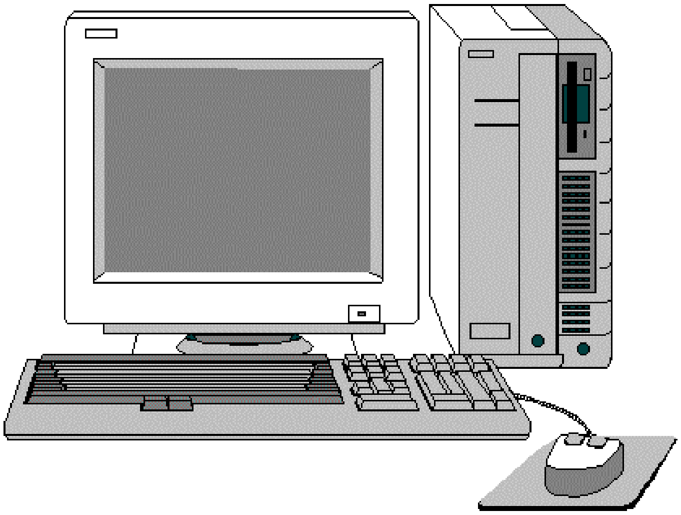

Center for Drug Evaluation and Research

Rockville, Maryland 20857

Presents…

NDA Electronic Submissions Training

NEST

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Introduction

In keeping with CDER's Electronic Regulatory Submission and Review (ERSR) goals, electronic submissions are currently being placed on the CDER network for access and review by CDER review staff. Currently, NDAs and their corresponding Amendments and Supplements are the only submissions received in electronic format. Before these submissions can be reviewed, CDER review staff must first be able to access an electronic submission folder on the network, save a drive path (map), copy the folders and files pertinent to their discipline, and learn to use the features available in Adobe Acrobat. Reviewer staff then can access these electronic files from their desktop.

NDA Electronic Submissions Training (NEST) covers how to search for a specific NDA via the Electronic Document Room (EDR) Intranet site as well as map the drive path of the folder using Windows 95 (mapping). Adobe Acrobat is then used to open, navigate, view, follow links, create electronic annotations, mark text, and copy and paste text, tables, and graphics into other applications from a sample electronic NDA.

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

Prerequisites

Before beginning these chapters 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.

Conventions

Variables and commands are in the `courier new` font. Each topic includes an exercise in bold. Answers to the exercises can be found in the Appendix at the end of the manual.

Chapter 1 – NEST Presentation

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

This chapter will take approximately 15 minutes to complete.

Slide 1

NDA Electronic Submissions Training (NEST)

CDER/OIT Training

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

Slide 2

NEST Overview

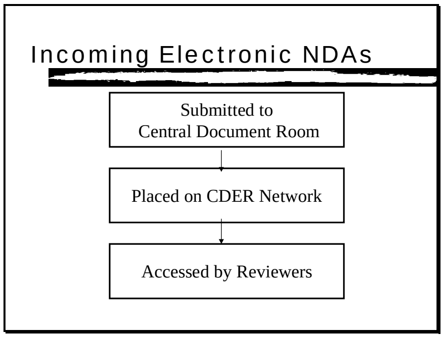
- Review of "Providing Regulatory Submissions in Electronic Format - NDAs"
- Review of Portable Document Format (PDF)
- Blueprint of Guidance
- NEST Objectives

Slide 3

CDER's ERSR Goals for 2002

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

Slide 4



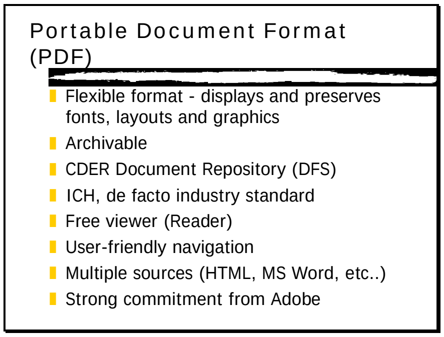
Incoming Electronic NDAs

Submitted to Central Document Room

Placed on CDER Network

Accessed by Reviewers

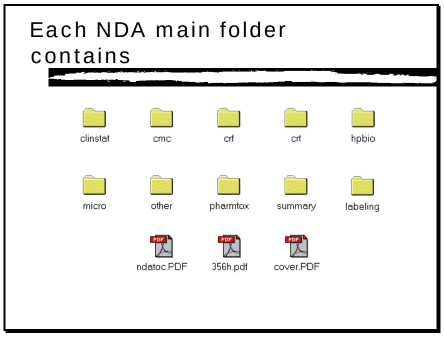
Slide 5



Portable Document Format (PDF)

- Flexible format - displays and preserves fonts, layouts and graphics
- Archivable
- CDER Document Repository (DFS)
- ICH, de facto industry standard
- Free viewer (Reader)
- User-friendly navigation
- Multiple sources (HTML, MS Word, etc..)
- Strong commitment from Adobe

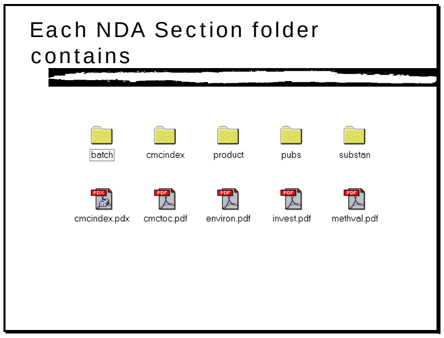
Slide 6



Each NDA main folder contains

clinstat
cmc
crf
crt
hpbio
micro
other
pharmtox
summary
labeling
ndatoc.PDF
356h.pdf
cover.PDF

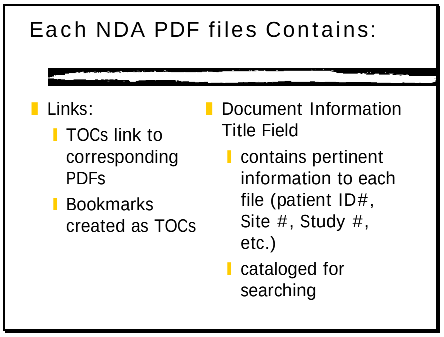
Slide 7



Each NDA Section folder contains

batch
cmcindex
product
pubs
substan
cmcindex.pdx
cmctoc.pdf
environ.pdf
invest.pdf
methval.pdf

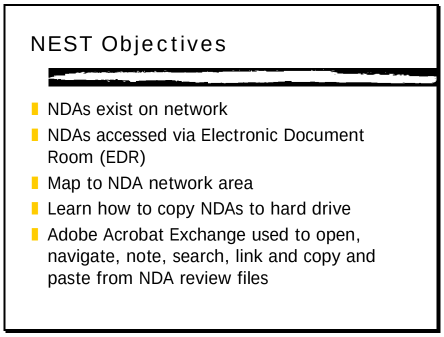
Slide 8



Each NDA PDF files Contains:

- Links:
  - TOCs link to corresponding PDFs
  - Bookmarks created as TOCs
- Document Information Title Field
  - contains pertinent information to each file (patient ID#, Site #, Study #, etc.)
  - cataloged for searching

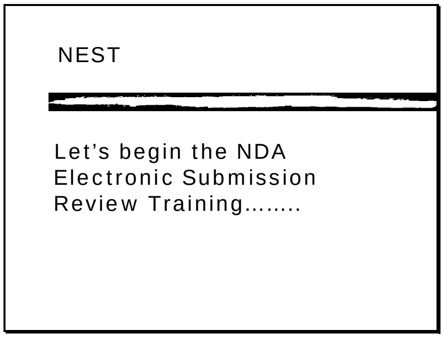
Slide 9



NEST Objectives

- NDAs exist on network
- NDAs accessed via Electronic Document Room (EDR)
- Map to NDA network area
- Learn how to copy NDAs to hard drive
- Adobe Acrobat Exchange used to open, navigate, note, search, link and copy and paste from NDA review files

Slide 10



NEST

Let's begin the NDA Electronic Submission Review Training……..

Chapter 2 - Accessing Electronic Submissions

Electronic submissions submitted to the Central Document Room (CDR) are placed on the CDER network for access and review. Before reviewing these documents, reviewers must first be able to access an NDA folder via the Electronic Document Room (EDR), save a drive path (map), and copy the folders and files pertinent to their review discipline. This chapter will cover how to search for a specific NDA via the EDR Intranet site. Once the drive path to the NDA folder is found on the network, the path to the folder can then be saved and assigned a drive letter (mapping.) Once the drive path has been mapped, a desktop shortcut to the NDA folder is created to repeat the mapping steps each time a reviewer logs on to the network. Windows 95 tools can also be used to copy relative Electronic Submission files to a reviewer's hard drive, where notes and changes can be made to the files without affecting the integrity of the original submission file.

Windows 95 file management tools and Microsoft's Internet Explorer are used to complete the tasks in this chapter.

This chapter will take about 30 minutes to complete.

Electronic Document Room (EDR)

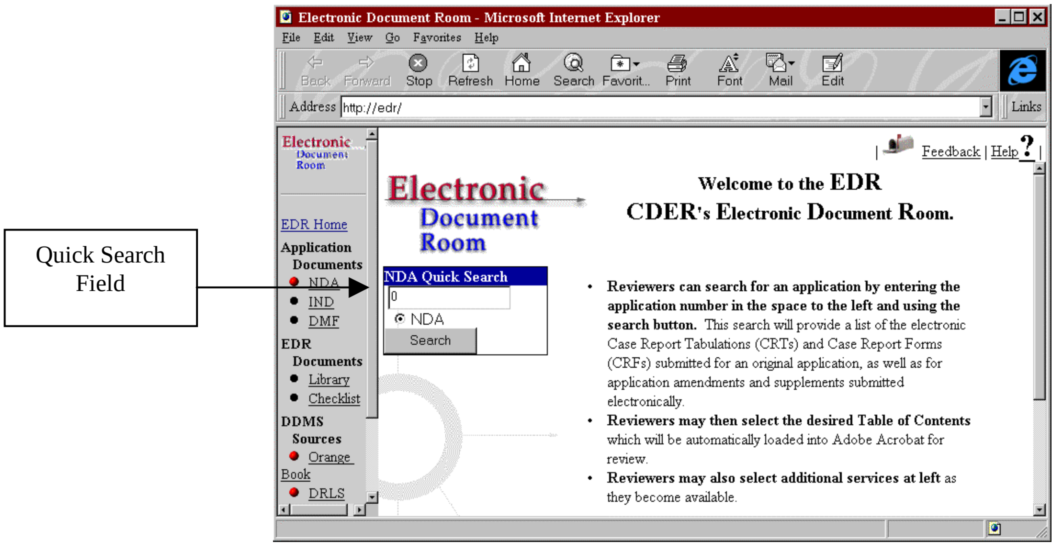
Once an NDA, Amendment, or Supplement has been placed on the CDER network, the location of the submission files can be found via the Electronic Document Room (EDR). The EDR is a Web based tool on the network that contains search capabilities for NDAs and their associated Amendments and Supplements. Once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

- In the `NDA Quick Search` field enter the NDA number and press the `Search` button


Electronic Document Room - Microsoft Internet Explorer
File Edit View Go Favorites Help
Back Forward Stop Refresh Home Search Favorit... Print Font Mail Edit
Address
Links
Electronic Document Room
EDR Home
Application Documents
NDA
IND
DMF
EDR Documents
Library
Checklist
DDMS Sources
Orange Book
DRLS
Feedback | Help
NDA Quick Search
NDA
Search

Address: http://edr/

Welcome to the EDR
CDER's Electronic Document Room.

