Welcome to SMARTS Annual Reports Help

SMARTS AR (Annual Reports) Help is designed to address the functional aspects of the SMARTS AR program. Help information concerning Annual Reports can be accessed using the **Contents**, **Index**, or **Search** commands at the top, left-hand side of this screen.

- The table of **Contents** is the default display in the left panel of this screen. Click a book icon to display the help topics it contains. Click a topic name to display the topic in this space.
- The **Index** presents an alphabetical list of all help topics and index keywords. Type any character or text into the field at the top of the index and the term that most closely matches that text will automatically be selected. Click the selected index term and either a help topic will appear or a list of associated help topics will appear.
- The **Search** command enables you to query all help topics concerning any term about which you would like more information. Type the desired term into the Search field and then click **Go**. All help topics are searched and only those containing the term are automatically listed for your selection.

Microsoft Word® Help

Microsoft Word Help should provide answers to any questions you have about using Word to work on your annual report. To access Word Help, on the Word menu bar open the **Help** menu and click **Microsoft Word Help**. The **Microsoft Word Help** dialog box appears.

Accessing Annual Reports

Annual Reports is a Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS) application accessed via the CTEP-ESYS front panel. Depending on your user access role, Annual Reports is accessed by either logging on to CTEP-ESYS directly or by logging on via CITRIX. See your system administrator or manager for access information.

To open Annual Reports from CTEP-ESYS perform the following steps.

1. Log on to CTEP-ESYS.
2. On the CTEP Enterprise System front panel, click the **Annual Reports** button.

   The **Annual Reports** window appears.

Related Topics:

Annual Reports Access via CITRIX.

User Credentials

Troubleshooting

Annual Reports Access via CITRIX

Users from TRI gain access to Annual Reports by logging on via Citrix ®.

To open Annual Reports using Citrix perform the following steps.

1. Open Internet Explorer ® and enter the address http://ctep.ts.nci.nih.gov.

   The CTEP Citrix user Login page appears.

2. Type your Citrix user credentials (**Username**, **Password**, and **Domain**).
3. Click **Log In**.

The Citrix application portal appears.

4. Click **CTEP Enterprise Application - TRI**.

   A **Logon** dialog box for the CTEP Enterprise System (CTEP-ESYS) appears.

5. Type your CTEP-ESYS user credentials (**Username**, **Password**, and **Database**).

   The CTEP ESYS front panel appears.

6. Click **Annual Reports**.

   The **Annual Reports** window appears.

Related Topics:

Accessing Annual Reports

User Credentials

Troubleshooting

User Credentials

Information you'll need for access to Annual Reports.

Citrix ®

- **Username**: Use your local TRI user name.
- **Password**: Use your local TRI password.
- **Domain**: *ncitri*

CTEP Enterprise System

- **Username**: Use your CTEP-ESYS Login ID.
- **Password**: Use your CTEP-ESYS Password.
- **Database**: *ctepesysprod*

Related Topics:

Accessing Annual Reports

Annual Reports Access via CITRIX

Troubleshooting

Troubleshooting

Messages concerning the log on process may appear in the Citrix ® Message Center. A brief description and possible solution for some common error messages are listed below:

- *You do not have the Citrix ICA CLient (AciveX) for 32-bit Windows installed on your system. You must install the ICA Client to launch the applications.*

The Citrix Client was not installed on your machine or the install was not successful. If you see this message contact your help desk.

- *ERROR: The MetaFrame server farm reported that the Credentials entered were incorrect.*

  Your user credentials (**Username**, **Password**, or **Domain**) entered on the CTEP Citrix user Login page are incorrect. Verify your user credentials and try again.

- *ERROR: Your session with the web-server expired. You have been logged out.*

  Your session with Citrix has expired due to inactivity. You will have to log on again.

Related Topics:

Accessing Annual Reports

Annual Reports Access via CITRIX

User Credentials

Accessing Microsoft Word Help

Microsoft Word Help should provide answers to any questions you have about using Word to work on your annual report. To access Word Help, on the Word menu bar open the **Help** menu and click **Microsoft Word Help**. The **Microsoft Word Help** dialog box appears.

Related Topics:

Contacting the CTEP Help Desk

Contacting the CTEP Help Desk

If you encounter problems while working with SMARTS Annual Reports please contact the CTEP Help Desk by sending an email, with a detailed description of the problem, to **ctephelp@ctisinc.com**

Related Topics:

Accessing Microsoft Word Help

About SMARTS Annual Reports

Annual reports containing clinical trial data and information concerning specific Investigative New Drugs (IND) are created for submittal to the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP), Investigational Drug Branch (IDB) and the Food and Drug Administration (FDA).

An annual report is a Microsoft® Word document comprised of many sections with each section designed to present unique information about any selected IND. The Scientific Management of Agents Reporting and Tracking System (SMARTS) Annual Reports application enables you to create, update, review, and generate annual reports. For more information see the following topics.

Related Topics:

About Creating an Annual Report

About Editing an Annual Report

About Completing an Annual Report

SMARTS Annual Reports Version History

Version Number	Release Number	Date	Release Notes
3	NA	03/14/2003	Production
3	2	07/04/2003	
3	3	07/31/2003	
3	4	08/07/2003	
3	5	09/25/2003	
3	7	05/28/2004	
3	8	08/26/2004	
3	9	04/11/2005	
3	10	07/13/2005	SMARTS AR v3 r10 Release Notes
4	1	09/29/2006	SMARTS AR v4 r1 Release Notes

About SMARTS Annual Reports System Requirements

The Scientific Management of Agents Reporting and Tracking System (SMARTS) Annual Reports application uses automated processes for the creation and maintenance of Annual Reports. Certain system requirements must be adhered too so that these automated processes function correctly. For more information see the following.

System Requirements for Annual Reports

Permitting Macro Execution by Microsoft Word

Accessing Annual Reports

Permitting Macro Execution by Microsoft Word

Most of the SMARTS Annual Reports application features and functions are driven by macros. To function correctly the Annual Reports application requires that Microsoft® Word is appropriately enabled to run macros. To enable macro execution by Word do the following when necessary.

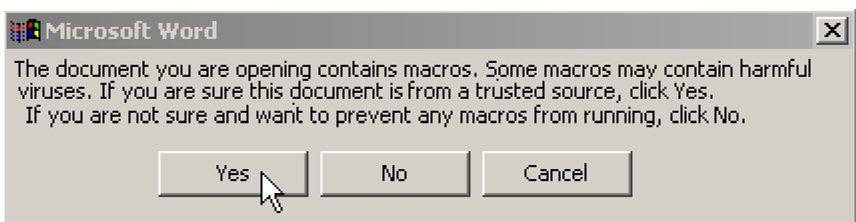
Macro Security

If a Re Run message appears while you are logging on to Annual Reports, perform the following steps to change your macro security settings for Word.

1. Open Microsoft Word.
2. From the **Tools** menu click **Macro**, then select **Security**.
3. Click the **Security Level** tab, then select **Medium** and click **OK**.

Enabling Macros

When you begin creating an annual report a macro warning appears. Click **Yes** to enable the correct functioning of Annual Reports.

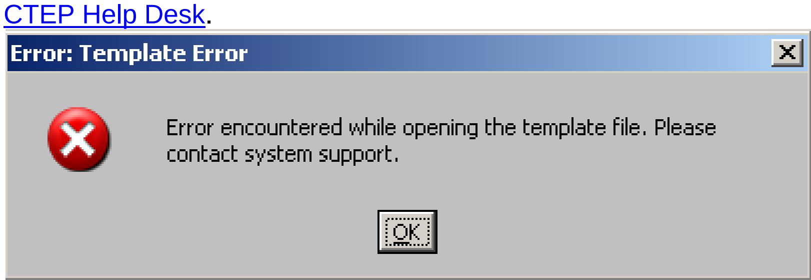


If you click **No** to prevent the macros from running, the Annual Reports application will not function properly.

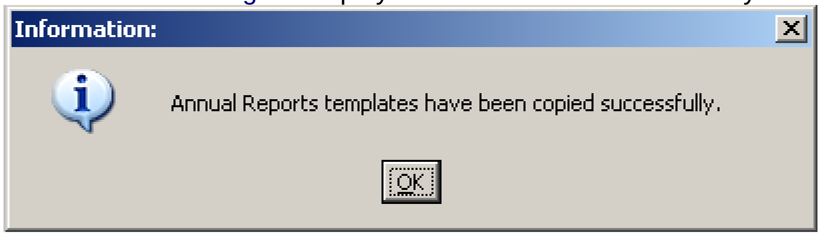
System Requirements for Annual Reports

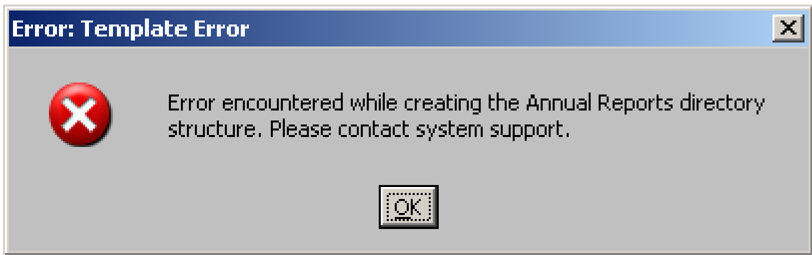
To ensure that the Annual Reports application performs correctly the following system requirements must be met.

