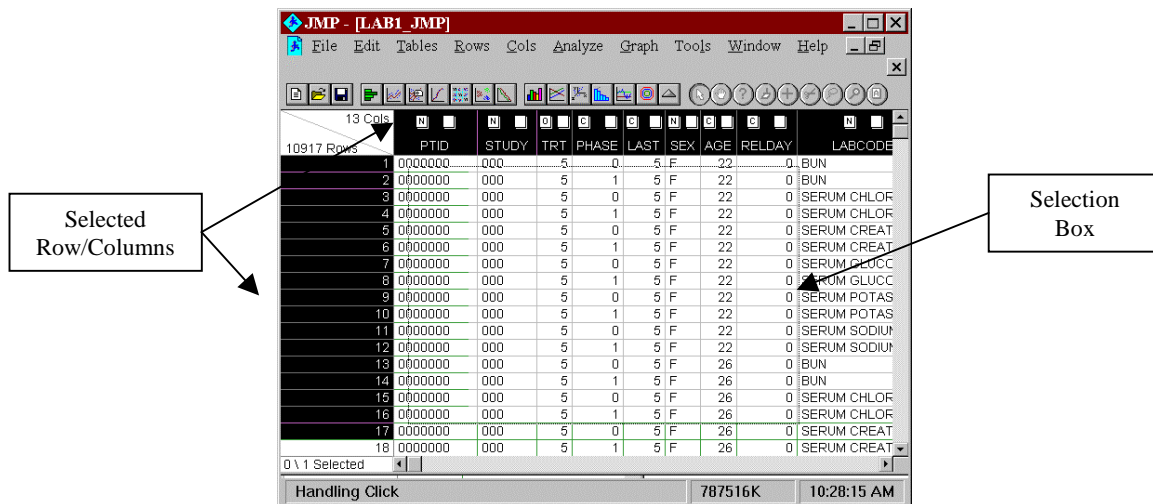
Exporting to Excel and Word


Now that you have completed your statistical analysis, you may want to export the information to applications for writing reports or additional analysis. Data, as well as charts and graphics can be exported to the spreadsheet, MS Excel, or word processing, MS Word, applications used in the Center.

Let’s go back to the table, *labmeans.jmp*, saved for serum sodium values.

Exercise 10: Copy the labmeans data to an MS Excel spreadsheet:

- ☞ On the pulldown windows, go to Window | labmeans
- ☞ Place your cursor over the first cell in the table. Make sure open cross, , is displayed (click deselect columns/rows if necessary.)
- ☞ Click, hold down on the mouse, and *drag* down to the right over all cells so the selection box covers all of the cells. All of the column and rows are highlighted.




- ☞ On the pulldown menu, go to Edit | Copy
- ☞ On the Windows 95 taskbar, click Start | Programs | Microsoft Excel
- ☞ On the Standard Excel toolbar, click the paste button, 

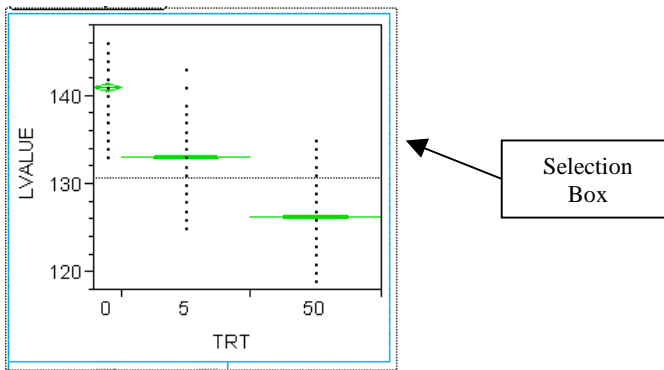
Note: Column labels (variables) are not copied


You can now use Excel to enhance the look of the data, or perform additional analysis or graphing. In order to move to the next Topic, close Excel and do not save any changes.

In addition to pasting the cells of a dataset into Excel, graphics and data can also be exported into MS Word.


Exercise 11: Copy the scatter plots (Fit y by X) paste the chart into Word.