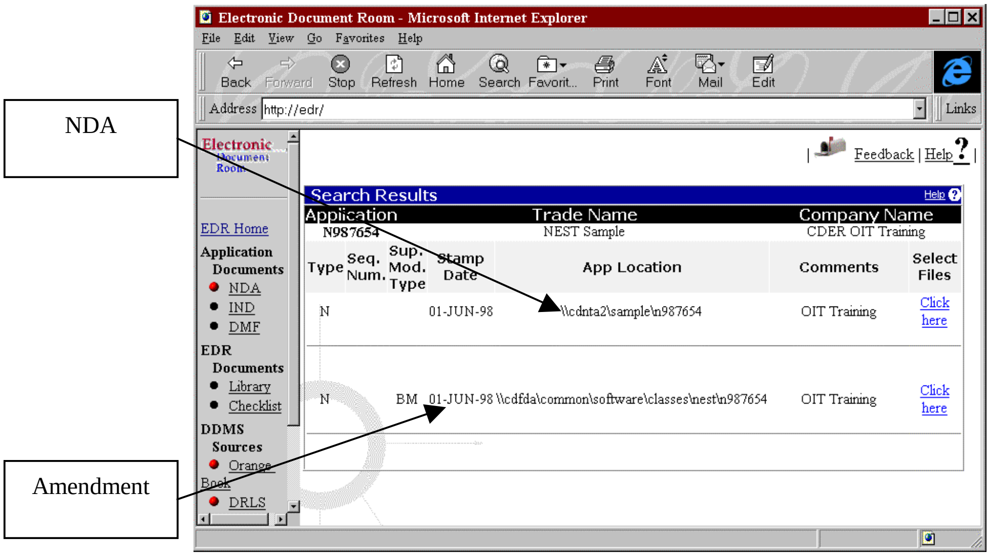
- **Reviewers can search for an application by entering the application number in the space to the left and using the search button.** This search will provide a list of the electronic Case Report Tabulations (CRTs) and Case Report Forms (CRFs) submitted for an original application, as well as for application amendments and supplements submitted electronically.
- **Reviewers may then select the desired Table of Contents** which will be automatically loaded into Adobe Acrobat for review.
- **Reviewers may also select additional services at left** as they become available.

Quick Search Field

Exercise 2-1: Access the Sample NDA 123456

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

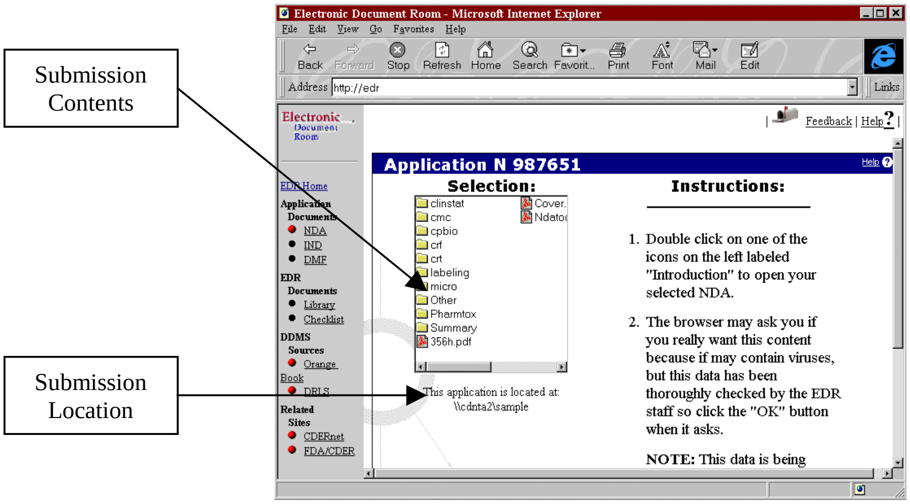

NDA
Amendment
Electronic Document Room - Microsoft Internet Explorer
File Edit View Go Favorites Help
Back Forward Stop Refresh Home Search Favorit... Print Font Mail Edit
Address http://edr/
Links
Electronic Document Room
Feedback | Help ?
EDR Home
Application Documents
NDA
IND
DMF
EDR Documents
Library
Checklist
DDMS Sources
Orange Book
DRLS
Help ?

Search Results

Application	Trade Name	Company Name
N987654	NEST Sample	CDER OIT Training

Type	Seq. Num.	Sup. Mod. Type	Stamp Date	App Location	Comments	Select Files
N			01-JUN-98	\\cdnta2\sample\n987654	OIT Training	Click here
N		BM	01-JUN-98	\\cdfda\common\software\classes\nest\n987654	OIT Training	Click here

To access and display the contents of the main NDA folder, click on Click here for the respective NDA, Amendment or Supplement. The next window displays a list of folders and files contained in the electronic NDA. To view these read-only, electronic submission files, click on the PDF icon or folder. When a PDF icon is clicked, Adobe Acrobat will launch and open the PDF file. Proceed to Chapter 3 to learn how to use Adobe Acrobat to work with electronic submission files.


Submission Contents
Submission Location
Electronic Document Room - Microsoft Internet Explorer
File Edit View Go Favorites Help
Back Forward Stop Refresh Home Search Favorit... Print Font Mail Edit
Address http://edr
Links
Electronic Document Room
Feedback | Help ?
EDR Home
Application Documents
NDA
IND
DMF
EDR Documents
Library
Checklist
DDMS Sources
Orange Book
DRLS
Related Sites
CDERnet
FDA/CDER
Help ?
clinstat
cmc
cpbio
crf
crt
labeling
micro
Other
Pharmtox
Summary
356h.pdf
Cover.
Ndatoc

Application N 987651

Selection:

This application is located at:
\\cdnta2\sample

Instructions:

1. Double click on one of the icons on the left labeled "Introduction" to open your selected NDA.
2. The browser may ask you if you really want this content because it may contain viruses, but this data has been thoroughly checked by the EDR staff so click the "OK" button when it asks.

NOTE: This data is being

Note the NDA drive path, as it will be used in the next section.

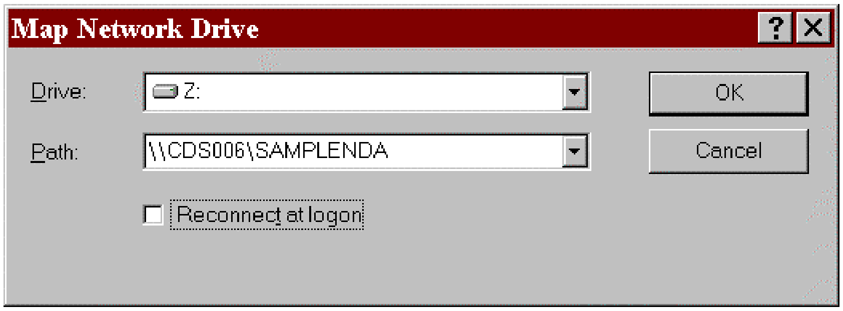
Exercise 2-2: Display the Sample NDA 123456 from the Search Results window in the EDR.

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.

To map to a network drive:

- Minimize any open applications
- Right-click on `My Computer` and click `Map Network Drive`
- Select a drive letter
- Enter the path to the NDA you found in the EDR (e.g., `\\cds006\samplenda`) in the `Path:` field
- Check the `Reconnect at logon` box if you want to repeat this process every time you log onto the network from this PC
- Click the `OK` button (you should now be mapped to the `NDA` shared area)



Drive: Z:

Path: \\CDS006\SAMPLENDA

☐ Reconnect at logon

Exercise 2-3: Map the drive letter Z: to sample NDA 123456 and DO NOT reconnect at logon.

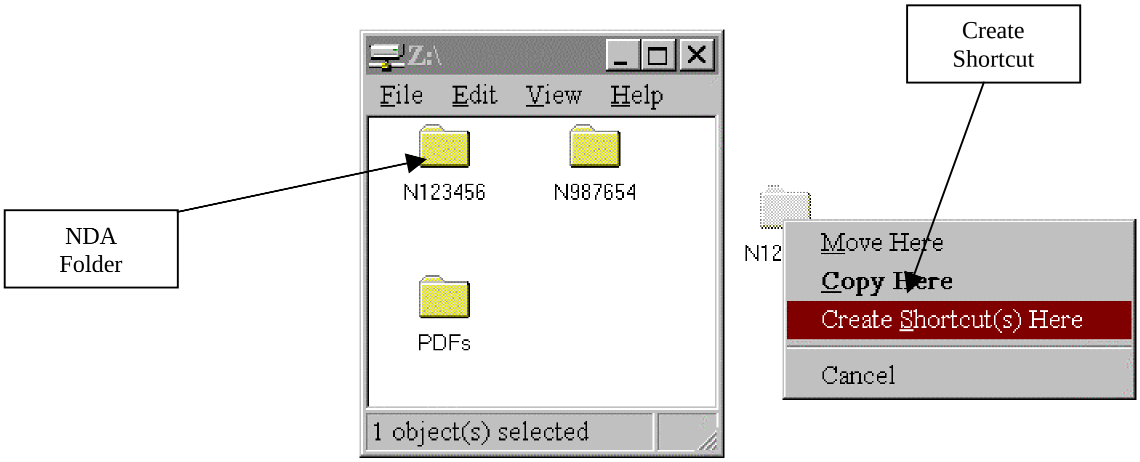
Create a Desktop Shortcut

Once you have mapped the network drive, a window will open displaying the contents of the shared area. You can create a shortcut on your desktop to quickly access the NDA folder without having to map to the shared area each time you need access.

To create a desktop shortcut:

- Right-click and hold down on the NDA folder (e.g., `N1234546`).
- Drag the icon onto your desktop
- Lift your finger off of the mouse. A pulldown menu will appear.

- Highlight and click `Create Shortcut(s) Here`
- The shortcut appears on your desktop


Create
Shortcut
NDA
Folder
Z:\
File Edit View Help
N123456
N987654
PDFs
1 object(s) selected
N12
Move Here
Copy Here
Create Shortcut(s) Here
Cancel

- To change the desktop shortcut label, right-click the shortcut and choose `Rename`. If you are creating a shortcut to an Amendment or Supplement, make sure to include this information when renaming the shortcut

---

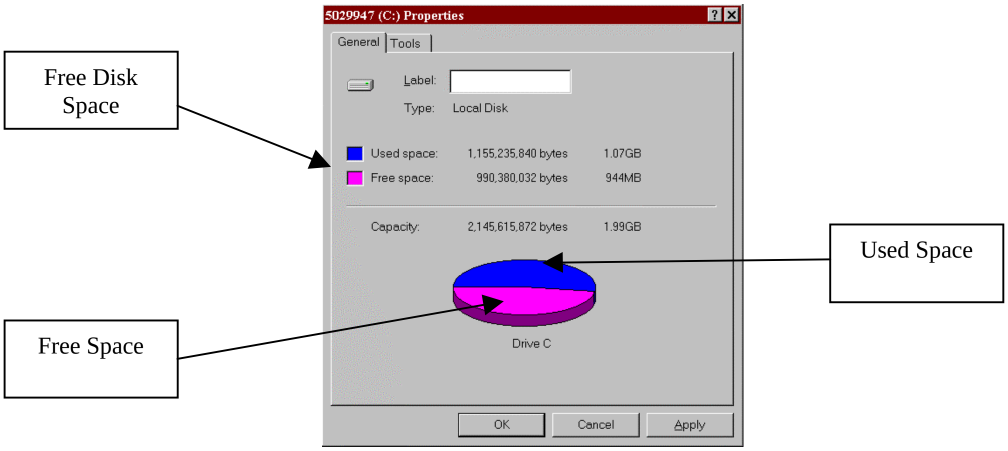
Exercise 2-4: Create a desktop shortcut to the folder for sample NDA 123456 and close the `Samplenda on 'Cds006' (Z:)` window

---

Copying Folders to Your Desktop

You can copy folders related to your discipline directly to your hard drive. This will allow you to open, note, and make changes to the PDF review files which exist in that folder. Before you copy the folder, 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`.