- **Availability of Annual Reports templates:** The AnnualReports.dot and ARAddEditSection.dot templates are necessary so that the Annual Reports application can correctly function within Microsoft Word. The Annual Reports application automatically copies these templates to your computer's local drive. If these template files are inaccessible or not present an error message is displayed. If this occurs then contact the CTEP Help Desk.

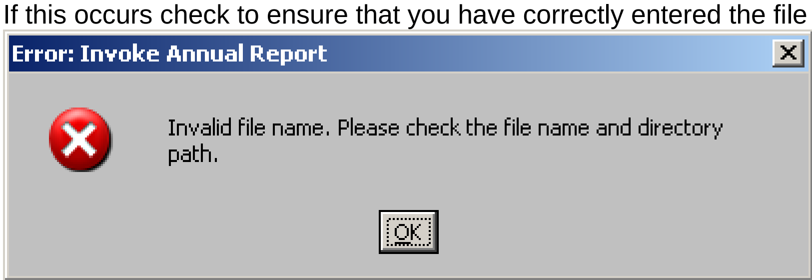


- **Local drive read/write permission:** The Annual Reports application creates temporary files and updates local versions of Section documents (used as format templates in reports) as a normal part of the report generation process. For this purpose, it is required that you have read/write permission for the local drive used by the application. After successfully connecting to the shared network data resource, the Annual Reports application determines whether you have read/write permission. If you do then a confirmation message is displayed. If you do not have read/write permission for this drive then an error message is displayed. If this occurs then contact your System Administrator.

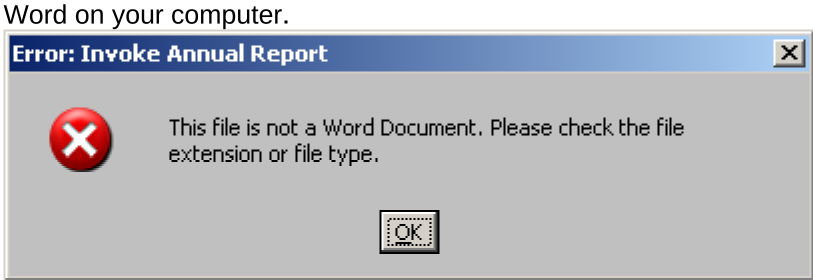




- **Valid file name and directory path:** When ever you open or save any annual report file the Annual Reports application validates that a correct file name and directory path are used. If you enter an invalid file name or directory path then an error message is displayed. If this occurs check to ensure that you have correctly entered the file name.



- **Must be a Word document**: All document files created, opened, or saved in the Annual Reports application must be Word documents. If the file name extension is not **.doc**, then an error message is displayed. If this occurs ensure that you have access to Microsoft Word on your computer.



About Creating Annual Reports

The Annual Reports application provides four distinct methods for creating an annual report.

- **Creating an Annual Report by Using the Wizard:** Annual Reports was designed around this method. The Annual Reports Wizard automates much of the report writing process. The Wizard prompts you to specify the IND and the report sections that you want included in the report and then generates a report document based on your responses. The report document opens in Microsoft Word and information from the appropriate annual report libraries is automatically populated. Finally edit (specify dates for select tables and insert information into areas where the application was unable too) and complete the report to ensure it is ready to be sent, and archived.
- **Creating an Annual Report from an Archived Annual Report:** An archived annual report for an IND can be used as the basis for creating a new report for the same IND. When you attempt to create a new annual report the application will give you the option to access an archived annual report for the same IND. Once the archived report is displayed, you simply update and edit the existing information.
- **Creating an Annual Report from a Similar Annual Report:** When you are creating a new annual report that will be substantially similar to an existing annual report for a different IND, it may be easiest to open the existing report, change the IND, and then update and edit the appropriate information. In a sense, you are using the existing report of one IND, as a very detailed report template for another IND.
- **Creating an Annual Report without Using the Wizard:** This method is used only when you have very specific reporting needs. This is the most labor-intensive of the methods offered and involves selecting sections, tables, and text one-by-one from the respective annual report libraries.

Once an Annual Report has been created using any of the methods described above you must edit and then complete the resulting document before it is ready to be sent. For more information see the following topics.

Related Topics:

About Editing an Annual Report

About Completing an Annual Report

Creating an Annual Report by Using the Wizard

The Annual Reports Wizard automates much of the report creation process and generates a report document based on the responses you make during the process.

Note: For important information concerning macro settings see Permitting Macro Execution by Microsoft Word.

To create an annual report by using the Annual Report Wizard

1. On the **Annual Reports** window, click **Create New** and then **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

2. Click **Yes**, and the **Annual Report Wizard** appears.
3. In the **Select an IND** field, enter the IND for which the report is being created.

   The remaining fields automatically populate with information concerning the selected IND.

4. Click **Next**.

   If an annual report for the selected IND was previously generated and archived, a message appears asking if you want to retrieve that report.

5. Click **No**.

The **Select Sections** field appears displaying the names of section templates available for inclusion in the report.

Note: In the **Select Sections** field, some sections are automatically selected based on whether or not the IND is a biologic or chemotherapeutic.

6. In the **Select Sections** field, ensure that the name of those sections you want to appear in the report are selected.
7. Click **Finish**.

   The draft annual report appears, ready for your editing and completion.

8. If necessary edit the report (see About Editing an Annual Report).
9. Perform the report's completion process as described in About Completing an Annual Report.
10. Save the report.

Related Topics:

About Creating an Annual Report

Saving an Annual Report

Creating an Annual Report from a Similar Annual Report

You can create an annual report for an IND by using an existing annual report of a different IND as a template.

To create an annual report from a similar report

1. On the **Annual Reports** window, click **Open Existing** and then in the adjacent field enter the path of the report you want to open and use as a template.
2. Click **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

3. Click **Yes**.

   The annual report document appears.

4. On the **Report Generator** menu (on the Word toolbar), click **Assign IND**.

   The **Assign IND to Document** dialog box appears.

5. In the **Select an IND** field, type or select the number of the IND for which the report is being creating .

   The **IND Title** field automatically populates.

6. Click **Assign**.

   Note: You will see no apparent change to the opened annual report document, but the information contained in all of the Annual Reports Libraries is now associated with the newly assigned IND.

7. Edit the report to include the appropriate information (see About Editing an Annual Report).
8. Perform the report's completion process as described in About Completing an Annual Report.
9. Save the report.

Related Topics:

About Creating an Annual Report

Saving an Annual Report

Creating an Annual Report from an Archived Annual Report

When a previous year's annual report for an IND exists, it can be used as the basis for creating this year's report concerning the same IND.

Note: This method of creating a subsequent year's annual report is only available when a previous annual report for the IND has been prepared for FDA submission and archived.

To create an annual report from an archived report

1. On the **Annual Reports** window, click **Create New** and then **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

2. Click **Yes**.

   The **Annual Report Wizard** appears.

3. In the **Select an IND** field, enter the IND for which the report is being creating.

   The remaining fields automatically populate with information concerning the selected IND.

4. Click **Next**.

   If an annual report for the selected IND was previously generated and archived, a message appears asking if you want to retrieve that report.

5. Click **Yes**.

   The last archived annual report for the selected IND appears (replacing the Annual Report Wizard) and is ready for your editing and completion.

6. Make any necessary changes to the report (see About Editing an Annual Report).
7. Perform the report's completion process as described in About Completing an Annual Report.
8. Save the report.

Related Topics:

About Creating an Annual Report

Saving an Annual Report

Creating an Annual Report without Using the Wizard

Annual reports can be created without using existing reports as templates and/or without the assistance of the Annual Report Wizard. When using this method all of the Annual Reports application Libraries are available from the Word toolbar to insert IND specific sections, tables, and data. To create a new annual report without using the annual report wizard perform the following steps.

1. On the **Annual Reports** window, click **Create New** and then **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

2. Click **Yes**.

The **Annual Report Wizard** appears.

3. Click **Cancel**.
4. On the **Report Generator** menu (on the Word toolbar), click **Assign IND**.

   The **Assign IND to Document** dialog box appears.

5. In the **Select an IND** field, type or select the number of the IND for which the report is being created.

   The **IND Title** field automatically populates.

6. Click **Assign**.

   The Annual Reports Libraries (**Data Library**, **Table Library**, **Section Library**, and **Special Library**) appear on the Word toolbar and a draft annual report is ready to edit.

7. Edit the report to include the appropriate information (see About Editing an Annual Report).
8. Perform the report's completion process as described in About Completing an Annual Report.
9. Save the report.

Related Topics:

About Creating an Annual Report

Saving an Annual Report

Designating Protocol Trial Types

A Trial Type indicates whether a protocol uses a single agent or a combination of multiple agents. When you open or create an annual report, all protocols associated with your selected IND are checked to see if they have an assigned Trial Type. If one or more protocols associated with the IND do not have an assigned Trial Type, then an Invalid Trials message appears and the annual report is not generated. The Annual Reports application provides you with the means to assign Trial Types to protocols when necessary.

To assign Trial Types to protocols perform the following steps.

1. When an Invalid Trials message appears click **OK**.
2. Return to the Annual Reports window, and click **Trial Designation**.

   The Protocol Trial Type Maintenance screen appears.