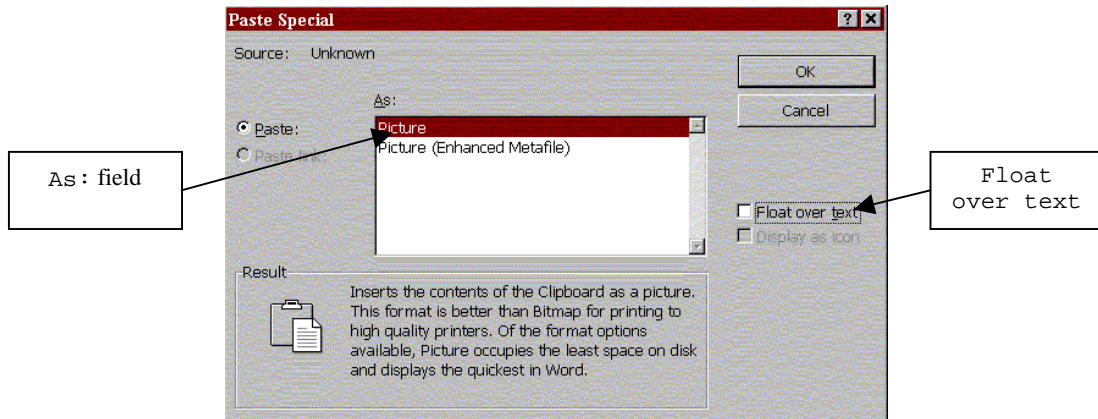
- ☞ On the pulldown menu, go to Window | Untitled 3: Y by X
- ☞ From the toolbar, choose the Scissors tool, 
- ☞ Place the cursor at the open end of the scissors on any corner on the chart
- ☞ Click and hold down on the mouse
- ☞ Drag a box over the entire chart



- ☞ On the pulldown menu, go to Edit | Copy
- ☞ On the Windows 95 taskbar, go to Start | Programs | Microsoft Word
- ☞ On the Standard Word toolbar, click the paste button, 

You may wish the chart just pasted into Word to not float over the text. In order to perform this function, you can use the **Paste Special** feature in Word:



- ☞ On the Standard Word toolbar, click the undo button, 
- ☞ On the pulldown menu, go to Edit | Paste Special
- ☞ Choose Picture from the As: field and uncheck the Float over text box. This will prevent the picture from floating over the text on the page (you may also use additional Word picture formatting procedures.)



Although the image looks the same, it will be placed within the text and features such as justification, tables, etc. can be used to align the graphic.

In addition to the chart, there are several tables located on the JMP window. These tables can be copied and pasted as graphics in the same manner as the chart. However, since JMP recognizes the text in these tables, the data can also be copied as text.

Exercise 12: Copy and paste the Analysis of Variance table from JMP to Word.

- Press [ENTER] to move down from the pasted chart in Word
- On the Windows 95 taskbar, click the JMP button, 
- Make sure the Scissors tool is selected. Click and drag a box over the Analysis of Variance table
- On the pulldown menu, go to Edit | Copy as Text
- On the Windows 95 taskbar, click the Word button
- On the Standard Word toolbar, click the paste button, 

The text has been pasted into word with tab delimitation separating the columns.

You can use Word formatting and table skills to convert the text, as long as the tab separations are proportionate, to a table.

You are now ready to write your report and finish for the day!

Review

In this lesson, you learned the user-friendly analytical tools available in JMP. It may require practice and review of the exercises in this lesson until you are comfortable with JMP analytical tools. Access to the files is available for all Center staff.

The next lesson will discuss additional Support for NDA Electronic Data Analysis, from manuals to OIT support.

To test your knowledge of the concepts and techniques you learned in this lesson, answer the following questions:

- What can be arranged using the Sort Command?
- What are the three data modeling types?
- Where on the pulldown menu do you find the Distribution of Y and Fit Y by X commands?
- What type of data source in the New Columns window will launch the JMP Calculator?
- What tool is used to rule out the baseline from statistical analysis?
- What tool is used to copy graphics as text?

Lesson 6 – Support

Now you are ready to go and work on Electronic Data. But what happens when you have a question or forget something covered in class? Is there advanced training? When should the Help Desk be called and what sort of information do you need to provide them to help find answer?

It is likely that **a person who can find an answer to their question on their own will not have that same question again**. This lesson covers how to find answers when to access additional technical and peer support.

This short lesson will instruct you how to access the following types of support in the Center:

- Classes and Manuals
- Additional Training
- Help Menu
- OIT Support
- Peer Support

This lesson will take about 10 minutes to complete.