Free Disk Space
Used Space
Free Space
5029947 (C:) Properties
General
Tools
OK
Cancel
Apply

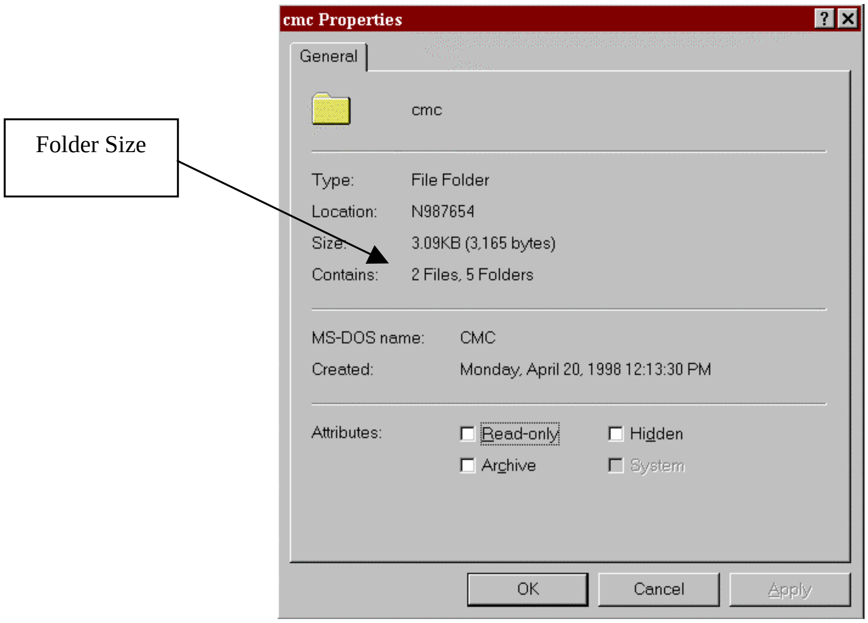
Label:
Type: Local Disk

Used space:	1,155,235,840 bytes	1.07GB
Free space:	990,380,032 bytes	944MB
Capacity:	2,145,615,872 bytes	1.99GB

Drive C

To check the size of the folder:

- Double-click on the NDA shortcut on your desktop
- Right-click on the Folder related to your discipline:
- Select `Properties` from the pulldown menu
- If the size of the folder you are copying is less than the space available on your `C:` drive, continue to the next step. If the folder is larger, you will not be able to copy the folder to your `C:` drive.


Folder Size
cmc Properties
General
OK
Cancel
Apply

cmc

Type: File Folder
Location: N987654
Size: 3.09KB (3,165 bytes)
Contains: 2 Files, 5 Folders

MS-DOS name: CMC
Created: Monday, April 20, 1998 12:13:30 PM

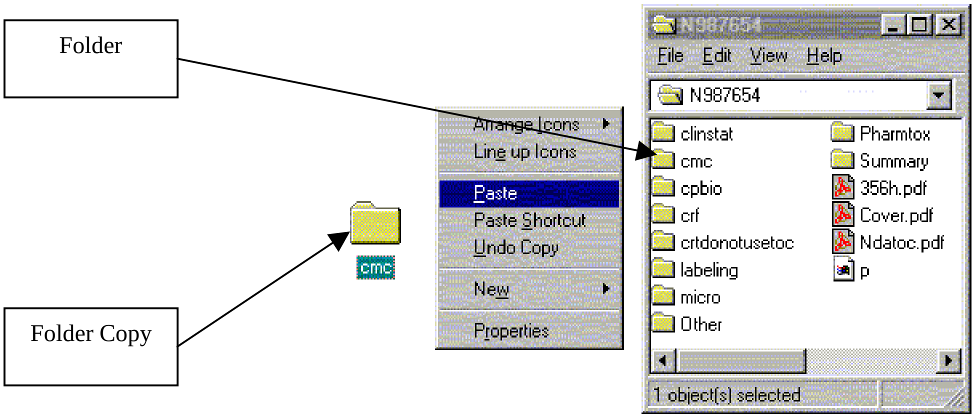
Attributes: ☐ Read-only ☐ Hidden ☐ Archive ☐ System

- Click `OK`

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

To copy the folder to your `C:` drive:

- Right-click on the folder related to your discipline:
- From the pulldown menu, select `Copy`
- Move your pointer onto the desktop and right-click. A pulldown menu will appear.
- Highlight and click `Paste`


Folder
Folder Copy
cmc
Arrange Icons
Line up Icons
Paste
Paste Shortcut
Undo Copy
New
Properties
N987654
File Edit View Help
N987654
clinstat
cmc
cpbio
crf
crtdonotusetoc
labeling
micro
Other
Pharmtox
Summary
356h.pdf
Cover.pdf
Ndatoc.pdf
p
1 object(s) selected

The folder now appears on your desktop.

You may also create a shortcut using the previous instructions.

Exercise 2-5: Check the size of the N123456\CMC folder and copy it to your desktop. Close all open windows when complete.

Review

This chapter introduced you to accessing NDAs, Amendments, and Supplements via the Electronic Document Room (EDR) to find review folders located on the network. You also learned how to map and save the drive path on your desktop. The following chapters will cover using Adobe Acrobat to open, navigate, create and modify annotations, and perform searches in the Electronic Submission files you have just accessed. To test your knowledge of the topics covered in chapter 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?
- How do you map to an NDA’s shared area location?
- How do you create a shortcut to the NDA?
- How do you copy NDA folders?
- How can I tell the difference between an NDA and an Amendment or Supplement?
- How much available hard drive space is recommended for optimum PC performance?

Chapter 3 - Exploring Electronic Submissions

In this chapter, you will learn the following:

- Access and view the NDA Table of Contents
- About Adobe Acrobat
- Compare labeling drafts
- Navigate a document using the buttons in the Adobe Acrobat toolbar.
- Change the magnification of a page view.
- Display and use Bookmarks
- Use the Find Tool
- Use the Search Tool

This chapter will take about 45 minutes to complete.

Opening the Electronic Submission Table of Contents

Electronic submissions have a table of contents with links to all PDF files contained in the submission. To access the electronic NDA Table of Contents:

- Access the NDA via the EDR or map to the NDA shared area
- Double-click the *Ndatoc.pdf* file found in the main NDA folder

Adobe Acrobat will launch with the Table of Contents open.

Looking At the Work Area

The Adobe Acrobat work area consists of the command menus at the top of the screen, the toolbar containing various tools and button controls, the document window containing the active document, and the informational status bar at the bottom of the screen.

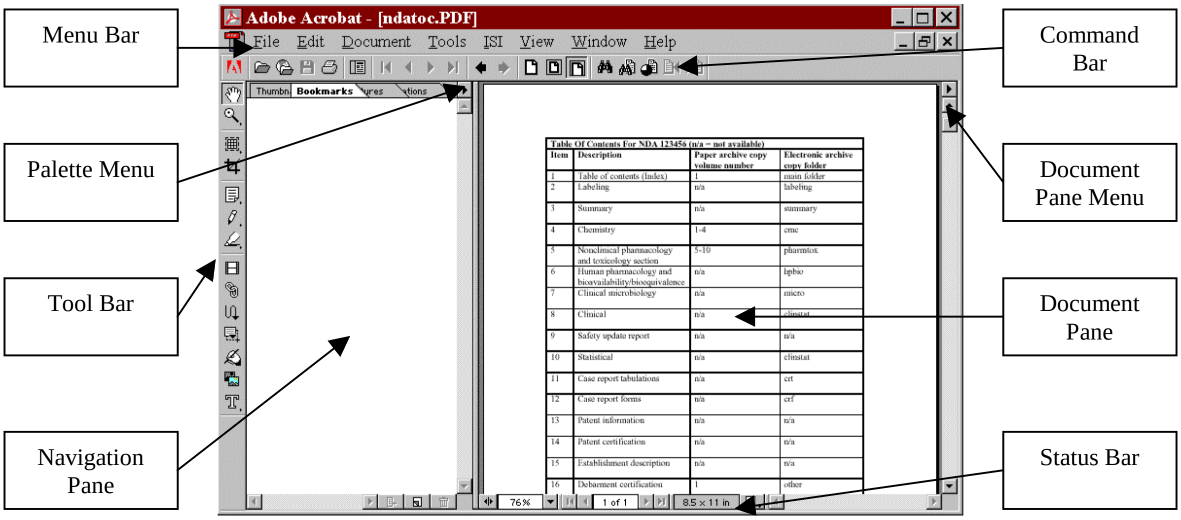
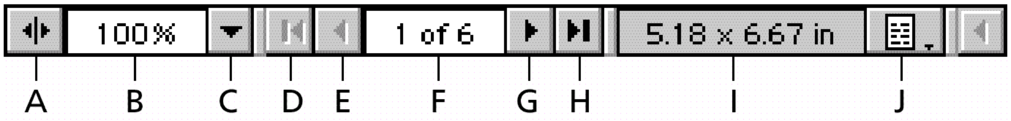

Menu Bar
Palette Menu
Tool Bar
Navigation Pane
Adobe Acrobat - [ndatoc.PDF]
File Edit Document Tools ISI View Window Help
Thumbn
Bookmarks
ures
ations
76%
1 of 1
8.5 x 11 in
Command Bar
Document Pane Menu
Document Pane
Status Bar

Table Of Contents For NDA 123456 (n/a = not available)

Item	Description	Paper archive copy volume number	Electronic archive copy folder
1	Table of contents (Index)	1	main folder
2	Labeling	n/a	labeling
3	Summary	n/a	summary
4	Chemistry	1-4	cmc
5	Nonclinical pharmacology and toxicology section	5-10	pharmtox
6	Human pharmacology and bioavailability/bioequivalence	n/a	hpbio
7	Clinical microbiology	n/a	micro
8	Clinical	n/a	clinstat
9	Safety update report	n/a	n/a
10	Statistical	n/a	clinstat
11	Case report tabulations	n/a	crt
12	Case report forms	n/a	crf
13	Patent information	n/a	n/a
14	Patent certification	n/a	n/a
15	Establishment description	n/a	n/a
16	Debarment certification	1	other

Looking At the Status Bar

The buttons and menus in the status bar provide quick ways to change your on-screen display and to navigate through documents.



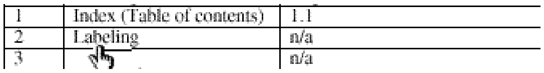
A. Navigation Pane button **B.** Magnification level **C.** Magnification pop-up menu **D.** First Page button **E.** Previous Page button **F.** Current page **G.** Next Page button **H.** Last Page button **I.** Page size **J.** Page Layout pop-up menu

Following A Link

The NDA table of contents contains links to a table of contents file for each main NDA folder. These links make it easy for you to locate review data by discipline and navigate through the document.

To navigate the NDA from the table of contents

- Click the hand tool () and move the pointer over the desired section in the table of contents. The pointer changes to a pointing finger icon (shown below), indicating that you are positioned over a link.



1	Index (Table of contents)	1.1
2	Labeling	n/a
3		n/a

- Click to jump to the link destination — the table of contents for that discipline.

Exercise 3-1: Open the table of contents for NDA 123456 and go to the Labeling table of contents.

Compare Word

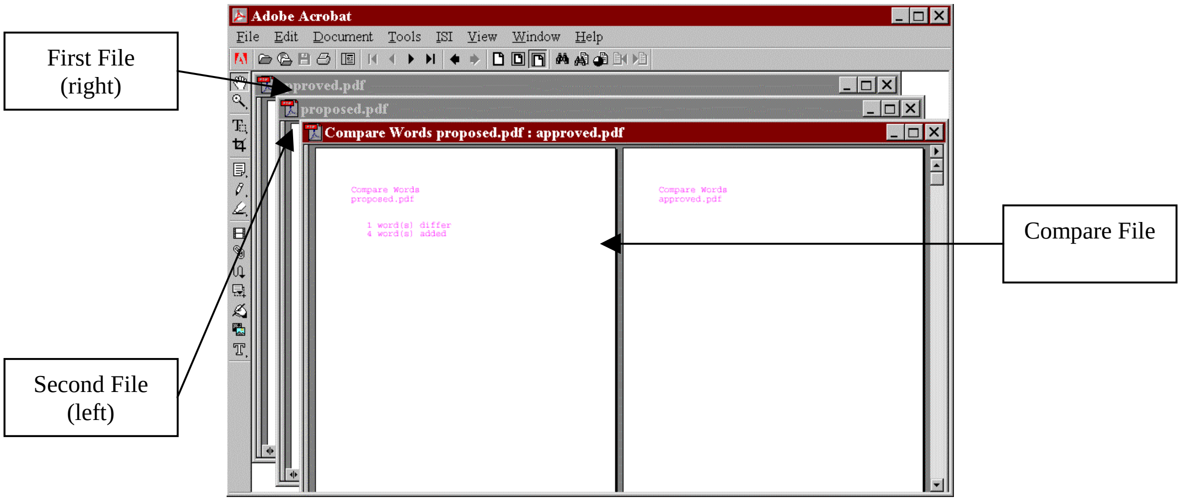
The Compare Word command compares the text content of text on corresponding pages in two documents. Differences are identified by:

- If text does not match on the two pages, the text is highlighted on both pages.
- If text is found on only one of the pages, the text is highlighted on that page, and a triangle marks the place on the corresponding page.

To compare text in two documents:

- Open two documents. The first document you open will be on the right in the comparison file. The second open document will be on the left.

- On the menu bar, go to `Tools` | `Compare Words`. The two documents appear side by side in a new, read-only comparison file.