3. Type the desired IND identification number into the **IND Number** field.
4. Enter the appropriate value into the **IND Prefix** field.
5. On the Toolbar, click **Execute Query** .

   Information concerning your queried IND appears in the IND Information area, and all protocols associated with that IND appears in the Protocols area. All protocols are sorted by **Trial Type** and **Protocol Number**. Those without a **Trial Type** are at the top of the list.

   Note: Only protocols having a **Current Status** of *Active*, T*emporarily Closed to Accrual, Temporarily Closed to Accrual and Treatment*, *Closed to Accrual*, and *Closed to Accrual and Treatment* are displayed.

6. Ensure that all protocols have an appropriate value entered into the **Trial Type** field.
7. Save your changes.

Note: Once your query results appear you can use **Previous Record** and **Next Record** to review information concerning other IND's.

Related Topics:

About Creating Annual Reports

Opening an Existing Annual Report

About Annual Report Section Templates

An annual report section template is a named section document which, when incorporated into an annual report, provides a format for a specific type of information concerning any IND for which the annual report was created. These named section templates (section documents) are comprised of text and/or tables formatted to best accommodate the information to be displayed in that section. Many of these section templates include macros which automatically populate the latest updated data whenever the reports are generated.

When an annual report is created all of the section templates selected for that report are automatically integrated into the report by the Annual Reports application.

Note: The AnnualReports.dot and ARAddEditSection.dot files mentioned in System Requirements for Annual Reports and used by the Annual Reports application are true Word templates that should not be modified.

After an annual report has been generated by the application, you can make changes to the content and format of any section in the report. However, these changes affect only that individual report and have no bearing on the section templates used by the application to generate any other report.

You can make changes to individual annual report section templates directly and then these changes will appear in or be available for all annual reports generated by the application thereafter. For specific instructions about changing or creating section templates see the Related Topics below.

Note: Administrator permission is required before altering an annual report section template (section document).

Related Topics:

Creating a Section Template

Editing a Section Template

Creating a Section Template

New annual report section templates (section documents) can be created and added to the list of section templates that are available for use in individual IND annual reports.

Note: Administrator permission is required before altering annual report section templates.

To create a new section template

1. On the **Annual Reports** window, click **Create New** and then **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

2. Click **Yes**.
3. In the **Annual Report Wizard**, click **Cancel**.

A blank Word document opens and three Annual Reports menus (**Report Generator, Administration**, and **Options**) appear in the tool bar.

4. On the **Administration** menu, click **Add New Section Template**.

   A second blank Word document opens and the following Annual Reports menus appear on the tool bar.

   Section Generator

   Data Library

   Table Library

   Special Library

5. In the document, type the desired section heading (formatted to be consistent with other annual report section headings) and other appropriate textual information.
6. Place the cursor were you want other text or tables to be automatically inserted during Annual Report generation and then select the desired text or table from the **Data Library**, **Table Library**, or **Special Library** menus.

   A field or bookmark representing your selection appears at the desired location. Repeat this step as often as necessary.

7. On the **Section Generator** menu, click **Save Section to Database**.

   The **Save Section** dialog box appears.

8. In the **Document Name** field, type the desired file name for the new section template (because this is a Word document include .doc).
9. In the **Display Name** field, type the name of the section.

   Note: In the **Version** field the number one is displayed. Do not change this value.

10. In the **Insert After** field, enter the name of the section you want preceding the new section in the **Annual Reports Wizard** list of sections.
11. In the **Format** area, click **Portrait** or **Landscape** to indicate the page orientation of the new section.
12. In the **Type** area, click **Biologic**, **Chemo**, **Neither**, or **Both** to indicate the type of IND for which the new section is available.

    Note: In the **First/Subsequent Queried Section** area, **No** is selected. Do not change this selection.

13. Click **Save**.

    The new section is added to the list of available section templates. All annual reports that are generated, will include this section for the specified IND type.

Related Topics:

About Annual Report Section Templates

Editing a Section Template

Existing annual report section templates (section documents) can be edited and after the edited template is saved the changes will appear when any report containing those sections is generated.

Note: Administrator permission is required before altering annual report section templates.

To edit a section template

1. On the **Annual Reports** window, click **Create New** and then **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

2. Click **Yes**.
3. In the **Annual Report Wizard,** click **Cancel**.

   A blank Word document opens and three Annual Reports menus (**Report Generator**, **Administration**, and **Options**) appear in the tool bar.

4. On the **Administrator** menu, click **Edit Section Template**.

   The **Edit Section** dialog box appears.

5. In the **Choose Section to Edit** field, enter the name of the section template you want to edit and then click **Edit**.

   The selected section template Word document opens and the following Annual Reports menus appear on the tool bar.

   Section Generator

   Data Library

   Table Library

   Special Library

6. Make desired changes to the existing document content (text or tables).
7. If necessary place the cursor were you want additional text or tables to be automatically inserted during Annual Report generation, and then select the desired text or table from the **Data Library**, **Table Library**, or **Special Library** menus.

   A field or bookmark representing your selection appears at the desired location. Repeat this step as often as necessary.

8. On the **Section Generator** menu (on the Word toolbar), click **Save Section to Database**.

   The **Save Section** dialog box appears.

9. Ensure that all fields and options in the **Save Section** dialog box are correct for your changes. (For more information see Creating a Section Template).
10. Click **Save**.

Related Topics:

About Annual Report Section Templates

About Editing an Annual Report

When an annual report is created information (document formatting, textual content, data) is automatically inserted by the Annual Reports application. Because the application requires you to modify some of the automatically inserted information (see About Editing Text in an Annual Report) any annual report you create must be edited to ensure that the correct information is displayed in the report. Before you start editing consider the following.

- **Document Formatting:** Click the **Show/Hide** button ¶ on the standard toolbar to ensure that document formatting marks are displayed. This helps you avoid changing document formatting unintentionally and makes it easier to select any formatting characteristics that you do want to change.

- **Bookmarks:** Bookmarks mark the location of tables or text that are automatically placed within an annual report document. On your screen bookmarks appear in the document as brackets (**[…]**) or an **I**-beam. These marks do not print. When you edit a report bookmarks must be displayed so that you do not inadvertently delete them. On the **Options** menu click **Hide/Show Bookmarks**. Remember that if you make changes to tables or text inside a set of bookmarks the changes will be undone when you later update the annual report.
- **Fields:** Annual report text enclosed in a grey background represent Word fields automatically placed within the document. Fields indicate text or data that is automatically inserted when a report is created or updated, or may ask you to type specific information at that location. Do not delete or type in a field unless it specifically asks you do so. For more information see Working with Green-Colored Text.

Information that can be inserted into an annual report is stored in and accessible from one of four Annual Reports Libraries described below. During the annual report editing process these libraries, accessible from the Word toolbar, make it easy for you to add, modify, or update annual report information.

- **Data Library:** A list of named blocks of text that can be inserted into an annual report.
- **Section Library:** A list of formatted annual report sections that can be inserted into a report.
- **Table Library:** A list of previously created data specific tables that can be inserted into a report.
- **Special Library:** A list of specially formatted information that can be inserted into a report.

All of the items listed in the libraries are Word documents whose content is indicated by the name of each item. Many of the library documents contain fields or bookmarks that automatically insert or update specific types of data.

Related Topics:

About Annual Report Sections

About Annual Report Tables

About Editing Text in an Annual Report

Using Page and Section Breaks

Opening an Existing Annual Report

To open an existing annual report perform the following steps.

1. On the **Annual Reports** window, click **Open Existing** and then type or select the path of the report you want to open.
2. Click **OK**.

   Microsoft Word opens with a message asking if you would like to open a document with it's attached macros running.

3. Click **Yes**.

   The selected annual report document appears.

Related Topics:

About SMARTS Annual Reports

About Editing an Annual Report

Using Page and Section Breaks

Page breaks are inserted into annual report documents to ensure that specific report sections begin at the top of a new page. For example, a page break is automatically inserted after the table of contents so that the following section begins at the top of the next page.

Section breaks are inserted into annual report documents when a change of section formatting is needed. Section breaks can be used to change the formatting in the middle of a page or to start different formatting on a new page. In an annual report, section breaks are commonly used to accommodate tables that need a landscape page orientation.

Editing, moving, or adding sections in an annual report may result in unnecessary or misplaced page or section breaks creating blank pages. You can add, delete, or move page and section breaks to correct this but to do this you must be able to see where they are located in the document. In an open annual report the following actions can be taken.

- To see page and section breaks click the **Show/Hide** button ¶ on the standard toolbar to ensure that document formatting marks are displayed.
- To delete a page or section break select the formatting mark of the desired break and then press **DELETE**.
- To add a page or section break:
    1. In the annual report, place the insertion point where you want a page or section break.
    2. From the **Insert** menu, choose **Break**.
    3. Select the type of page or section break you want to add and then click **OK**.

Related Topics:

About Editing an Annual Report

Opening an Existing Annual Report

About Annual Report Sections

An annual report is divided into named sections each of which is formatted to accommodate a specific type of information concerning the IND for which the report is created. When using the Annual Report Wizard to create a draft report, sections to be inserted are automatically selected based upon whether the IND is biologic or chemotherapeutic.

During the annual report creation process you can change which sections are inserted into the draft report (see About Creating an Annual Report). You can also add or delete report sections after the draft report has been created. See the Related Topics below for more details.