Classes and Documentation

Class and Course Evaluation

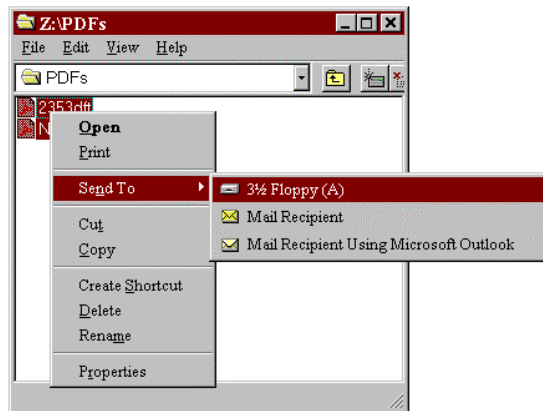
The NDA Electronic Data Analysis Training (NEDAT) class offered by OIT is dependent upon you to make constructive insights and comments on the course. Please make sure to fill out and return the OIT Course Evaluations at the end of class. These evaluations will help us shape the class so it is most beneficial to review staff.

Manual and ERSR Guidance

The NEDAT manual can be found on the OIT Web ([HTTP://OITWEB/OIT](http://OITWEB/OIT)) under the Documentation/ Applications Training section. Those attending the NEDAT training have also been asked to bring a formatted, 3 ½” floppy disk to class. PDF copies of the NEDAT manual and ERSR guidance can be copied to a floppy disk.

To copy the NEDAT manual and guidance in PDF:

- ☞ Minimize any open windows
- ☞ Insert the 3 ½ “ floppy into the floppy drive
- ☞ Double-click on My Computer
- ☞ Double-click on the Sample on ‘cdnta2’ (Z:) drive
- ☞ Double-click on the PDFs folder
- ☞ Hold [CTRL] down and click on both the nedat.pdf and the 2353dft.pdf files. Both files should be highlighted.
- ☞ Right-click over the highlighted files
- ☞ From the pulldown menu, choose Send to | 3 ½ Floppy (A)



- ☞ Once the files are done being copied, remove the floppy disk

Trifolds

Quick reference desktop **trifolds** for JMP and NEDAT have been provided in class. Use these trifolds for answers to frequently asked questions. Additional trifolds for other OIT courses can be found via the OIT Help Desk.

Additional Training

The following Advanced NEDAT Software courses are currently available, or are being formulated, within the Center.

MS Windows 95 and Internet Explorer

OIT offers introductory courses or tutorials for each. Consult the OIT web ([HTTP://OITWEB/OIT](http://OITWEB/OIT)) under the Training Schedules area for documentation and class schedules.

MS Word

OIT Offers Introductory, Formatting, and MS Word Tables Classes. Consult the OIT Web site for details.

Adobe Acrobat

OIT offers introductory courses, as well as **NEST**, which incorporates the use of Acrobat in the Electronic Review process. Consult the OIT Web site for details.

JMP

Medical Officers are currently offering advanced NEDAT courses in JMP per discipline. Contact Randy Levin (LEVINR), Associate Director for Electronic Review, ORM for details on attending, or instructing advanced JMP courses.

NDA Electronic Submissions Training (NEST)

NEST covers how to search for a specific Electronic NDA. Adobe Acrobat is then used to open, navigate, view, follow links, create electronic notes, and copy and paste text and graphics into MS Word. Consult the OIT Web site for details.

MS Excel and Access

OIT offers introductory courses on Excel and Access, as well as advanced query and report writing courses for Access. OIT and ERSR management are currently formulating advanced NEDAT courses for both software packages. Contact Randy Levin (LEVINR), Associate Director for Electronic Review, ORM if you are interesting in attending, or assisting in the creation of NEDAT Excel and Access courses.

Help Menus

Access the help menus in each of the applications discussed under Help on the pulldown menu for each application respectively.

OIT Support

If you are unable to find the answers you need via class instruction, manuals, or the Online Guides, please call the Help Desk at X7-0911 or e-mail them at HELPDESK. Please indicate whether your problem is related to an application or Electronic Submissions feature. Questions related to MS Windows, MSIE, Adobe Acrobat, The SAS System Viewer, StatTransfer, MS Excel, MS Access, JMP, and MS Word can be answered by the Help Desk or visited by OIT Desktop Support. Questions related to Electronic Submissions (missing folders, files, etc.) are forwarded directly to OIT Level II Support.

Peer Support

Some of the best resources for learning are those who work with us every day. Those of you who have taken the NEDAT course and have a firm grasp of the Electronic Data Analysis process can help share your expertise with others by acting as a mentor to those seeking information and feedback to their ERSR related situations. Also, if you have an interest in contributing to the additional Excel, Access, and JMP NEDAT courses, contact Randy Levin (LEVINR), Associate Director for Electronic Review, ORM.

Look for a more formalized Peer Support system as more Center staff become familiar with NEDAT and ERSR regulations.

Thank you for your participation and please take advantage of all support options available in the Center.