First File (right)
Second File (left)
Compare File
Adobe Acrobat
File Edit Document Tools ISI View Window Help
pproved.pdf
proposed.pdf
Compare Words proposed.pdf : approved.pdf

Compare Words
proposed.pdf

1 word(s) differ
4 word(s) added

Compare Words
approved.pdf

The first page provides an overview of the text discrepancies found in the files. Scroll through the new comparison file to see the actual changes (marked by highlighting and triangles).

Using the Browse Buttons

Use these browse buttons in the command bar:

- The Next Page button, ▶
- The Previous Page button, ◀
- The Last Page button, ▶|
- The First Page button, |◀

Exercise 3-2: Compare the approved labeling with the proposed labeling file and browse through the new compare words file. Browse back to the beginning and then close the new file and *proposed.pdf* when you are done.

Retracing Your Viewing Path

In Acrobat, a view consists of a specific page and a specific magnification displayed on your screen. Acrobat’s links and interactive features let you jump quickly and easily to different views.

The Go To Previous View button, ⬅, is useful for retracing your viewing path through a document, especially when you have followed a complex series of links and changed magnification levels several times.

To retrace your viewing path:

- Click the Go To Previous View button, ⬅, in the command bar
- Click the Go To Next View button, ➡, for each step forward
- To retrace your viewing path through other PDF documents, press `[SHIFT]` and click the Go Back or Go Forward button. This command opens the other PDF documents if the documents are closed.

You can click the Go Back button repeatedly to retrace your viewing path, view by view for up to 64 views, through a document. If you have followed a link to another PDF document, the Go Back button can also return you to your original document.

Changing the View Magnification

When accessing electronic submission files, you can change the magnification of the page view using built-in controls in the toolbar, or by clicking or dragging in the page with the zoom tool.

Magnification tools:

- To resize the page to fit entirely in the window, click the Fit In Window button, 🗋
- To resize the page to fit the width of the window, click the Fit Width button, 🗋
- To return a page to its actual size, click the Actual Size button, 🗋
- Click the zoom tool (🔍) in the toolbar. You can either drag a rectangle around the area of the page you want magnified (this is called marquee zooming) or you can click on an area of the page to magnify.

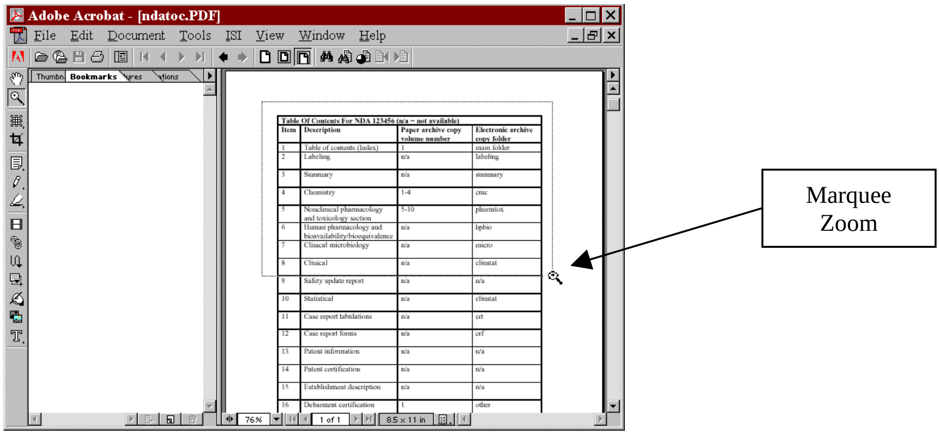


Table Of Contents For NDA 123456 (n/a = not available)			
Item	**Description**	**Paper archive copy volume number**	**Electronic archive copy folder**
1	Table of contents (Index)	1	main folder
2	Labeling	n/a	labeling
3	Summary	n/a	summary
4	Chemistry	1-4	cmc
5	Nonclinical pharmacology and toxicology section	5-10	pharmtox
6	Human pharmacology and bioavailability/bioequivalence	n/a	hpbio
7	Clinical microbiology	n/a	micro
8	Clinical	n/a	clinstat
9	Safety update report	n/a	n/a
10	Statistical	n/a	clinstat
11	Case report tabulations	n/a	crt
12	Case report forms	n/a	crf
13	Patent information	n/a	n/a
14	Patent certification	n/a	n/a
15	Establishment description	n/a	n/a
16	Debarment certification	1	other

Exercise 3-3: Navigate back to the NDA table of contents and go to the Summary section of the NDA. Display the first page of the summary document at three different magnifications - 100%, fit the whole page inside the main window, and fit the width of the page inside the main window.

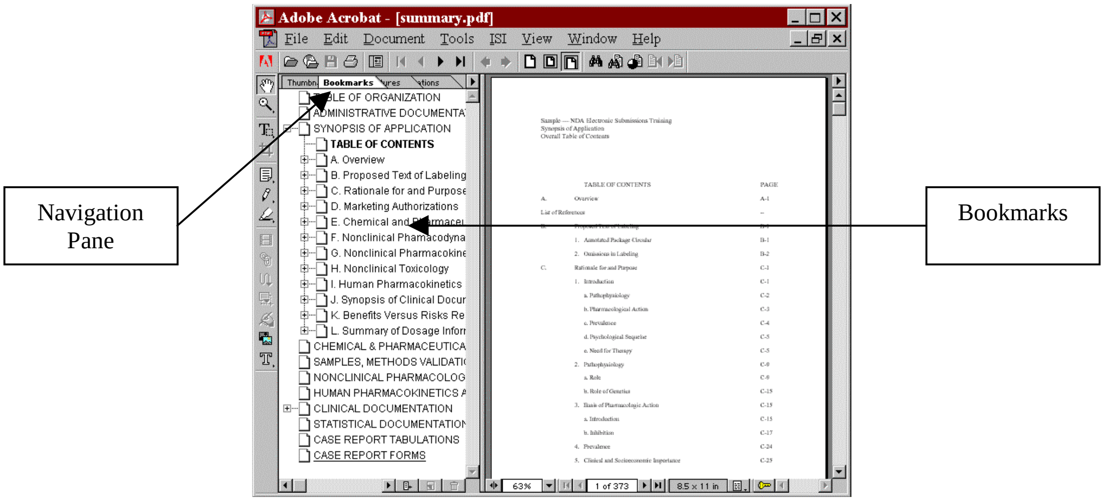
You can also use the magnification option on the status bar, 79% ▾, at the bottom of the screen to change the magnification.

Using Bookmarks

A bookmark is a type of link in the navigation pane. Each bookmark in the navigation pane goes to a different view or page in the document. As part of the comprehensive table of contents, bookmarks are included in each PDF review document in an electronic NDA. When bookmarks are included in the PDF review document, the navigation pane should automatically appear when you open the review file.

To use bookmarks:

- Click the Show/Hide Navigation Pane button, , and then click the `Bookmarks` tab
- Move your pointer over a bookmark in the navigation pane and click to go that selection


Adobe Acrobat - [summary.pdf]
File Edit Document Tools ISI View Window Help
Navigation Pane
Bookmarks
ADMINISTRATIVE DOCUMENTA
SYNOPSIS OF APPLICATION
TABLE OF CONTENTS
A. Overview
B. Proposed Text of Labeling
C. Rationale for and Purpose
D. Marketing Authorizations
F. Nonclinical Pharmacodyna
G. Nonclinical Pharmacokine
H. Nonclinical Toxicology
I. Human Pharmacokinetics
J. Synopsis of Clinical Docur
K. Benefits Versus Risks Re
L. Summary of Dosage Inforr
CHEMICAL & PHARMACEUTICA
SAMPLES, METHODS VALIDATI
NONCLINICAL PHARMACOLOG
HUMAN PHARMACOKINETICS A
CLINICAL DOCUMENTATION
STATISTICAL DOCUMENTATION
CASE REPORT TABULATIONS
CASE REPORT FORMS
63%
1 of 373
8.5 x 11 in

Exercise 3-4: Use the bookmarks to go to the Nonclinical Toxicology section of the summary document. Go back to the first page of the summary document when done.

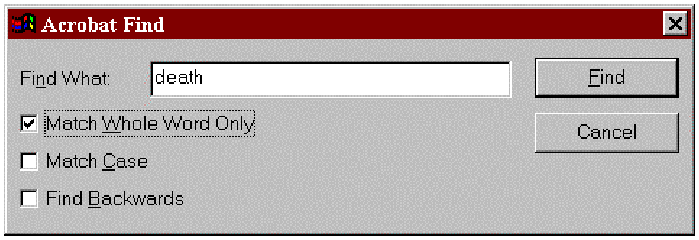
Searching For A Word - the Find Tool

Adobe Acrobat gives you the following ways to search through a file or a collection of files for a desired piece of information:

- The find tool lets you search through a single document for occurrences of a specific word or phrase
- The search query tool lets you search for information in a collection of documents, using an index that has been created in Acrobat Catalog

To use the find tool:

- Click the find tool () in the command bar to display the Find dialog box. The Find dialog box lets you enter the word or phrase you want to find.


Acrobat Find
Find
Cancel

Find What: death

☑ Match Whole Word Only

☐ Match Case

☐ Find Backwards

- Selecting the `Match Whole Word Only` option displays all occurrences of the text as it appears in the `Find What` field. The `Match Case` options allows you to look for words in the same case. `Find Backwards` lets you search backward starting from the current page in the document.

- Click the `Find` button to begin the search.

- To repeat your find, click the find tool () and press the `Find Again` button to search again.

Exercise 3-5: Find the patient deaths in the summary document using the Find tool.

The find tool in Exchange suffices when you want to search for a word or phrase in a single document. For more sophisticated searching of multiple documents at once, you can use the Search command.

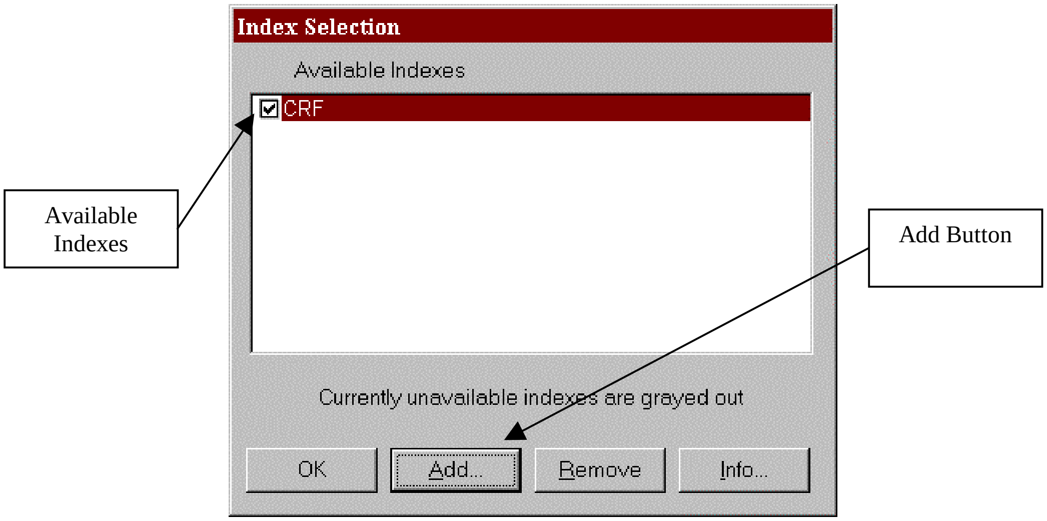
Searching For Words and Phrases in the Indexes

The Find Tool is beneficial when searching for one word or one group of words in one file. However, you can also perform a search over multiple files at once. Each section of an electronic submission will be cataloged. Each folder in an electronic NDA will have an index, a PDX file, which contains a complete listing of the all the text in all the files in that particular folder.

To search a NDA folder, you first must add the folder's index files, PDX files, to the index list using the Search Query tool ().