Note: Adding or deleting sections from an existing annual report will not change which sections the Annual Reports application automatically select's for insertion when generating future reports. To permanently modify the section templates available for use in this process see About Annual Report Section Templates.

Related Topics:

Adding an Annual Report Section

Deleting an Annual Report Section

Adding an Annual Report Section

The Annual Reports application uses previously created section templates to automatically insert formatted sections into newly created reports. You can also use these section templates to insert additional sections into an existing report.

Note: To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

To insert a section

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).
3. In the annual report document place the insertion point where you want to insert the section.
4. On the **Section Library** menu, click the name of the desired section.

   The selected section (and any included text or tables) appears in the annual report.

   Note: Formatted page and section breaks contained in the added section may be integrated into the report imperfectly and may need to be moved or deleted. For more information see Using Page and Section Breaks.

Related Topics:

About Annual Report Sections

Deleting an Annual Report Section

Deleting an Annual Report Section

To delete a section from an annual report perform the following steps.

Note: To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Select the text and formatting marks of the report section you want to delete.
3. Press **Delete**.
4. Save the report.

Related Topics:

About Annual Report Sections

Adding an Annual Report Section

About Annual Report Tables

Tables used repeatedly in annual reports are stored in the Table Library. The Table Library can be used to select and then insert tables into existing or draft annual reports. After being inserted into a report some tables require that you specify a date range (see Generating Date Parameter Tables) from which data is drawn for display in the table. Therefore, before a draft annual report is ready to be completed and sent you must edit the report to ensure that all appropriate tables are present and contain the correct information.

You can edit the textual content of annual report tables directly by using a combination of Word tools and tools provided by the Annual Reports application for this specific purpose. For more information see the **Related Topics** below.

Note: To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

Related Topics:

Generating Date Parameter Tables

Editing a Table

Inserting a Table

Moving a Table

Updating a Table

Displaying Table Statistics

Listing Updated Clinical Trials

Displaying Table Statistics

Displaying the table statistics of an open annual report allows you to determine the time and date a table or special section was last updated by the application.

To display table statistics, on the **Options** menu click **Report Statistics**. When you are done reviewing the information click **Close** to return to the report.

Related Topics:

About Annual Report Tables

About Editing Text in an Annual Report

Editing a Table

In an annual report the textual content and format of any table can be edited directly by using a combination of Word tools and tools provided by the Annual Reports application for this specific purpose.

Note: In your annual report, bookmarks indicate the locations of automatically inserted tables. To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

The textual contents of a table can be edited just like the text in your annual report. After creating or opening an annual report some of the actions you can take to edit any tables in the document are listed below.

- Change the size of table columns and rows by dragging their boundaries until the desired size is achieved.
- Delete columns, rows, or cells by selecting them and then from the **Table** menu (on the Word menu bar) select **Delete**, and choose either **Column**, **Row**, or **Cell**.
- Clear the contents of columns, rows, or cells by selecting them and then press **Delete**.
- Add information by placing the insertion point at the desired location in the table and then type the desired text.

- Make the table columns automatically fit the contents by placing the insertion point in the table and then from the **Table** menu select **AutoFit** and choose **AutoFit to Contents**.

For more detailed information concerning the above actions and other methods of table editing see Microsoft Word Help.

Note: For tables having bookmarks (**[**...**]**) any modifications made will be undone if the table is later updated (see Updating a Table). For this reason, editing tables directly in a report should only be done after all automated updates have been made and the report is being completed for submission.

Related Topics:

About Annual Report Tables

About Editing Text in an Annual Report

Generating Date Parameter Tables

An Annual Report can include tables that do not appear until you generate the tables using specific date parameters. This is applicable to the Patient Deaths, Expedited Adverse Events, and Patient Dropouts tables.

To generate tables requiring date parameters

1. Open the desired Annual Report (see Opening an Existing Annual Report) and ensure that it contains a table requiring date parameters (Patient Deaths, Expedited Adverse Events, and/or Patient Dropouts).
2. On the **Report Generator** menu, click **Enter** **Table Dates**.
3. In the **Table Dates** dialog box, select the **Update** checkbox for each table you want to generate.

   Note: The date parameters used for generating tables in the latest archived report are displayed in **Previous Year's From Date** and **Previous Year's To Date.**

4. For each table, type the desired date parameters into the **From Date** and **To Date** text boxes.
5. Click **Update**.

   Word will generate and then insert the tables into your report.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Inserting a Table

To insert a table into an existing or draft annual report perform the following steps.

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).
3. In the report, place the insertion point where you want the table.
4. On the **Table Library** menu, click the name of the desired table.

   The selected table appears in the annual report.

5. On the **Reports Generator** menu, click the **Enter Table Dates** command if necessary to generate tables that require date parameters (see Generating Date Parameter Tables).

Related Topics:

About Annual Report Tables

Inserting a Table to Replace an Existing Table

Inserting a Table while Keeping an Existing Table

Inserting a Table to Replace an Existing Table

While editing a table in an annual report, instead of modifying or fixing undesirable changes made earlier, it may be easier to replace the existing table, with the same named table from the Table Library.

Note: In your annual report bookmarks indicate the locations of automatically inserted tables. To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

To insert a replacement for an existing table

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).
3. Place the insertion point inside the existing table you are replacing.

   Note: If the existing table is without bookmarks (**[**...**]**) then the table is not linked to the Table Library and cannot be automatically replaced per these steps. You must delete the existing table before inserting the replacement (see Inserting a Table).

4. On the **Table Library** menu click the name of the table you are replacing.

   Note: Ensure that the table selected in the Table Library is the same as the one in which you have placed the insertion point.

   The existing table is replaced.

Related Topics:

About Annual Report Tables

Inserting a Table

Inserting a Table while Keeping an Existing Table

Inserting a Table while Keeping an Existing Table

While creating a new annual report from an archived report, you may want to include comparisons between new data and historical data already contained in the report. An easy way to do this is to keep a table of historical data in the report and then add an updated version of the same table.

Note: In your annual report bookmarks indicate the locations of automatically inserted tables. To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

To insert a second version of a table while keeping the existing table in the report

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).
3. In the report place the insertion point where you want the new table.

   Note: Ensure that the insertion point is placed outside of the bookmarks (**[**...**]**) for the existing table.

4. On the **Table Library** menu click the name of the table you are inserting.

   Note: Ensure that the table selected in the **Table Library** is the same table already existing in the report.

   The selected table appears in the annual report. In the document any references to the old table are automatically changed to apply to the newly inserted table. Note that the old table no longer has bookmarks and any updates will be applied to the new table (see Updating a Table).

Related Topics:

About Annual Report Tables

Inserting a Table

Inserting a Table to Replace an Existing Table

Listing Updated Clinical Trials

In any annual report, immediately following the table of contents is the Listing of Updated Clinical Trials section. This section contains (or will contain) an Updated Clinical Trials table which is a complete list of current clinical trials related to the IND for which the report has been created. The Updated Clinical Trials table needs to be generated after the annual report is created and should be updated prior to reviewing or submitting the report.

To generate or update the Updated Clinical Trials table

1. On the **Report Generator** menu click **Refresh Updated Clinical Trials Table.**

   The **Protocol List** dialog box appears.

   Note: The **Previous Year's From Date** and **Previous Year's To Date** fields display the dates used for the most recent archived report.

2. Type the desired dates into the **From Date** and **To Date** fields.
3. Click **Refresh List**.

   All open protocols associated with the IND, and which also had a status or accrual change within the specified dates, are displayed and selected. If no protocols appear, then for your selected time period data is not available to generate a table for the report.

4. Click **Update**.

   The Updated Clinical Trials table is automatically generated and inserted into your report.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Moving a Table

There are three ways to move a table from one annual report location to another.

- **Select and drag the table to a new location.** Use this method when moving the table a short distance on a single page.
- **Cut and paste the table into a new location.** Use this method for moving tables that have prior modifications which you do not want to lose.
- **Delete and then insert the table into a new location.** Use this method to move tables that can be reinserted from the Table Library (prior modifications may be lost).

After creating or opening an annual report ensure that the desired table has been generated (see Generating Date Parameter Tables) and then follow the appropriate steps below to move the table.

To select and drag the table to a new location

1. Rest the pointer on the table until the table move handle ⊞ appears at the upper-left corner of the table.
2. Rest the pointer on the table move handle until a four-headed arrow appears.
3. Drag the table to the new location.

To cut and paste the table into a new location

1. Select the table.
2. On the **Edit** menu, click **Cut**.
3. Place the insertion point where you want the table in the report.
4. On the **Edit** menu, click **Paste**.

To delete and then insert the table into a new location

1. Select the table.
2. On the **Table** menu, point to **Delete**, and then click **Table**.
3. Place the insertion point where you want the table in the report.
4. On the **Table Library** menu, click the name of the table.

Related Topics:

About Annual Report Tables

Inserting a Table

Updating a Table

When you update a table, the Annual Reports application replaces all of the table information with information currently found in the Table Library.

Note: In your annual report, bookmarks indicate the locations of automatically inserted tables. To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

To update a table

> **Note:** Prior modifications made to tables having bookmarks (**[**...**]**) will be erased when the table is updated.

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).
3. Click to place the cursor in the table you want to update (be sure to click within the bookmarks).

