



# **InteliNotion**

## **User Guide Module 5:**

# **Document Authoring**

For InteliNotion Version: 2024.GR2.0

Last Modified: November 2024

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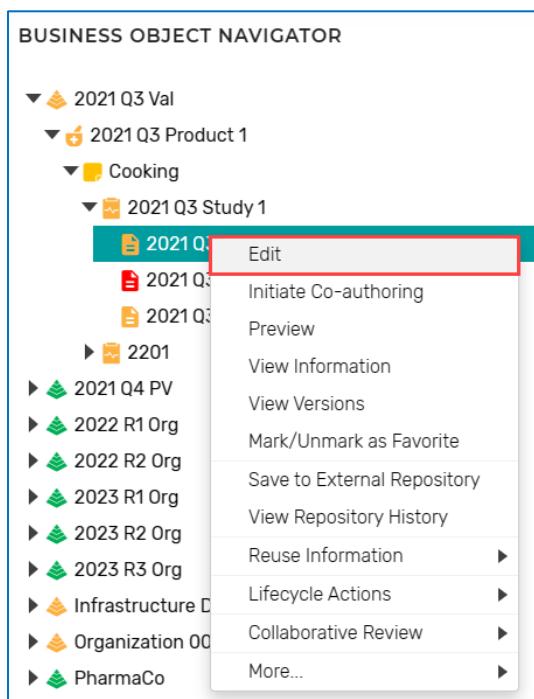
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## 1. AUTHORIZING A DOCUMENT

1. To open the document for single user authoring, right-click on the document name and click **Edit**.



### **Notes:**

- In the *Web Console*, open the document using the right-click **Edit** option.
- When a document is opened in single authoring, the displayed filename will include an `_#` if there is already a local cache copy present in the user's Data folder.

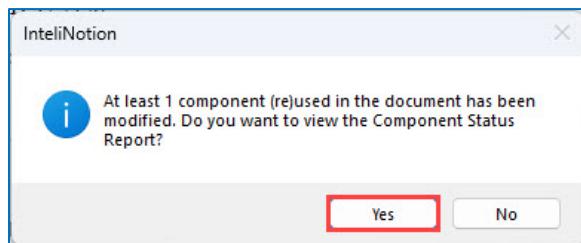
2. The document will open in *MS Word* and the *InteliNotion Word App* will open automatically with it.

**Note:** If the document opens in compatibility mode an error message will display informing the user that this is not a supported file type, and any changes made cannot be saved to the system.

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- a. When the user opens the document, if any (re)used components have been changed at source (eg, in the parent document, in library), a pop-up will display. Click **No** to proceed without viewing the changes to the component(s). To view changes in the **Component Status Report**, click **Yes**.



**Note:** In almost all cases, this alert will trigger for an updated reused component. However, occasionally, it will trigger due to a component being edited individually, ie, outside the document.

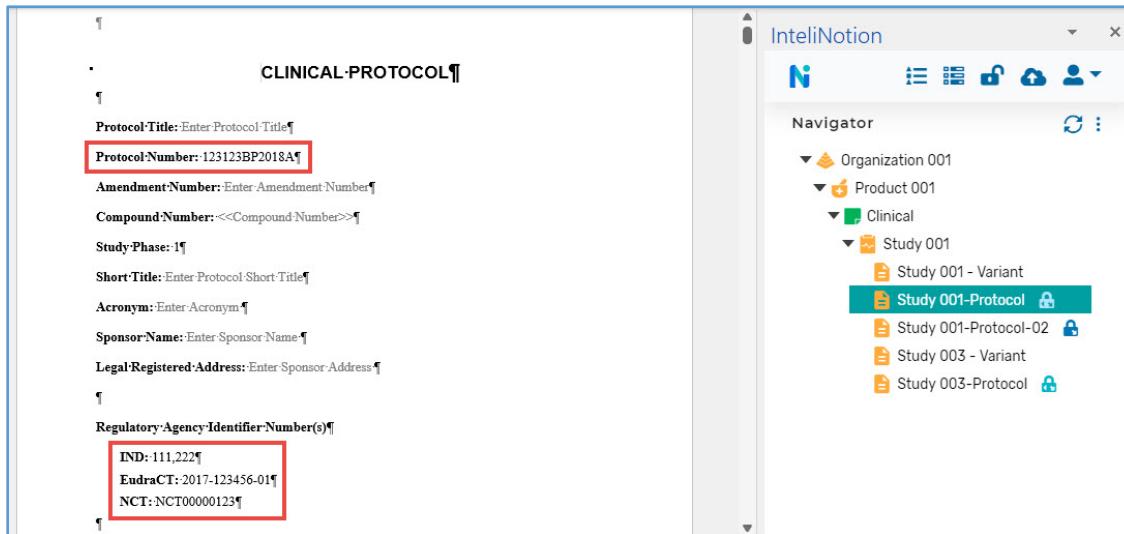
- b. The **Component Status Report** will open and list all components in the document within a relevant section such as **New**, **Modified**, or **Not Modified**. Refer to [Module 8, Section 2](#) for details on how to view and accept the changes made to reused components using this report.