To add indexes:

- Click the Search Query Tool ()
- Click the `Indexes` button
- Remove any existing indexes by:
  - Clicking on them
  - Clicking on the `Remove` button
- Click the `Add` button



Currently unavailable indexes are grayed out

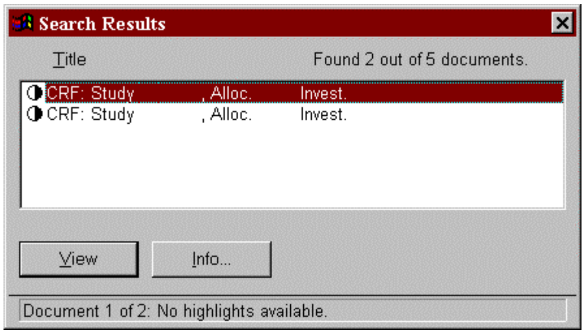
- Navigate to and find the folder you want to search
- Click on the index file (e.g., *crfindex.pdx*, and click `Open`)
- Click `OK`

Once you have added the index of the folder you want to search, you can now search the discipline's folder for a simple word or phrase, search fields associated with each file, or you can expand your search query by using wild-card characters and operators.

To perform a full-text search:

- Type the text you want to search for in the `Find Results Containing Text` box
- Click the `Search` button

If a match is found, the file will appear in the document pane. If multiple files match you search, the Search Results window appears. Click the `View` button to open the PDF file. Click the `Info`... button to find information related to the location, author, and history of the electronic submission file.



Found 2 out of 5 documents.

◑ CRF: Study , Alloc. Invest.
◑ CRF: Study , Alloc. Invest.

Document 1 of 2: No highlights available.

You can also use the Search Results ( ) button on the toolbar to bring back the Search Results window. Use the `Search Next` and `Search Previous` buttons ( ) to go to other matches in your search. Close the Search Results window by clicking the (`X`) in the top right corner.

To search document information fields:

NDA PDF files also contain valuable information stored with each file in the document information fields. These fields contain important, searchable information about that file. Sponsors are asked to include information such as patient ID numbers, site number, studies, etc in these fields.

In order to display the document information fields in the search window:

- Go to `File|Preferences|Search`
- Click the first box, `Show Fields`
- Click `OK`

Use these fields to search for text associated with that document. The table on the following pages outlines what you can expect to find in the document information fields for the PDF files located in electronic NDAs.

Folder	Document Information Field	Information
Table of Contents	**NA**	NA
Labeling	**Title** **Subject** **Author** **Keywords**	brand name generic name applicant, applicant's label code NDA number, approval status, date of labeling. For drafts - changes being affected. For annual report changes - date of submission. For approved labeling - date of approval.
Summary	**NA**	NA. Not indexed.
CMC	**Title**	
drug substance files		*ds*, the name of the active ingredients, brief description of the document (limited to a couple of words)
drug product files		*dp*, the name of the drug product, brief description of the document
Environmental assessment		*ea*, name of the drug product, brief description of the document
Nonclinical Pharmacology and Toxicology	**Title**	
Summary document		summary should be identified as pharmtox summary (clarified)
each study report		Designated study and followed by the study report number and the study type. Helpful information may also be included, such as the species and treatment duration (e.g., *study 2001*, *toxicity study, dog, 12 month*)
animal line listing files		the word data should also be added
Human Pharmacokinetics and Bioavailability	**Title**	
summary document for the clinical pharmacology and biopharmaceutics		identified as cpbio summary (clarification)
Study Subfolders		type of study (e.g., biopharm, pk, pd, subpops, drugint, invitro, assay, pubs) and the study number

Folder	Document Information Field	Information
Clinical Microbiology	**Title**	
summary document		Identified as micro summary (clarification - how should they be identified?)
Studies		type of study and the appropriate reference number
Clinical	**Title**	
study reports		brief description of the document, usually consisting of a couple of words. Includes the study number as a description
Safety Update	**NA**	NA
Statistical Section	**Title**	
Study reports		brief description of the document, usually consisting of a couple of words. Includes the study number as a description
Case Report Tabulations (CRTs)	**Title**	
patient profiles organized by site		*pp*, the study number, the site identification and the patient's unique ID number
patient profiles organized by study		*pp*, the study number, and the site identification
patient profiles organized by patient		*pp* and the study number
domain profiles organized by study		*dp* and the study number
domain profiles organized by domain		*dp*, the study number and the appropriate CRF domain name
Case Report Forms (CRFs)	**Title**	
case report forms organized by study		*crf* and the study number
case report forms organized by site		*crf*, the study number and the site identification
case report forms organized by case report form		*crf*, the study number, the site number and the unique patient ID number

Searching with Wild-Card Characters

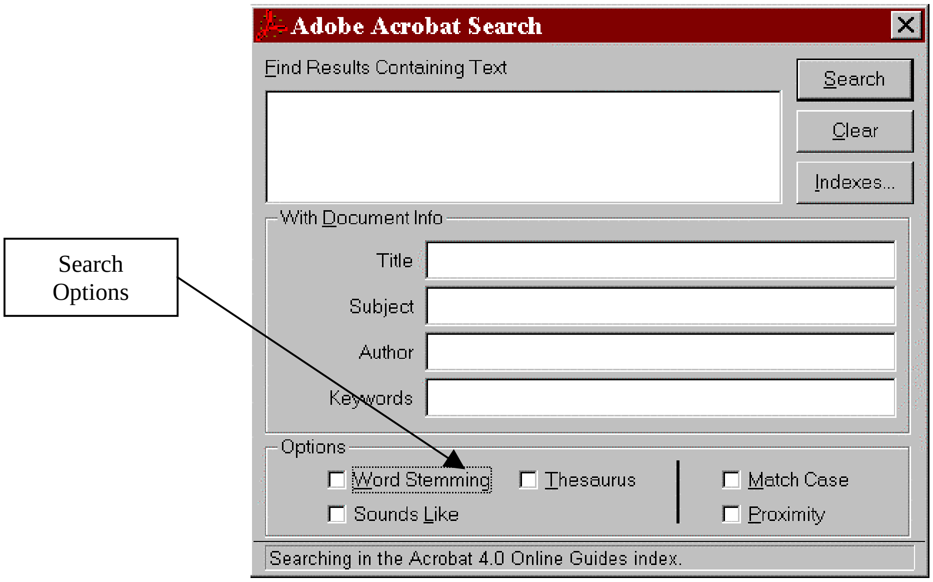
When entering text in the document information fields, the full text character string may not be known. Wild-card characters can be used to find all the words that contain a word fragment or all the terms that match an arbitrary character pattern:

- (*) asterisk, matches zero, one, or more characters
- (?) question mark, matches any one character

You can use wild-card characters in a term that is part of a Boolean expression. You can also use wild cards to specify Document Info field values. You cannot use wild cards to represent separator characters such as the hyphen [-] and the slash [/].

Searching with Boolean Expressions

You can use AND, OR, and NOT operators to build a Boolean expression that will search for specific words. Using AND between two words returns only documents containing both words. NOT before a word excludes documents containing the word or search term. Use OR between two words to return documents containing either word.


Adobe Acrobat Search
Find Results Containing Text
Search
Clear
Indexes...
With Document Info
Title
Subject
Author
Keywords
Options
☐ Word Stemming
☐ Thesaurus
☐ Match Case
☐ Sounds Like
☐ Proximity

Searching in the Acrobat 4.0 Online Guides index.

Search Options

Search Options

The options in the Search window expand or limit the results of searches:

- **Word Stemming** finds words that share a stem with the search word.
- **Thesaurus** finds words that have similar meanings

- **Sounds Like** finds different spellings of proper names.
- **Match Case** finds text only when it has the same capitalization as the text you type
- **Proximity** searches so that words must be within three pages of each other.

Exercise 3-6: Search the CRF index for any file related to 1) patient0000 and 2) patient 1111 or any patients that start with the numbers 23.

Review

This chapter introduced you to the basic navigational techniques and interactive elements that you can use within an electronic NDA. The following chapters and projects provide in-depth instructions for working with NDA PDF files that you copy to your hard drive, as well as finding support for electronic submissions.

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

- How do you return to a previous view of an Electronic NDA document?
- How do you navigate to the last page?
- What is the difference between the Find tool and the Search command?
- How do you add Indexes to your search?
- What features are displayed in the navigation pane?
- What is a Boolean expression?
- How do you navigate using *ndatoc.pdf*?

Chapter 4 – Electronic Review Tools

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

- Create and view annotations
- Create and annotate mark up tools
- Summarize Annotations
- Copy and Paste Text
- Copy and Paste Tables
- Copy and Paste Graphics using the ISI Graph Copy Plus lug-in

This chapter will take about 40 minutes to complete.

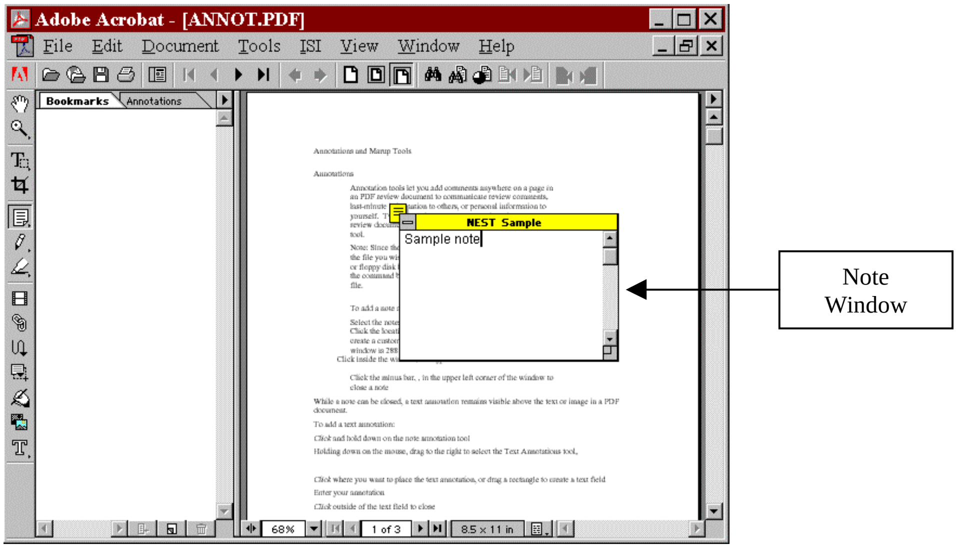
Annotations

Annotation tools let you add comments anywhere on a page in an PDF review document to communicate review comments, last-minute information to others, or personal information to yourself. Two types of annotations are optimal for annotating review documents - the **Notes tool** and the **Text Annotation tool**.

NOTE: Since the NDA files on the network are read-only, copy the file you wish to annotate to your hard drive, network share, or floppy disk before creating notes. Click the save button, , on the command bar to save annotations to your copy of the PDF file.

To add a note annotation:

- Select the notes tool,
- Click the location where you want to place the note, or drag to create a custom-sized window. The maximum size for the note window is 288 pixels high and 432 pixels wide
- Click inside the window, and type the text for the note



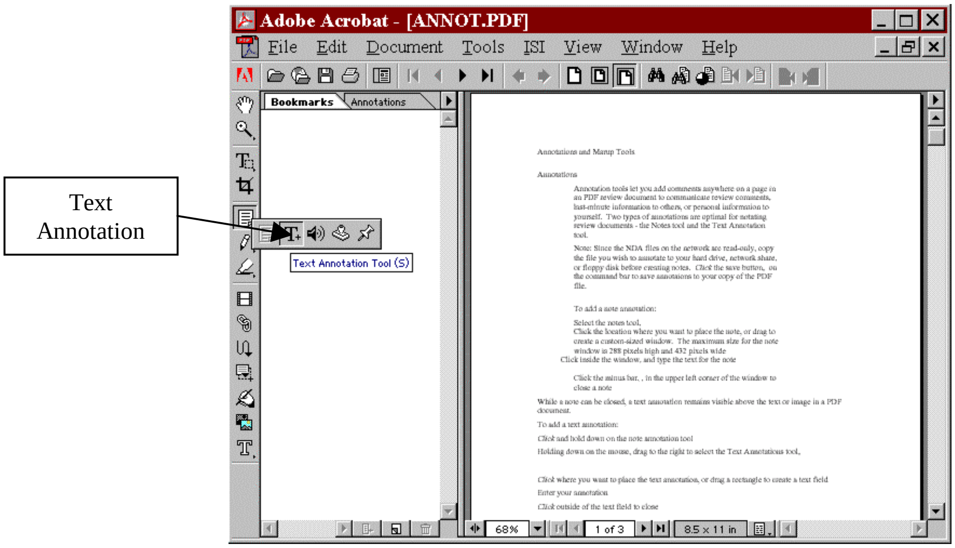
Note Window

- Click the minus bar, , in the upper left corner of the window to close a note

While a note can be closed, a text annotation remains visible above the text or image in a PDF document.