   Note: If the table is without bookmarks (**[**...**]**) then the table is not linked to the Table Library and cannot be automatically updated per these steps.

4. On the **Table Library** menu, click the name of the table.

   Note: Ensure that the table selected in the **Table Library** is the same as the one in which you have placed the insertion point.

   The existing table is replaced.

Note: The Patient Deaths, Expedited Adverse Events, and Patient Dropouts tables require date parameters prior to being inserted into a report. If these tables already exist in the report and you want them updated then follow the steps described in Generating Date Parameter Tables.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Agent-Specific Adverse Events

Following are Agent-Specific Adverse Events table specifications.

Data source	AdEERS/SMARTS, Agent Specific Adverse Event report.
Table placement	In the Adverse Events section.
Data displayed	All NSCs for the IND. All adverse events for the IND. Data breaks on Adverse Events Category. Cumulative data of all protocols for this IND. Alphabetically by Adverse Events Category. By protocol number.
Categories not displayed	Those with no adverse events listed.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

DCTD, NCI-Sponsored Clinical Trials

DCTD, NCI-Sponsored Clinical Trials table specifications.

Data source	Protocol #: Document number from PATS. Title: Title from PATS Abstraction screens. Status: Current Status from PATS. Date: Current Status Date from PATS. Institution: Lead Organization from PATS - Study Participants screen. PI: Principal Investigator from PATS Study Participants screen.
Data parameters	Protocols are related to the IND. Doc. Type is P Current status of protocol is Active, Temporarily Closed to Accrual, Closed to Accrual, Temporarily Closed to Accrual and Treatment, Closed to Accrual and Treatment, Administratively Complete, or Complete.
Free text fields	Rationale, Objectives, Design, Patients, Results, Conclusions
Data sort order	The sort order for data in this table. 1. Phase: Pilot, I, I/II, II, III, then Other. 2. Single Agent Trials/Combination Agents Trials: Single Agent Trials are protocols with only one agent; Combination Agent trials are protocols with more than one agent (See PATS Study Agents screen). 3. Type: (as designated in Disease Category table) Hematologic, then Solid Tumor. 4. Lead disease: Lead Disease on the protocol (see PATS Study Diseases screen).
Navigation feature	Click the protocol number to move from the DCTD, NCI-Sponsored Clinical Trials table to the same protocol displayed in the IDB Clinical Trials Summary table or FDA Clinical Trials Summary table.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Expedited Adverse Events

When the Expedited Adverse Events table is inserted automatically or selected from the Table Library only the bookmarked table name appears in the annual report. Either method of insertion requires you to then select date parameters for the table data before the table itself appears. For more details see Generating Date Parameter Tables.

Expedited Adverse Events table specifications.

Data source	The AdEERS back end system Short Form.
Data parameters	Data from 13 months prior to table generation date.
Data displayed	Protocol Number

	Ticket Number File/Hold Adverse Event/Other Specify Grade IND Agent Attribution Other Treatments Attribution Concomitant Meds Attribution Diseases Attribution Other Causes Attribution
Data sort order	Protocol Number, Ticket Number, and Grade.
Automatic location	The annual report Tables section or the Adverse Events section, depending on the table size.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

FDA Clinical Trials Summary

FDA Clinical Trials Summary table specifications.

Data source	CDUS.
Data parameters	Adverse events suffered by all patients on protocols (Doc. Type P) related to the IND.
If Adverse Events have not been reported	An empty row appears containing the text "Enter Adverse Events." This is a reminder to enter adverse events if any exist.
If the monitoring method is NOT CDUS Complete or CTMS	Accrual and Response values will be blank rather than "0".'
Data displayed	Protocol # / Protocol Name Institution / PI Monitoring Method Current Status Activation Date Cut-Off Date Accrual Response

	Organ System Adverse Events Reported per Patient Grade
Data sort order	Phase. Single Agent studies, then Combination studies.
Automatic location	The annual report section titled DCTD, NCI-Sponsored Clinical Trials Summary Tables. This table cannot be inserted elsewhere.
Navigation feature	Click the protocol number to move from the FDA Clinical Trials Summary table to the same protocol displayed in the DCTD, NCI-Sponsored Clinical Trials table.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

IDB Clinical Trials Summary

IDB Clinical Trials Summary table specifications.

Data source	CDUS-complete monitored trials.
Data displayed	Protocol # / Protocol Name Institution / PI Current Status Cut-Off Date Patients Registered / Treated / On Study Activation Date Monitoring Method Planned Accrual Diease Funding Information Dose De-escalated Lead IND # NSC Total # of Courses (All Patients) Median # of Courses (Per Patient) Range # of Courses (Per Patient) Subgroup

	Eval RR Treatment Assignment Response Organ System Adverse Events Reported (All Courses) Grade
Automatic location	The annual report section titled DCTD, NCI-Sponsored Clinical Trials Summary Tables. This table cannot be inserted elsewhere.
Navigation feature	Click the protocol number to move from the IDB Clinical Trials Summary table to the same protocol displayed in the DCTD, NCI-Sponsored Clinical Trials table.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Most Serious Adverse Experiences in Phase 1 and 2 Trials

Most Serious Adverse Experiences table specifications.

Data source	CDUS complete monitored trials.
Data parameters	Cumulative data for all indicated protocols on the IND.
Data displayed	Organ System Adverse Experience Total Number of Patients Treated • % Grade 3 • % Grade 4 • % Grade 5
Adverse Events displayed	Possibly, Probably, Definitely IND-related.
Display cutoff	Set at 1/5 of the highest percentage. For example, if the highest percent is 90, the cutoff will be any value less than 18% (1/5 of 90 = 18).
Percentage calculated	Total number of patients on the trial divided by number of patients reporting the adverse event. Result multiplied by 100.
Adverse Events sort order	Greatest percentage of patients. Then alphabetically.

Automatic location	The annual report Adverse Event section.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Most Frequent Adverse Experiences in Phase 1 and 2 Trials

Most Frequent Adverse Experiences table specifications.

Data source	CDUS complete monitored trials.
Data parameters	Cumulative data for all CDUS-monitored protocols on the IND
Data displayed	Adverse Experience Organ System Percentage of 25 Patients
Adverse Events displayed	Possibly, Probably, Definitely IND-related.
Percentage calculated	Total number of patients on the trial divided by number of patients reporting the adverse event. Result multiplied by 100.
Organ systems sort order	Alphabetically.
Adverse Events sort order	Greatest percentage of patients. Then alphabetically.
Automatic location	The annual report Adverse Event section.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Non-DCTD Clinical Trials Summary

Non-DCTD Clinical Trials Summary table specifications.

Data source	Table is populated by the user.
References appearing in this section	This section queries all references associated with the queried IND. A reference is linked to an IND via the Agent. An Agent is directly related to an IND. Each reference queried in this section has at least one disease cited in the reference material.

Categories not displayed	Each reference queried in this section is not associated with a Protocol in the CDUS system, which would identify it as a DCTD trial. Since this table shows only non-DCTD trials, a reference to a Protocol relationship does not exist.
Data displayed	Reference/Title: Includes First Author, Year of Publication, Reference Title, and Article Title. Disease: Includes a list of all diseases cited in the reference material. Agent Dose/Schedule: Includes Agent Name, Dose, Unit of Measurement, Route—i.e., how administered, and Schedule. Patients Treated: Provides the number of subjects on which the test was conducted and for which results were collected. Results: Identifies the actual name of the test and the results of the parameters or tests that were collected and cited in the reference material. AE Information • Adverse Events: Includes the list of toxicities for a specific test, CTC or non-CTC. • Grade: Displays the grade levels of adverse reactions to a treatment entered for an AE in the SMARTS Web application) • Number of Subjects: The number of subjects that experienced this toxicity. • Dose Limiting: Indicates whether this AE was dose limiting.
Automatic location	Follows the annual reports References section.

Related Topics:

[About Annual Report Tables]

[Displaying Table Statistics]

Nonclinical Studies

Nonclinical Studies table specifications.

Data source	SMARTS
Data parameters	Reference related to agents on the IND and that have results recorded. References with a status of Active. References with the Non-Clinical Table flag set to Yes.
Data displayed	Reference/Title Cell Line Name/Species Cell Line Tissue Origin/Cell Line Type Exposure Time

	Animal Model Species Agent/Dose Schedule Results
Data sort order	Alphabetically by reference author.
Automatic location	The annual report Nonclinical Studies section at end of In vivo Antitumor Studies subsection.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Patient Deaths

When the Patient Deaths table is inserted automatically or selected from the Table Library only the bookmarked table name appears in the annual report. Either method of insertion requires you to then select date parameters for the table data before the table itself appears. For more details see Generating Date Parameter Tables.

Patient Deaths table specifications.

Data source	AdEERS
Data parameters	Data from 13 months prior to table generation date. All Grade 5 adverse events.
Data displayed	Protocol Number Ticket Number File/Hold Patient ID Adverse Event/Other Specify Grade IND Agent Attribution Other Treatments Attribution Concomitant Meds Attribution Diseases Attribution Other Causes Attribution
Data sort order	Protocol Number, and Ticket Number.
Automatic location	The annual report Tables section or Patient Deaths section depending on the table size.

Related Topics:

[About Annual Report Tables]

[Displaying Table Statistics]

Patient Demographics

Patient Demographics table specifications.

Data source	CDUS
Protocols not displayed	Status of In Review, Withdrawn, or Approved.
Automatic location	The annual report Tables section (last table in section).

Related Topics:

[About Annual Report Tables]

[Displaying Table Statistics]

Patient Dropouts

When the Patient Dropouts table is inserted automatically or selected from the Table Library only the bookmarked table name appears in the annual report. Either method of insertion requires you to then select date parameters for the table data before the table itself appears. For more details see Generating Date Parameter Tables.

Patient Dropouts table specifications.

Data source	CDUS - Patient Dropout report.
Data parameters	Only patients on protocols (Doc. Type P) related to the IND. Patients are off the study. Off Treatment Reason does not equal Treatment Completed per Protocol. Patient's last treatment was within the dates specified. Does not include patients who took two or more courses and for whom the Off Treatment Reason is Disease progression or relapse during treatment.
Data displayed	Protocol Number Patient ID Course Number Off Treatment Reason
Data sort order	Phase, and Protocol Number.
Automatic location	The annual reports Patient Dropouts section.

Related Topics:

About Annual Report Tables

Displaying Table Statistics

Updated Clinical Trials

When the Updated Clinical Trials table is inserted automatically or selected from the Table Library only the bookmarked table name appears in the annual report. Either method of insertion requires you to then select date parameters for the table data before the table itself appears. For more details see Listing Updated Clinical Trials.

Updated Clinical Trials table specifications.

Data source	Protocol #: Document number from PATS. Status: Current Status from PATS. Date: Current Status Date from PATS. Institution: Lead Organization from PATS - Study Participants screen. Title: Title from PATS Abstraction screens. Accrual Now: Total number of patients accrued as of the From Date. Accrual Goal: Estimated Accruals calculated by the number of months between study activation date and max patient collection date, multiplied by the patient accrual rate (from PATS Study Accruals). Page Txt: DCTD, NCI-SPONSORED CLINICAL TRIALS page number from which the protocol is referenced. Page Tbl: IDB/FDA Tables page number from which the protocol is referenced.
Protocols displayed and highlighted for selection	Related to the IND. Status change within the specified date range. Accrual change within the specified date range.
Protocols displayed but not highlighted for selection	Related to the IND. Open protocols without a status or accrual change within the specified date range and the Current Status is Active, Temporarily Closed to Accrual, Closed to Accrual, Temporarily Closed to Accrual and Treatment, Closed to Accrual and Treatment. Open protocols without a status or accrual change within the specified date range and the Current Status is Complete or Administratively Complete within the three years prior to the specified From Date.
Protocols not displayed	Protocols with status of In Review, Withdrawn, or Approved.
Data parameters	Data which has changed within the specified date range.

Data displayed	Protocol Number Status/Date Investigator Title Accrual • Actual • Planned Page Number Txt/Tbl
Protocols sorted under each Phase	Type within the Disease Category. Types include Solid Tumor and Hematologic. Within each type, protocols are sorted by lead disease.
Abbreviations	The following abbreviations describe the protocol status. AC = Active CP = Complete CL-A = Closed to Accrual CL-B = Closed to Accrual and Treatment TC = Temporarily Closed TC-A = Temporarily Closed to Accrual TC-B = Temporarily Closed to Accrual and Treatment

Related Topics:

About Annual Report Tables

Displaying Table Statistics

About Editing Text in an Annual Report

When you create a draft annual report sections appear without textual content which you must then provide. Some sections also require you to answer questions or select one of several choices of automatically inserted textual content. Therefore, before the draft annual report is ready to be completed and sent you must edit the report ensuring that the textual content represents the correct information.

You can edit the textual content of an annual report directly by using a combination of Word tools and tools provided by the Annual Reports application for this specific purpose. For more information see the **Related Topics** below.

Note: To avoid unintentional changes it is recommended that you display document format marks and bookmarks before starting the editing process. For details see About Editing an Annual Report.

Related Topics:

Inserting Text from the Data Library

Changing Data Library text in an Annual Report

Working with Blue-Colored Text

Working with Green-Colored Text

Changing Annual Report Data Library Text

Information used repeatedly in annual reports is stored in the Data Library. The information stored in the Data Library cannot be changed directly. Once Data Library information has been inserted into a report you can change the text by using the **Edit Tag Values** command.

For example, *IND Title* is Data Library information that may appear many times in an annual report. If you decide to change the way the *IND Title* appears (spacing, capitalization, spelling, etc.), the **Edit Tag Values** command enables you to make the change once so that the same change appears at all other locations in the report where the *IND Title* was inserted from the Data Library.

Note: Edit Tag Values changes apply only to Data Library items that already exist in the report. The original text of the Data Library item remains unchanged in other reports and when inserted later. Typed information that duplicates the Data Library item also remains unchanged.

To change Data Library text in an annual report

1. Open the desired annual report (see Opening an Existing Annual Report).
2. On the **Report Generator** menu, click **Edit Tag Values**.

   The **Edit Tag Values** dialog box appears.

3. In the **Select Data Tag** field, enter the name of the Data Library item you want to change.
4. In the **Data Tag Value** field, edit the text as you want it displayed in the annual report.
5. Click **Update**.

   The system updates the text of the Data Library item throughout the report.

Note: Changes to Data Library text that have been made using these instructions will be undone if the report is later updated. For this reason, changing Data Library text in a report should only be done after all automated edits have been made and the report is being completed for submission.

Related Topics:

About Editing Text in an Annual Report

About Completing an Annual Report

Inserting Data Library Text

Information used repeatedly in annual reports is stored in the Data Library. In addition to it's textual content the information often contains bookmarks and fields which present data such as IND or Agent identification that can be automatically updated after completion of the report. Although often incorporated automatically into an annual report the Data Library information is accessible from the Annual Reports Library toolbar so that you can select and insert any desired additional information.

Inserting this information from the Data Library ensures that the text is correct and represented consistently throughout the report. Inserting text from the Data Library also makes it easy to change the text later (see Changing Annual Repot Data Library Text).

To insert text from the Data Library

1. Open the desired annual report (see Opening an Existing Annual Report).
2. Ensure that the Annual Reports Libraries toolbar is displayed (if necessary refer to Microsoft Word Help).

3. In the annual report document place the insertion point where you want to insert the Data Library information.
4. On the **Data Library** menu, click the name of the desired information.

   The selected information appears in the annual report.

Related Topics:

About Editing Text in an Annual Report

Updating Data Library Text

In the Annual Reports application, information available in the Data Library is updated to stay current. These updates are not automatically incorporated into any Data Library text or fields that have already been inserted into currently existing annual reports. The **Update Data Fields** command is provided for you to do this when necessary.

Note: Previous Data Library text changes made directly in an annual report (see Changing Annual Report Data Library Text) will be undone when the **Update Data Fields** command is used.

To update Data Library text in an annual report

1. Open the desired annual report (see Opening an Existing Annual Report).
2. On the **Report Generator** menu, click **Update Data Fields**.
3. Save the report.

Related Topics:

About Editing Text in an Annual Report

Working with Blue-Colored Text

Blue colored text is automatically inserted into an annual report to provide you with the option of selecting from two or more versions of textual content each of which contain different information. Each text choice is separated by the word OR. You must delete the text that is not appropriate and then change the color of the remaining text.

When you discover blue-colored text in your annual report perform the following steps.

1. Determine which of the blocks of blue text you want to delete.
2. Select the text you want to delete (and the "OR") and then press **DELETE**.
3. Select the blue text you elected to keep.
4. On the **Format** menu, click **Font**.

   The **Font** dialog box appears.

5. In the **Font color** list, click **Automatic** and then click **OK**.
6. Save the report.

Note: If an error message is contained in the text you decided to keep see Working with Error Messages.

Related Topics:

About Editing Text in an Annual Report

Working with Green-Colored Text

Green colored text in a grey background is an automatically inserted field asking you to type specific information that is necessary for the annual report. An example of this is: **[Click here and type the company name]**.

When you discover green colored text in your annual report perform the following steps.

1. Place the insertion point in the green text.

   The entire field becomes highlighted.

2. Type the requested information.

   The field disappears and is replaced by your typed text although the text color is still green.

3. Select the green text you just typed.
4. On the **Format** menu, click **Font**.

   The **Font** dialog box appears.

5. In the **Font color** list, click **Automatic** and then click **OK**.
6. Save the report.

Related Topics:

About Editing Text in an Annual Report

About Completing an Annual Report

There are a number of tasks that are better performed after you have created and edited your annual report and just prior to report submittal or archiving. The following table lists these tasks in the recommended order of performance.

Show Formatting Marks	Formatting marks, bookmarks, and fields must be displayed to complete these tasks. To do this see About Editing an Annual Report.
Change Data Library Text	Make any desired changes to automatically inserted Data Library text. To do this see Changing Annual Report Data Library Text.
Remove Page Breaks	Remove any unnecessary page breaks that may have been created during the editing process. To do this see Using Page and Section Breaks.
Review Table Placement	Check all tables in your report to ensure that columns and rows have been resized appropriately to fit their contents, if necessary. Ensure that none of the tables break needlessly across pages. Adjust page breaks if necessary (see Using Page and Section Breaks).
Check Spelling	Use the automatic spell-checking capability provided by Microsoft Word. To do this, press **F7**.
Update the Table of Contents	Ensure that your report's Table of Contents correctly displays the appropriate items and associated page numbers by following the steps described in Updating the Table of Contents.