To add a text annotation:

- Click and hold down on the note annotation tool
- Holding down on the mouse, drag to the right to select the Text Annotations tool,



Annotations and Markup Tools

Annotations

Annotation tools let you add comments anywhere on a page in an PDF review document to communicate review comments, last-minute information to others, or personal information to yourself. Two types of annotations are optimal for notating review documents - the Notes tool and the Text Annotation tool.

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Click inside the window, and type the text for the note

Click the minus bar, , in the upper left corner of the window to close a note

While a note can be closed, a text annotation remains visible above the text or image in a PDF document.

To add a text annotation:

Click and hold down on the note annotation tool

Holding down on the mouse, drag to the right to select the Text Annotations tool,

Click where you want to place the text annotation, or drag a rectangle to create a text field

Enter your annotation

Click outside of the text field to close

- Click where you want to place the text annotation, or drag a rectangle to create a text field
- Enter your annotation
- Click outside of the text field to close

Graphic Markup Tools

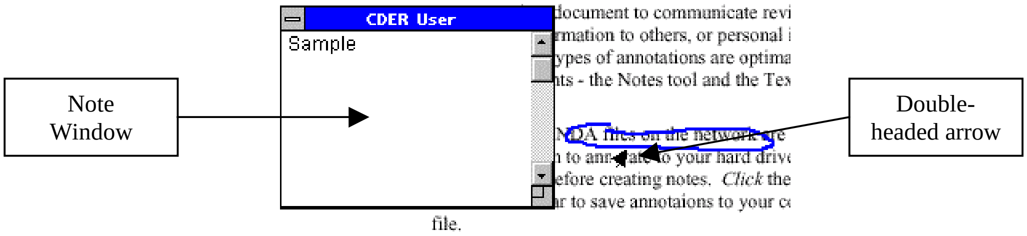
Markup tools are available on the Acrobat toolbar beneath the Annotations tools. Markup tools visually annotate a PDF review document with free form pencil lines, rectangles, ellipses, and straight lines. Notes can also be attached to better define the marked text.

To draw with the pencil tool:

- Click the pencil tool, , in the toolbar
- Move the cursor where you want to begin drawing. The graphic does not have to be one consistent stroke. You can let go and draw in as many places as desired.
- Select the hand tool, , when finished

To annotate the pencil markup:

- Annotating PDF Documents
- Move the cursor over a the pencil line until the cursor changes to a double-headed arrow and double-click to open the notes window



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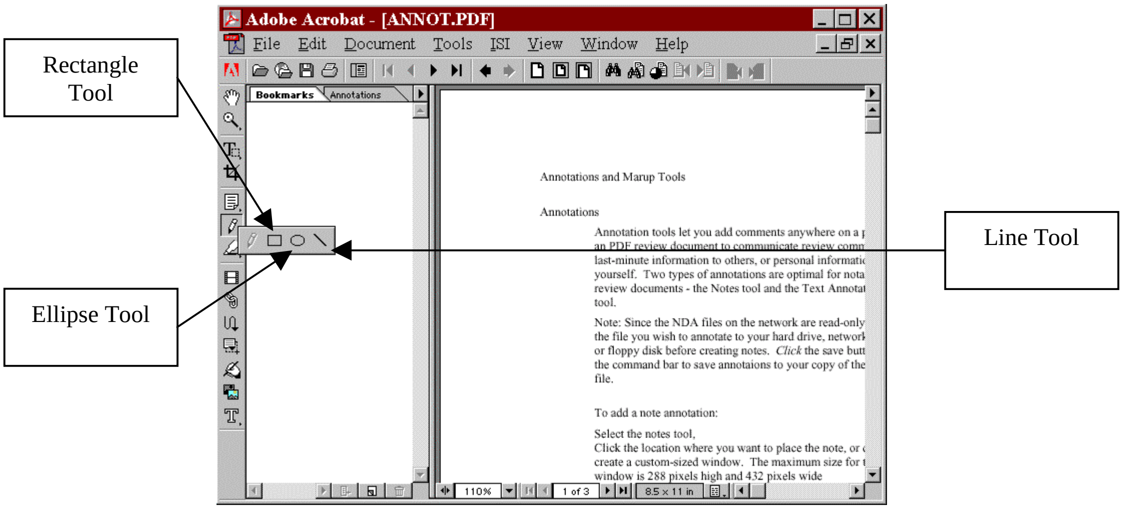
efore creating notes. *Click* the
ar to save annotaions to your co
file.

- Type in your text note
- Click the minus bar, ⊟, in the upper left corner of the window to close a note

To use the line, rectangle, or ellipse tool:

- Click on the pencil tool and drag to the right
- Select the line, ╲, rectangle, ▭, or ellipse, ⬭, tool



Annotations and Marup Tools

Annotations

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an PDF review document to communicate review comm
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yourself. Two types of annotations are optimal for nota
review documents - the Notes tool and the Text Annotat
tool.

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the file you wish to annotate to your hard drive, network
or floppy disk before creating notes. *Click* the save butt
the command bar to save annotaions to your copy of the
file.

To add a note annotation:

Select the notes tool,
Click the location where you want to place the note, or c
create a custom-sized window. The maximum size for t
window is 288 pixels high and 432 pixels wide

- Click a start point, hold down the mouse button and drag the object to your desired size. Let go of the mouse when done
- Click and drag to move the object around the page or change its size, if necessary

To associate an annotation:

- Double-click the markup object
- Type in your text note
- Click the minus bar, ⊟, in the upper left corner of the window to close a note

Text markup tools

Text markup tools can be used by themselves or in with other annotation types. The types of markups allow you to highlight, strike through, or underline text.

To use the text markup tools:

- On the toolbar, select the highlight text tool, ✎, or *click* and *drag* to the right to select the strikethrough text tool, S, or the underline text tool, U
- Click and *drag* over the selected text

NOTE: The printed version of a document marked up with highlighted text looks different from the screen version. Text that is highlighted on-screen prints with a box around it

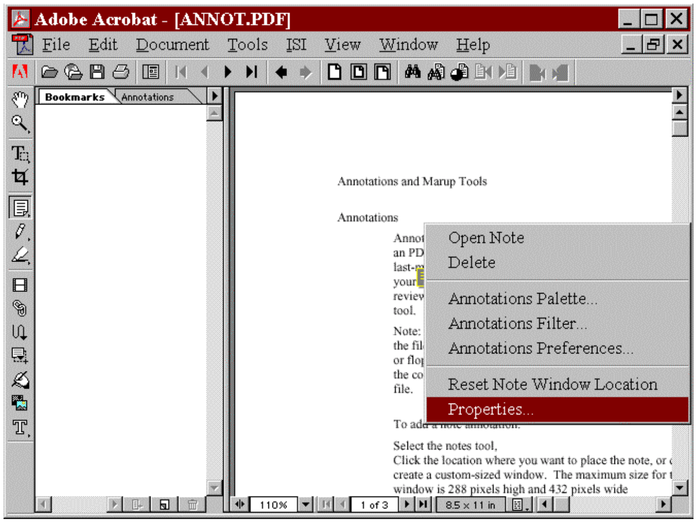
To associate an annotation:

- Double-click the markup object
- Type in your text note
- Click the minus bar, ⊟, in the upper left corner of the window to close a note

Delete, Change Preferences For, Or Change Individual Properties For Notes And Markup Annotations:

To delete, change preferences for, or change individual properties for notes and markup annotations:

- Right-click on the closed noted, then choose the desired option from the menu



Annotations and Marup Tools

Annotations

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To add

Select the notes tool,
Click the location where you want to place the note, or
create a custom-sized window. The maximum size for
window is 288 pixels high and 432 pixels wide

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Edit
Document
Tools
ISI
View
Window
Help
Bookmarks
Annotations
Open Note
Delete
Annotations Palette...
Annotations Filter...
Annotations Preferences...
Reset Note Window Location
Properties...
110%
1 of 3
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or

- Click on the object and go to `Edit` | `Properties` on the menu bar

Exercise 4-1: Put a square around the three paragraphs at the top of page 266 of the N123456 summary document and leave a text note that reminds you to copy the paragraphs into your review. Circle the third paragraph and leave a text note that states there was no investigator report. Highlight the table on page 265 and leave a text note reminder to copy the table into your review. Save your annotations.

Summarize Annotations

Summarize Annotations

When you add annotations to your file, you may create a summary PDF file of all the notes contained in the PDF file. The summary arranges the annotations in order as they appear in the file with note #, label, create date and time, and full text content.

To create a note summary:

- Go to `Tools` | Annotations | `Summarize Annotations`

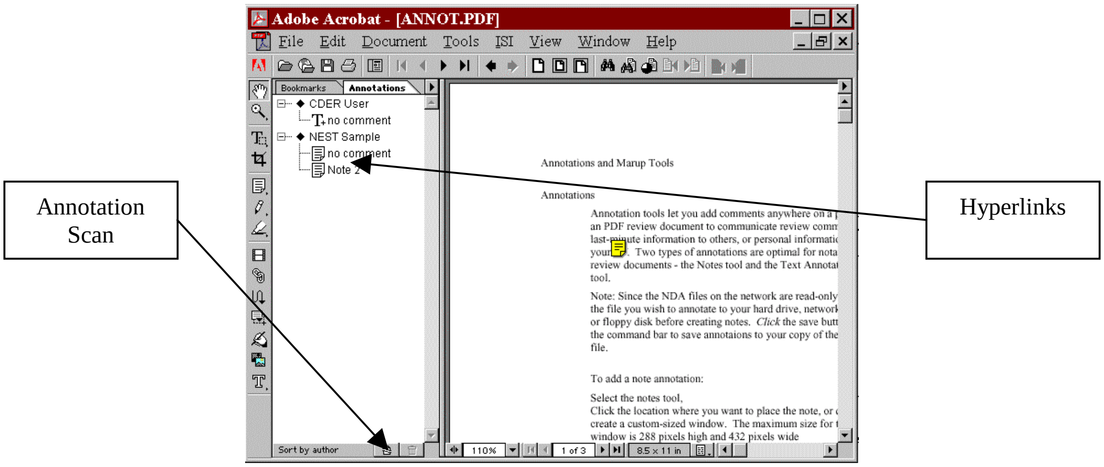
A new PDF file will be created (e.g., *Notes from ndatoc.pdf*). You may wish to save these files on your hard drive or close them without saving.

Annotation Scan

You can also display annotations in the navigation pane on the `Annotations` palette. Using the annotation scan feature will allow you to create, or update, a list of annotations in the current file. The items in the list also contain hyperlinks to that annotation location in the file.

To perform an annotation scan:

- Click on the `Annotations` tab in the Navigation Pane
- At the bottom of the Navigation Pane, click on the Start Annotation Scan, , button
- Click the Save button



Annotations and Marup Tools

Annotations

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Note: Since the NDA files on the network are read-only
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or floppy disk before creating notes. *Click* the save butt
the command bar to save annotaions to your copy of the
file.

To add a note annotation:

Select the notes tool,
Click the location where you want to place the note, or
create a custom-sized window. The maximum size for
window is 288 pixels high and 432 pixels wide

Exercise 4-2: Summarize your annotations for the summary document in a new file, then close the file. Summarize your annotations in the Navigation Pane. Save your file.

Copy and Paste Text

Text from a review document may be copied from PDF files and pasted to other applications such as Microsoft Word or TeamLinks. However, when using the default text select tool in Acrobat, the pasted text retains the line breaks that appeared in the PDF file. In order to paste text into applications that will fill the margins, the table/formatted text select tool must be used.

The table/formatted text select tool allows you to select tables and text in a PDF document and retain the original formatting when the material is copied (or imported) into other applications. You can specify vertical or horizontal format, the type of text flow, and whether you want ANSI (simple text) or Rich Text Format (RTF).