Highlight Changes	If your report has been created from an archived annual report and you want to display the differences between the two reports then follow the steps described in Highlighting Annual Report Changes.

Highlighting Annual Report Changes

When you create a new annual report by using an archived annual report you can highlight the differences between last year's report and this year's report. This should be the last thing done to the annual report before it is submitted and archived.

NOTE: This function will only work on a report created from an archived annual report (see Creating an Annual Report from an Archived Annual Report).

To highlight the differences between last year's report and this year's report then, while the new annual report is open, on the **Report Generator** menu, click **Highlight Changes**.

NOTE: If a difference exists in a single table cell between this year's and last year's annual reports, the application will highlight the entire row in which the cell resides. In all cases where an entire row of a table is highlighted, you may want to compare the two reports and remove highlighting from cells that have not changed.

Related Topics:

About Completing an Annual Report

About Annual Report Tables

Saving an Annual Report

While working on an annual report save the document often to avoid the risk of accidentally losing completed work.

To save your annual report, on the **File** menu, click **Save**.

NOTE: If this is the first time you are saving the annual report, Word will display the **Save As** dialog box. When this occurs select the path of where the annual report is to be stored, assign a name to the report, then click **Save**.

Updating the Table of Contents

While editing your annual report the page numbers are automatically updated. Unfortunately, when this occurs the Table of Contents may become out of sync with the updated page numbers. Additionally, the Table of Contents will not reflect any section title changes (such as additions or deletions). After all changes have been made and you are ready to stop work on the annual report, you should make a final update to the Table of Contents.

To update the table of contents of an open annual report, on the **Report Generator** menu click **Update TOC and Paginate**.

NOTE: To update the Table of Contents, the application searches for all occurrences of Heading1-style text. For each instance of Heading1-style text, the application inserts an entry in the Table of Contents matching the heading and its location page number. Because of this, if you manually add (without using the Section Library) a section to the annual report, ensure that you apply Heading1-style formatting to the section heading.

Related Topics:

[About Completing an Annual Report]

Archiving an Annual Report

After an annual report has been completed and then reviewed by IDB for final approval, the report should be archived prior to FDA submittal. Archiving the report ensures that a permanent record of the submitted report is retained and available for use as the basis for the following year's annual report.

NOTE: Only archive a report that is complete and ready for submittal.

To archive an annual report

1. On the **Annual Reports** window, click **Archive Annual Reports** to display the Archive Report screen.
2. In the **IND #** field, enter the number identifying the IND contained in the report you want to archive.
3. At the end of the **File to Archive** field, click the **Open** button. 
4. In the **Open** dialog box, find and select the annual report document.

   The path of the selected document appears in the **File to Archive** field.

5. In the **Version Date** field, enter the appropriate date.
6. In the **Sent To** field, ensure that the appropriate value (*FDA* or *IDB*) is selected.
7. In the **Version Type** field, ensure that the appropriate value (*Original* or *Amendment*) is selected.
8. If your selected **Version Type** is *Amendment*, then in the **Original Version** field, select the annual report document you are amending.
9. Type additional information into the **Comments** field.
10. Click **Save**.

    Note: To return to the **Annual Reports** window click the **Close** button. 

Add New Section Template

The **Add New Section Template** command enables you to create new annual report section templates (section documents).

Add New Section Template is found on the **Administrator** menu located on the Word toolbar. Click **Add New Section Template** and a blank Word document opens with the tool bar changed to display the following Annual Reports menus.

Section Generator

Data Library

Table Library

Special Library

Related Topics:

[Creating a Section Template]

Annual Reports Help

To access SMARTS AR (Annual Reports) Help at any time choose the **Annual Reports Help** command on the **Report Generator** menu located on the Word toolbar.

Related Topics:

Welcome to SMARTS Annual Reports Help

Annual Reports Wizard

If you want to create, edit, or review an annual report in addition to a report you already have open then choose the **Annual Reports Wizard** command on the **Report Generator** menu located on the Word toolbar. The Annual Reports Wizard will appear.

Related Topics:

Creating an Annual Report by Using the Wizard

Archive Annual Reports

Located on the **Annual Reports** window, choose the **Archive Annual Reports** command to open the **Archive Report** screen which enables you to select and archive an annual report.

Related Topics:

Archiving an Annual Report

Assign IND

The **Assign IND** command enables you to select an IND and then assign it to an annual report. Located on the **Report Generator** menu, when you choose **Assign IND** the **Assign IND to Document** dialog box appears.

Related Topics:

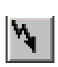
Creating an Annual Report from a Similar Annual Report

Cancel

Closes a screen area or dialog block without saving modifications performed since the last save.

Related Topics:

Cancel Query

The **Cancel Query** command  enables you to end any currently existing query effort displayed on the screen.

Edit

Opens the annual report section template document identified in the **Choose Section to Edit** field.

Located on the **Edit Section** dialog box (see **Edit Section Template**) click **Edit** and the Word document containing the identified section template opens.

Related Topics:

Editing a Section Template

Edit Section Template

The **Edit Section Template** command enables you to open and edit existing annual report section templates (section documents).

Edit Section Template is found on the **Administrator** menu located on the Word toolbar. Click **Edit Section Template** and an **Edit Section** dialog box appears.

Related Topics:

Editing a Section Template

Edit Tag Values

The text of specific Data Library items inserted into an annual report can be changed using the **Edit Tag Values** command. When a Data Library item is changed using **Edit Tag Values** the same change appears where ever that Data Library item had been inserted into the report.

Located on the **Report Generator** menu (on the Word toolbar), click **Edit Tag Values** and the **Edit Tag Values** dialog box appears. For more details see Changing Annual Report Data Library Text.

Related Topics:

About Editing Text in an Annual Report

Enter Query

The **Enter Query** command  enables you to enter on the screen information upon which a query is to be conducted.

Enter Table Dates

The **Enter Table Dates** command enables you select new or change existing date parameters for tables in a currently open annual report.

On the **Report Generator** menu, click **Enter Table Dates**, and the **Table Dates** dialog box appears.

Related Topics:

Generating Date Parameter Tables

Execute Query

The **Execute Query** command  initiates a query based on information you've entered or selected on the screen.

Hide/Show Bookmarks

Bookmarks mark the location of tables or text that are automatically placed within an annual report document. The **Hide/Show Bookmarks** command enables you to see or not see the bookmarks in a document. For more details see About Editing an Annual Report.

With an open annual report document, on the **Options** menu click **Show/Hide Bookmarks**.

Related Topics:

About Completing an Annual Report

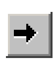
Highlight Changes

While creating a new annual report from an archived annual report the **Highlight Changes** command enables you to identify where differences exist between the new and archived annual report. Located on the **Report Generator** menu, click **Highlight Changes** and a copy of the new report will appear with the change locations highlighted.

Related Topics:

Highlighting Annual Report Changes

Next Record

The **Next Record** command  displays the next sequential data record occurring later then what's displayed in the line or field where the insertion point is currently located.

Open

The **Open** command enables you to select and open an annual report document.

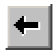
Click the **Open** button  and then in the **Open** dialog box find and select the desired annual report document. The path of the selected document appears in the field adjacent to the **Open** button..

Related Topics:

[Archiving an Annual Report](#)

[Creating an Annual Report from a Similar Annual Report](#)

Previous Record

The **Previous Record** command  displays the next sequential data record occurring earlier then what's displayed in the line or field where the insertion point is currently located.

Refresh List

When generating or updating an Updated Clinical Trials table displayed in an annual report, the **Refresh List** command is used to find protocols associated with the report's IND's in a specified time period.

In the **Protocol List** dialog box (see [Listing Updated Clinical Trials](#)), after selecting the dates for the desired time period, click **Refresh List** and all appropriate protocols are displayed.

Related Topics:

[About Annual Report Tables](#)

Refresh Updated Clinical Trials Table

Each annual report displays a list of clinical trials related to IND's identified in the report. Located in the Listing of Updated Clinical Trials section of an annual report, the list is displayed in the Updated Clinical Trials table. The **Refresh Updated Clinical Trials Table** command enables you to generate or refresh the Updated Clinical Trials table.

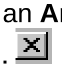
After creating or opening an annual report, from the **Report Generator** menu, choose **Refresh Updated Clinical Trials Table.** The **Protocol List** dialog box appears. For more details see [Listing Updated Clinical Trials](#).

Related Topics:

[About Annual Report Tables](#)

Report Statistics

After opening an annual report, use the **Report Statistics** command to see the time and date that all tables or special sections were last updated by the application.

Click **Report Statistics** and an **Annual Report Statistics** dialog box appears. To return to the report click the **Close** button. 

Related Topics:

Save Section to Database

To save an annual report section template you have created or edited choose the **Save Section to Database** command on the **Section Generator** menu located on the Word toolbar. The **Save Section** dialog box appears (for details see Creating a Section Template).

Related Topics:

Creating a Section Template

Editing a Section Template

Trial Designation

Located on the **Annual Reports** window, choose the **Trial Designation** command to open the **Protocol Trial Type Maintenance** screen which enables you to assign protocol trial types.