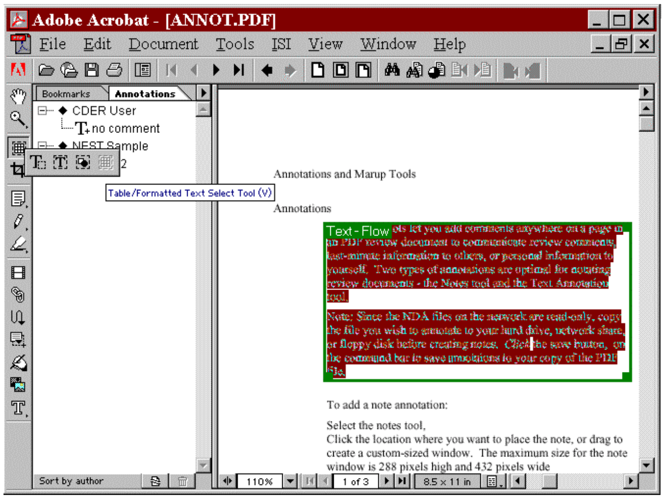
Before copying and pasting text into another application, a preference needs to be changed in Acrobat. The indentation paragraph formatting preference must be turned off to allow the pasted text to fill the margins in the destination file.

To turn off the indentation paragraph formatting:

- On the Menu bar, go to `File`|`Preferences`|`Table/Formatted Text`
- Click the `RTF Export` tab
- *Uncheck* the `Indentation` box
- Click `OK`

To copy and paste formatted text:

- On the tool bar click on the text select tool, , and drag to the right and select the table/ formatted text select tool,
- Click and drag a box around the desired text
- Make sure the type is `Text-Flow` (If not, right-click in the paragraph and choose `Text` | `Flow` from the popup menu)
- On the menu Bar, go to `Edit` | `Copy`


Adobe Acrobat - [ANNOT.PDF]
File Edit Document Tools ISI View Window Help
Bookmarks
Annotations
CDER User
no comment
NEST Sample
2
Table/Formatted Text Select Tool (V)
Sort by author
110%
1 of 3
8.5 x 11 in

Annotations and Marup Tools

Annotations

Text - Flow ols let you add comments anywhere on a page in an PDF review document to communicate review comments, last-minute information to others, or personal information to yourself. Two types of annotations are optimal for notating review documents - the Notes tool and the Text Annotation tool.

Note: Since the NDA files on the network are read-only, copy the file you wish to annotate to your hard drive, network share, or floppy disk before creating notes. Click the save button, on the command bar to save annotations to your copy of the PDF file.

To add a note annotation:

Select the notes tool,
Click the location where you want to place the note, or drag to create a custom-sized window. The maximum size for the note window is 288 pixels high and 432 pixels wide

- Go the destination application (e.g., Microsoft Word)
- On that application's pulldown menu, go to `Edit` | `Paste` or click the paste button on the toolbar

---

Exercise 4-3: Change the Acrobat formatted text preferences to remove indentation paragraph formatting when exporting. Copy the three paragraphs on page 266 of the summary document to a Microsoft Word document.

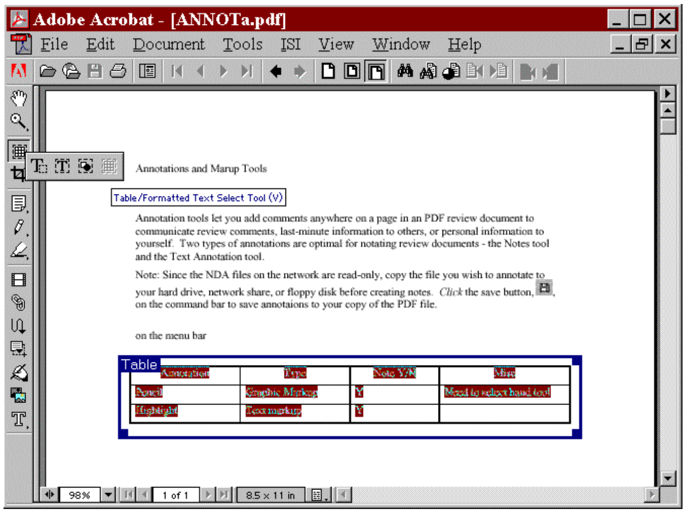
Copy and Paste Tables

The same tool that is used to copy formatted text is also used to copy and paste tables from PDF to other applications. Tables copied from PDF maintain the original format of the table, preserving the data as rows and columns of cells.

To copy and paste a table:

- On the tool bar click on the Text Select Tool, , and drag to the right and select the Table/ Formatted Text Select Tool,

- Click and drag a box around the table
- Make sure the type is `Table` (If not, right-click in the table choose `Table` from the popup menu)
- On the Menu bar, go to `Edit` | `Copy`



Annotations and Marup Tools

Table/Formatted Text Select Tool (V)

Annotation tools let you add comments anywhere on a page in an PDF review document to communicate review comments, last-minute information to others, or personal information to yourself. Two types of annotations are optimal for notating review documents - the Notes tool and the Text Annotation tool.

Note: Since the NDA files on the network are read-only, copy the file you wish to annotate to your hard drive, network share, or floppy disk before creating notes. *Click* the save button, , on the command bar to save annotaions to your copy of the PDF file.

on the menu bar

Annotation	Type	Note Y/N	Misc
Pencil	Graphic Markup	Y	Need to select hand tool
Highlight	Text markup	Y	

- Go the destination application (e.g., Microsoft Word)
- On that application's pulldown menu, go to `Edit` | `Paste` or click the paste button on the toolbar

If you are using Microsoft Word

Additional cells may be created when the table is pasted. Follow the directions below to merge the extra cells and recreate the PDF table:

- Select the table
- Click the borders button, ⊞, on the Formatting toolbar
- Use the eraser tool, , or the merge cells tool, , to remove the excess borders

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Exercise 4-4: Copy the table on page 265 of the summary document to a Microsoft Word document. Put borders on the table.

Copy and Paste Graphics

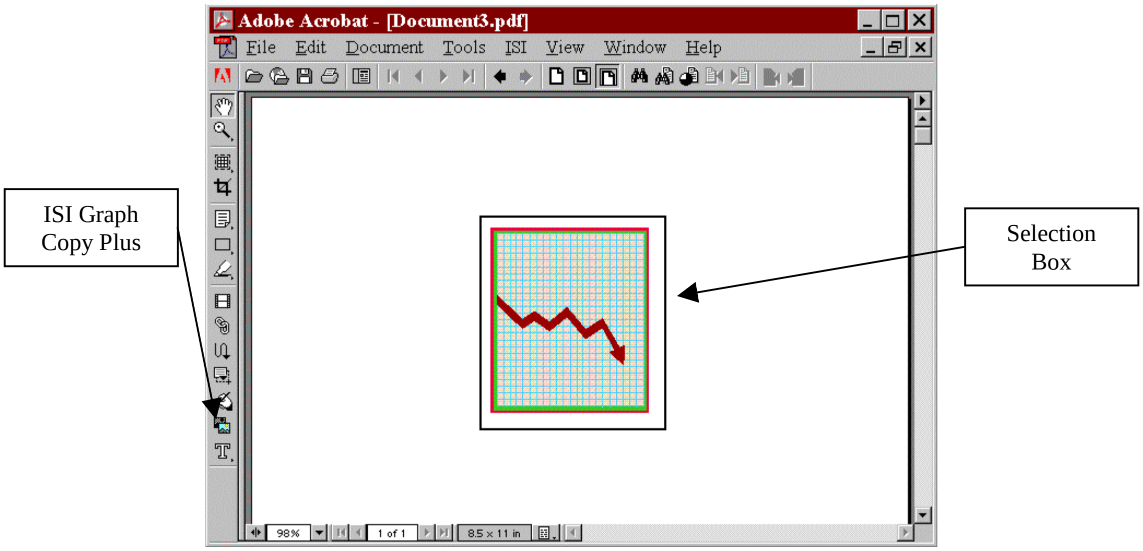
Graphics that appear in PDF files can be copied to other applications used in the review process. In order to capture the best resolution of the graphic, an additional plug-in, ISI Graph Copy Plus, is included in the standard CDER install of Acrobat 4.0. ISI graph Copy Plus copies the graphic from the PDF file and pastes it as a bitmap image.

Although Acrobat does contain a graphic copy tool, **use the ISI Graph Copy Plus when copying and pasting graphics from PDF to other applications**. Follow the directions below to copy and past graphics using the ISI Graph Copy Plus plug-in.

NOTE: In order for the ISI Graph Copy Plus plug-in to work, your monitor color palette must be set to 256 color. To check this setting, go to `Start`|`Settings`|`Control Panel` and double-click on the `Display` icon. Click the Settings tab. If you need to change the color palette to 256 color, close all programs first as the change will require you to restart your computer.

To copy and paste graphics:

- On the tool bar, select the ISI Graph Copy Plus button,
- Click and drag a box around the graphic
- When you let go of the mouse, wait a few moments until the box disappears


Adobe Acrobat - [Document3.pdf]
File Edit Document Tools ISI View Window Help
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8.5 x 11 in

ISI Graph Copy Plus

Selection Box

The ISI Graph Copy Plus plug-in automatically copies the graphic to the clipboard so there is no need to use the copy feature in Acrobat.

- Go to the destination application (e.g., Microsoft Word)
- On that application's pulldown menu, go to `Edit`|`Paste` or click the paste button on the toolbar

If you are pasting into a Microsoft Office application and do not wish the graphic to “float” over text, follow these directions to paste the graphic:

- On the pulldown menu, go to `Edit`|`Paste Special`
- Uncheck the `Float over text` box
- Click `OK`

Exercise 4-5: Copy the scatter plot on page 242 of the N123456 summary document to a Microsoft Word document as a graphic that does not float over text.

Review

In this chapter, you learned how to work with notes, control the number of open windows, change page views, and copy and past text and graphics. In the last chapter, you will learn how to find Support when you have questions related to electronic submissions and Adobe Acrobat.

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

- What tool is used to copy text and tables?
- What are the different types of graphic markup tools?
- Can you save notes on the network copies of the electronic submissions files?
- What table/formatted text preference needs to be changed before copying text?
- Where do you find the ISI Graph Copy Plus tool?
- What color palette setting is required to use ISI Graph Copy Plus?
- What Microsoft Word feature allows you to paste graphics that do not “float” over text?

Chapter 5 – Support

Now you are ready to go and work on electronic submissions. But what happens when you have a question or forget something covered in class? When should the Help Desk be called and what sort of information do you need to provide them to help find an 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 chapter covers how to find answers independently and how and when to access additional technical and peer support.

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

- Classes and Manuals
- Adobe Acrobat Online Guide
- Acrobat Preferences
- OIT Support
- Peer Support

This chapter will take about 20 minutes to complete.

Classes and Documentation

Class and Course Evaluation

The NDA Electronic Submissions Training (NEST) 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 Draft Guidance

The NEST manual can be found on the OIT Web (`HTTP://OITWEB/OIT`) under the `Documentation`/ `Applications Training` section. PDF copies of the NEST manual and draft Guidance can be copied to your hard drive or floppy disk.

Trifolds

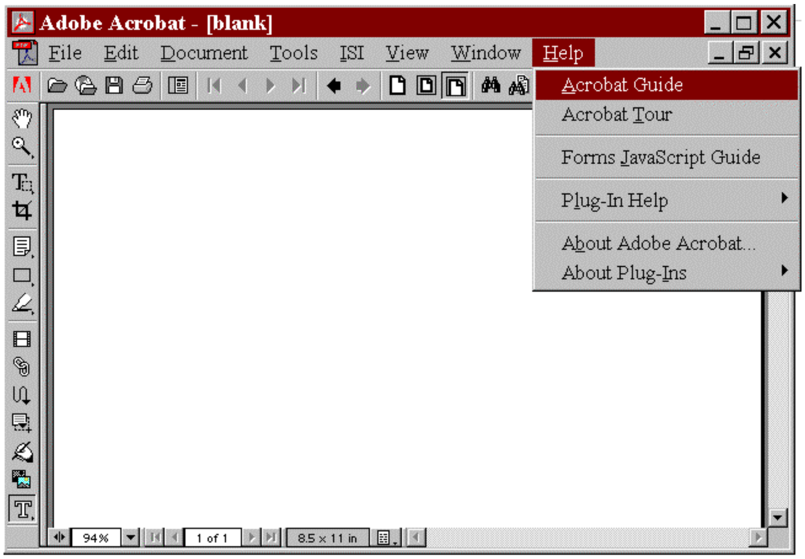
Quick reference desktop **trifolds** for Adobe Acrobat and NEST are provided in class or can be accessed and downloaded from the OIT Web. Use these trifolds for answers to frequently asked questions.

Adobe Acrobat Online Guide

NDA Electronic Submissions Training (NEST) introduces CDER staff to the features available in Adobe Acrobat 4.0. Additional information on the features discussed in this course, as well as Acrobat features not covered in this manual, can be found in the Acrobat Guide.