Related Topics:

Designating Protocol Trial Types

Update

The **Update** command is used to automatically incorporate tag value changes or date parameters at all locations where the effected items (text or tables) appear in a currently open annual report.

The **Update** command is also used to automatically generate or update an Updated Clinical Trials table by incorporating a selected list of protocols into the table.

Located on the **Protocol List** dialog box (see Listing Updated Clinical Trials), click **Update** and all selected protocols are incorporated into the Updated Clinical Trials table in a currently open annual report.

Related Topics:

Changing Annual Report Data Library Text

Generating Date Parameter Tables

Update Data Fields

When the **Update Data Fields** command is used on an open annual report, externally updated Data Library information is automatically incorporated into any Data Library text or fields that have already been inserted into the report.

Note: Previous Data Library text changes made directly in an annual report (see Changing Annual Report Data Library Text) will be undone when the **Update Data Fields** command is used.

Related Topics:

Updating Data Library Text

Update TOC and Paginate

The **Update TOC and Paginate** command ensures that the Table of Contents for an annual report is updated to reflect any changes made to the document, and that each page is correctly numbered.

Related Topics:

Updating the Table of Contents

Choose Section to Edit

The **Choose Section to Edit** field is used to identify a specific annual report section template that you want to open for editing.

Located on the **Edit Section** dialog box (see **Edit Section Template**) type the desired section template name into the **Choose Section to Edit** field or select it from drop down list.

Related Topics:

Editing a Section Template

Comments

The **Comments** field is provided for you to add additional information concerning an associated record. To add information select the **Comments** field and type.

Related Topics:

Archiving an Annual Report

Data Tag Value

The text of a selected Data Library item is displayed for editing in the **Data Tag Value** field. In the **Data Tag Value** field edit the text as you want it displayed in an annual report.

Related Topics:

Changing Annual Report Data Library Text

Display Name

The section name which is displayed in the annual report to identify the section's location prior to report generation. In the **Display Name** field, type the name of the section.

Related Topics:

Creating a Section Template

Editing a Section Template

Document Name

The file name for the Word document containing the annual report section template you are creating or editing. In the **Document Name** field, type the desired file name for the new section template (because this is a Word document include .doc).

Related Topics:

Creating a Section Template

File to Archive

The document name and file path of an annual report to be archived.

Click the **Open** button located at the end of the **File to Archive** field, and then select the desired annual report document. The path of the selected document then appears in the **File to Archive** field.

Related Topics:

Archiving an Annual Report

IND

The identification number of the Investigational New Drug (IND) described in an annual report you want to archive. Type (10 characters maximum) or select the desired IND number from the **IND #** field list of values.

Related Topics:

Archiving an Annual Report

IND Number

The identification number of an Investigational New Drug (IND) that you intend to query on the Protocol Trial Type Maintenance screen.

Related Topics:

Designating Protocol Trial Types

IND Prefix

Additional identification characters integrated into IND Numbers that you intend to query on the Protocol Trial Type Maintenance screen.

Related Topics:

Designating Protocol Trial Types

IND Status

The **IND Status** field displays the current status of a selected IND. On the **Annual Report Wizard**, when a value is entered into the **Select an IND** field, the **IND Status** field automatically populates

Related Topics:

Creating an Annual Report by Using the Wizard

IND Title

The **IND Title** field displays the name of a selected IND (Investigative New Drug). On the **Assign IND to Document** dialog box when a value is entered into the **Select an IND** field, the **IND Title** field automatically populates

Related Topics:

Creating an Annual Report from a Similar Annual Report

Insert After

The name of the section which you want preceding a newly created section in the **Annual Reports Wizard** list of sections. In the **Insert After** field, type or select the desired section name.

Related Topics:

Creating a Section Template

Editing a Section Template

Original Version

Identifies the annual report document for which you are archiving an amended version. Select the desired annual report document from the **Original Version** field list of values .

Note: The **Original Version** field is only enabled when a **Version Type** value of *Amendment* has been previously selected.

Related Topics:

Archiving an Annual Report

Select an IND

The identification number of a desired IND. Type the IND number into the **Select an IND** field, or select it from the drop-down list.

Related Topics:

Creating an Annual Report by Using the Wizard

Select Data Tag

A specific Data Library item that you want to edit is identified in the **Select Data Tag** field. In the **Select Data Tag** field, type or select the name of the desired Data Library item.

Related Topics:

Changing Annual Report Data Library Text

Select Sections

The **Select Sections** field is pre-populated with a list of annual report sections available for inclusion in an annual report. Some sections are automatically selected based on whether or not the IND, for which the report is being created, is a biologic or chemotherapeutic. In the **Select Sections** field, ensure that the name of those sections you want to appear in the report are selected.

Related Topics:

Creating an Annual Report by Using the Wizard

Sent To

Identification of the recipient of an archived annual report. Select either *FDA* or *IDB* from the **Sent To** field drop-down list.

Related Topics:

Archiving an Annual Report

Version

The version identification automatically assigned to document sections.

Related Topics:

Creating a Section Template

Version Date

A date you select for a report you are archiving. It is recommended that you use the FDA or IDB submittal date.

Type (mm/dd/yyyy format) or select the appropriate date from the **Version Date** field list of values.

Related Topics:

Archiving an Annual Report

Version Type

Identifies an archived annual report document as either the Original or an Amendment to a previously archived annual report. Select either *Original* or *Amendment* from the **Version Type** field drop-down list.

Note: Selecting *Amendment* enables the **Original Version** field and you must then select the annual report document you are amending.

Related Topics:

Archiving an Annual Report

Trial Type

Indicates whether a protocol trial involves a single agent or a combination of multiple agents. Type the appropriate value into the **Trial Type** field, or select it from the drop-down list.

Related Topics:

Designating Protocol Trial Types

Administration

Appearing on the Word toolbar when creating or editing an annual report the **Administration** menu contains the following commands.

- Add New Section Template
- Edit Section Template

Related Topics:

Creating a Section Template

Editing a Section Template

Data Library

Appearing on the Word toolbar when creating or editing an annual report the **Data Library** menu contains a collection of textually formatted information that you can select and insert into the report.

Related Topics:

Inserting Data Library Text

Options

Appearing on the Word toolbar when creating or editing an annual report the **Option** menu contains the following commands.

- Hide/Show Bookmarks
- Report Statistics

Related Topics:

About Creating Annual Reports

About Editing an Annual Report

Report Generator

Appearing on the Word toolbar when creating or editing an annual report the **Report Generator** menu contains the following commands.

- Annual Reports Wizard
- Assign IND
- Edit Tag Values
- Update Data Fields
- Update TOC and Paginate
- Refresh Updated Clinical Trials Table
- Enter Table Dates
- Highlight Changes
- Annual Reports Help

Related Topics:

About Creating Annual Reports

About Editing an Annual Report

Section Generator

Appearing on the Word toolbar when creating a new annual report section template or editing an existing section template the **Section Generator** menu contains the following command.

- Save Section to Database

Related Topics:

Creating a Section Template

Editing a Section Template

Section Library

Appearing on the Word toolbar when creating or editing an annual report, the **Section Library** menu contains a collection of named report text and table sections that you can select and insert into the report.

Note: Some **Section Library** menu commands used to insert named table sections do not include the table. If necessary, after selecting a table section, select the appropriate table from the **Table Library**.

Related Topics:

Adding an Annual Report Section

Special Library

Appearing on the Word toolbar when creating or editing an annual report the **Special Library** menu contains commands that enable you to insert specially formatted information. The following information can be selected from the **Special Library** menu.

- DCTD NCI Sponsored Clinical Trials
- FDA Clinical Trials Summary

Although commands with the same name appear in the **Section Library** menu, the information represented by these **Special Library** commands is not formatted to create separate report sections.

Related Topics:

About Creating Annual Reports

About Editing an Annual Report

Table Library

Appearing on the Word toolbar when creating or editing an annual report the **Table Library** menu contains a collection of tables that you can select and insert into the report.

Related Topics:

Inserting a Table

Inserting a Table to Replace an Existing Table

Inserting a Table while Keeping an Existing Table

Updating a Table

Create New

When you want to create a new annual report or section template choose the **Create New** option located on the **Annual Reports** window.

Related Topics:

Creating a Section Template

Editing a Section Template

Creating an Annual Report by Using the Wizard

Creating an Annual Report from an Archived Annual Report

Creating an Annual Report without Using the Wizard

First/Subsequent Queried Section

Refers to the sequential order in which a section is queried when the document is searched.

Related Topics:

Creating a Section Template

Format

Indicate in the **Format** area whether a new section must be displayed on a page in a portrait or landscape orientation. Generally the decision is dependent upon the configuration of tables contained within the section. In the **Format** area click either the **Portrait** or the **Landscape** option.

Related Topics:

Creating a Section Template

Editing a Section Template

Open Existing

When you want to open and review or edit an existing annual report choose the **Open Existing** option located on the **Annual Reports** window.

After choosing **Open Existing**, you must identify in the adjacent field the document name and file path of the desired report. Type or select this information by clicking the **Open** button. 

Related Topics:

Creating an Annual Report from a Similar Annual Report

Type

Determine what type of IND a new section must be made available for, and then indicate this in the **Type** area. In the **Type** area click one of the following options.

- **Biologic**
- **Chemo**
- **Neither**
- **Both**

Related Topics:

Creating a Section Template

Editing a Section Template