To access the Acrobat Guide:

- Go to `Help` | `Acrobat Guide` on the menu bar


Adobe Acrobat - [blank]
File
Edit
Document
Tools
ISI
View
Window
Help
Acrobat Guide
Acrobat Tour
Forms JavaScript Guide
Plug-In Help
About Adobe Acrobat...
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The Acrobat Guide will appear. Use the links on the front page or go to the index and the end of the file to browse topics alphabetically.

Exercise 5-1: Look up information about page layouts in the Acrobat Guide.

Acrobat Preferences

In order to utilize Acrobat in the electronic review environment and customize features for your use, preference changes can be made in Adobe Acrobat. Use the File | Preferences feature on the menu bar to change preferences for text and tables, annotations, page layouts, web integration, and other tools. Several preference changes are listed in this manual and the documentation provided when you install Adobe Acrobat from the OIT Web.

OIT Support

If you are unable to find the answers you need via class instruction, manuals, or the Acrobat Guide, please call the Help Desk at X7-0911 or e-mail them at HELPDESK. Please indicate whether your problem is related to Adobe Acrobat or electronic submissions (e.g., missing NDA folder).

Peer Support

Some of the best resources for learning are those who work with us every day. Those of you who have taken the NEST course and have a firm grasp of the electronic submissions process can help share your expertise with others by acting as a mentor to those seeking information and feedback to their ERSR related situations. Look for a more formalized peer support system as more Center staff become familiar with NEST and ERSR regulations.

Appendix - Exercise Solutions

Use this appendix to find the answers to the classroom exercises found throughout the manual.

Exercise 2-1: Access the Sample NDA 123456

- Start MS Internet Explorer by double-click 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, **987654** (Actual NDAs begin with 0) and press the `Search` button

Exercise 2 -2: Display the Sample NDA 123456 from the Search Results window in the EDR.

- Click on Click here for NDA 123456

Exercise 2-3: Map the drive letter Z: to sample NDA 123456 and DO NOT reconnect at logon.

- Minimize any open applications
- Right-click on `My Computer` and click `Map Network Drive`
- Select `Z` as the Drive letter and enter **\\cds006\samplenda** in the path field
- Make sure the `Reconnect at logon` box is not checked
- Click the `OK` button (you should now be mapped to the `sample` shared area)

Exercise 2-4: Create a desktop shortcut to the folder for sample NDA 123456 and close the `Samplenda on 'Cds006' (Z:)` window

- Right-click and hold down on the `n987654` folder.
- Drag the icon onto your desktop
- Lift your finger off of the mouse. A pulldown menu will appear.
- Highlight and click `Create Shortcut(s) Here`

- To change the desktop shortcut label, right-click the shortcut and choose `Rename`. If you are creating a shortcut to an Amendment or Supplement, make sure to include this information when renaming the shortcut
- Close the `Samplenda on 'Cds006' (Z:)` window

The shortcut appears on your desktop.

Exercise 2-5: Check the size of the N123456\CMC folder and copy it to your desktop.

To check the size of the folder:

- Double-click on the `Shortcut to N987654` icon on your desktop
- Right-click on the `CMC` folder
- Select `Properties` from the pulldown menu
- If the size of the folder you are copying is less than the space available on your `C:` drive, continue to the next step. If the folder is larger, you will not be able to copy the folder to your `C:` drive. Click `OK`

To copy the folder to your `C:` drive:

- Right-click on the `CMC` folder
- From the pulldown menu, select `Copy`
- Move your pointer onto the desktop and right-click. A pulldown menu will appear.
- Highlight and click `Paste`
- Close `My Computer` and the shortcut windows.

The folder now appears on your desktop.

Exercise 3-1: Open the table of contents for NDA 123456 and go to the labeling table of contents.

- Double-click the `Shortcut to N987654` shortcut on your desktop
- Double-click the *Ndatoc.pdf* file.

- Click the hand tool (✋) and move the pointer over the Labeling section of the Table of Contents. The pointer changes to a pointing finger icon (shown below), indicating that you are positioned over a link.

- Click the Labeling text to jump to the link destination—the Table of Contents for the Labeling folder.

Exercise 3-2: Compare the approved labeling with the proposed labeling file and browse through the new compare words file. Browse back to the beginning and then close the new file and *proposed.pdf* when you are done.

- Click the last approved labeling link in the labeling table of contents

- Click the Open button, 📂, on the command bar

- Double-click on the labeling folder

- Double-click on the *proposed.pdf* file

- While both files are open, go to `Tools` | `Compare Words` on the Acrobat menu bar

A new file titled `Compare Words proposed.pdf : appoved.pdf` appears listing the changes found in comparison of the two documents

- Click the Next Page button, ▶, to scroll and see how the documents differ

- Click the Last Page button, ▶|. You are now at the end of the document

- Click the First Page button, |◀, to return to the start of the document

- Close the new compare and *proposed.pdf* files

Exercise 3-3: Navigate back to the NDA table of contents and go to the Summary section of the NDA. Display the first page of the summary document at three different magnifications - 100%, fit the whole page inside the main window, and fit the width of the page inside the main window.

- Click the Go to Previous button, ◀, twice to go back to ndatoc.pdf

- Click on `Summary` in the table of contents

- Click on the Actual Size button, 🗋, to change the magnification to 100%

- Click on the Fit in Window button, , to fit the whole page inside the window
- Click on the Fit Width button, , to fit the width of the page in the window

You can also use the magnification option on the status bar, 79% ▾, at the bottom of the screen to change the magnification.

Exercise 3-4: Use the bookmarks to go to the Nonclinical Toxicology section of the summary document. Go back to the first page of the summary document when done.

- If the overview window is not displayed, click the Show/ Hide Navigation Pane button, , or the Navigation Pane button, , at the bottom of the screen
- Click the `Bookmark` tab
- Highlight and click on the `H. Nonclinical Toxicol`ogy bookmark
- Click the First Page button (**I**◂) to return to the start of the document

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Exercise 3-5: Find the patient deaths in the summary document using the Find tool.

- Click the find tool () in the command bar to display the Find dialog box. The Find dialog box lets you enter the word or phrase you want to find.
- For `Find What:`, enter **death**
- Select the Match Whole Word Only option. Selecting this option displays all occurrences of “death” only as it appears. The Match Case options allows you to look for words as they appear. Find Backwards lets you search backward starting from the current page in the document.
- Click the `Find` button to begin the search.

The word “death” appears towards the bottom of page 47 but it does not relate to deaths specific to this submission. To look for the word “death” in the rest of the document, use the Find Again option.

- To repeat your Find, click the find tool () and press the `Find Again` button to search again. As you can see the word “death” appears again on page 265 of the Summary document. Three deaths related to this submission are listed. It is noted to look in the case report form section for information on two of the deaths.

Exercise 3-6: Search the CRF index for any file related to 1) patient 0000 and 2) patient 1111 or any patients that start with the numbers 23.

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1) Patient 7839

- Click the Search Query Tool (🔍)
- Type the first patient ID# – **0000**
- Click the `Indexes` button
- Remove any existing indexes by clicking on them, then clicking on the `Remove` button
- Click the `Add` button
- Navigate to and find the *crf* folder
- Click on the index file, *crf.pdx*, and click `Open`
- Click `OK`
- In the Search window, click the `Search` button
- You will receive the message – No documents were found that matched your query.

Expand the search to the document information fields:

- Go to `File`|`Preferences`|`Search`
- Click the first box, `Show Fields`
- Click `OK`
- Enter **0000** in the Title section of the Document Information Field
- Click `Search` again.

2) Patient 0000 or any patient starting with the numbers 23

- Click the Search Query Tool (🔍)
- Put a comma (,) after 0000 (you can also use the Boolean expression *`OR`* instead of the comma)
- Add the second patient ID number and type**, 23***
- Click the `Search` button.

Exercise 4-1: Put a square around the three paragraphs at the top of page 266 of the N123456 summary document and leave a text note that reminds you to copy the paragraphs into your review. Circle the third paragraph and leave a text note that states there was no investigator report. Highlight the table on page 265 and leave a text note reminder to copy the table into your review. Save your annotations.

Rectangle Annotation:

- On the Menu Bar, go to File | Save As
- Save the summary document to the `C:\Classes\NEST` folder (The network copy is read-only)
- In the current page section of the status bar, type **266** and press [`ENTER`]
- On the tool bar, press and hold down on the pencil tool, ✎. Drag to the right and select the rectangle tool, ▭
- Click and *drag* a rectangle around the first three paragraphs on the page.
- Move your pointer on the rectangle so the arrow, ▲, appears and double-click
- Type in your note and click the minus bar to close the note field

Pencil Annotation:

- On the tool bar, press and hold down on the rectangle tool. Drag to the right and select the pencil tool
- Click and draw a circle around the third paragraph.
- Select the hand tool
- Move your pointer on the line around the third paragraph so the arrow, ▲, appears and double-click
- Type in your note and click the minus bar to close the note field

Highlight Text Annotation:

- Click the Previous Page button
- On the tool bar, click Highlight Text button, ✎
- Click and drag over the text in the table at the bottom of the page.
- Move your pointer on the line around the table until the arrow, ▲, appears and double-click
- Type in your note and click the minus bar to close the note field

- Select the Hand Tool

Save the file to a local drive:

On the menu bar, go to `File` | `Save As`

Save *Summary.pdf* in the `C:\Classes\NEST` folder

Exercise 4-2: Summarize your annotations for the summary document in a new file, then close the file. Summarize your annotations in the Navigation Pane. Save your file.

Summarize Annotations:

- On the menu bar, go to Tools | Annotations | Summarize Annotations
- After reviewing, close the summary file without saving

Annotation Palette:

- Click on the `Annotations` tab in the Navigation Pane
- At the bottom of the Navigation Pane, click on the Start Annotation Scan button
- Click the Save button

Exercise 4-3: Change the Acrobat formatted text preferences to remove indentation paragraph formatting when exporting. Copy the three paragraphs on page 266 of the summary document to a Microsoft Word document.

- On the Menu bar, go to File | Preferences | Table/Formatted Text
- Click the `RTF Export` tab
- *Uncheck* the `Indentation` box
- Click `OK`
- Navigate to page 266
- On the tool bar click on the Text Select Tool, , and drag to the right and select the Table/ Formatted Text Select Tool,
- Click and drag a box around the three paragraphs

- Make sure the type is `Text-Flow` (If not, right-click in the paragraph and choose `Text` | `Flow` from the popup menu)
- On the Menu Bar, go to `Edit` | `Copy`
- Launch Microsoft Word
- On the pulldown menu, go to `Edit` | `Paste` or click the Paste button, , on the Toolbar

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Exercise 4-4: Copy the table on page 265 of the summary document to a Microsoft Word document. Put borders on the table.

- Go back to Adobe Acrobat
- Navigate to Page 265
- Click the Formatted Text Select Tool,
- Click and drag a box around the table
- Make sure the type is `Table` (If not, right-click in the table choose `Table` from the popup menu)
- On the Menu bar, go to `Edit` | `Copy`
- Go back to Microsoft Word
- On the pulldown menu, go to `Edit` | `Paste`
- Select the table
- Click the borders button, , on the Formatting toolbar
- Use the eraser tool, , or the merge cells tool, , to remove the excess borders

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Exercise 4-5: Copy the scatter plot on page 242 of the N123456 summary document to a Microsoft Word document as a graphic that does not float over text.

- Go back to Adobe Acrobat
- Navigate to page 242 of the Summary document
- On the Tool Bar, select the ISI Graph Copy Plus button,
- Click and drag a box around the scatter plot

- When you let go of the mouse, wait a few moments until the box disappears
- Go to Microsoft Word
- On the pulldown menu, go to `Edit`|`Paste Special`
- Uncheck the `Float over text` box
- Click `OK`

Exercise 5-1: Look up information about page layouts in the Acrobat Guide.

- On the menu Bar, go to `Help`|`Acrobat Guide`
- Use the index to search for **P**age layouts. Click the last page button, ⏭, on the command bar
- Make sure the hand tool is selected and click the `P` hyperlink on the right hand side of the page
- Page layouts will appear at the bottom of the page and the categories with links can be found on the next page. Click the next page button, ▶, on the command bar
- Click on the `for document viewing 41-43` link at the top left of the page. Browse through the topic