Component	Reuse Type	State	Version	Modified On	Change Type	Action
<b>&gt;Status: Modified (3 items)</b>						
Protocol ...	Use As Is	Approved	1.0 (2.0)	2024-09-11 8:23 AM	Content	Select
AE Gradi...	Use As Is	Approved	17.0 (19.0)	2024-09-11 3:53 PM	Content	Select
Study Rati...	Repurpose	Approved	2.0	2024-09-11 8:24 AM	Parent Content	Select
<b>&gt;Status: Not Modified (86 items)</b>						
Header		Draft	0.1	2024-09-10 9:26 AM		
Amendment...		Draft	0.1	2024-09-10 9:26 AM		
Protocol Sh...		Draft	0.1	2024-09-10 9:26 AM		
Acronym		Draft	0.1	2024-09-10 9:26 AM		
Sponsor Na...		Draft	0.1	2024-09-10 9:26 AM		
Sponsor Ad...		Draft	0.1	2024-09-10 9:26 AM		
Title		Draft	0.1	2024-09-10 9:26 AM		
Regulatory ...		Draft	0.1	2024-09-10 9:26 AM		
Status	Use As Is	Approved	3.0	2024-09-09 3:17 PM		
Protocol Date		Draft	0.1	2024-09-10 9:26 AM		
<span style="float: left; margin-right: 10px;"></span> <span><a href="#">Close</a></span> <span><a href="#">Update</a></span>						

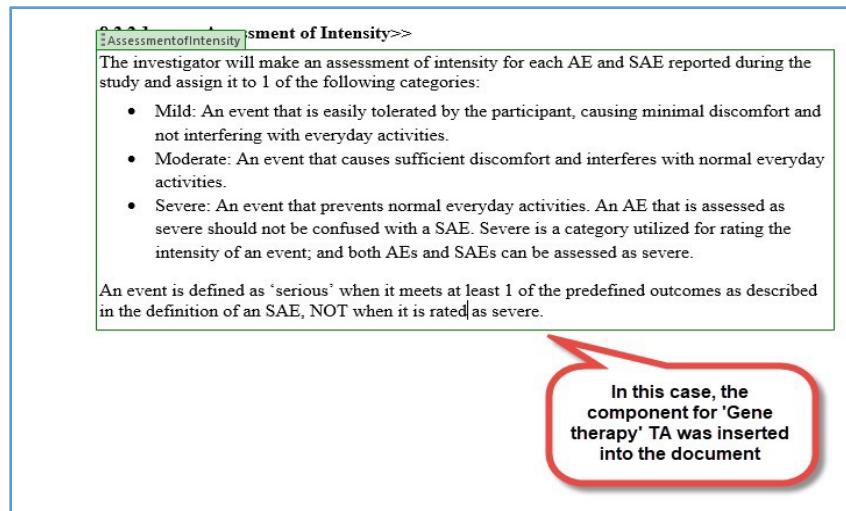
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3. The document may have some of its components pre-populated based on the selected property value(s) for the relevant object/item in the navigation scheme under which the document was generated; these types of components are called **variables**. (Refer to [Section 1.2](#) for more information on variables.)



4. Other content components may be pre-populated with either:
  - Reused content from the selected base document(s).
  - Library content based on prespecified matching property value(s) (eg, therapeutic area [TA]).



The screenshot shows a section of a clinical study document. A repeating library component titled "Assessment of Intensity" is inserted into the document. The component contains instructions for investigators to assess intensity for each AE and SAE. It lists three categories: Mild, Moderate, and Severe. A note at the bottom defines 'serious' events. A red callout bubble points to the component with the text: "In this case, the component for 'Gene therapy' TA was inserted into the document".

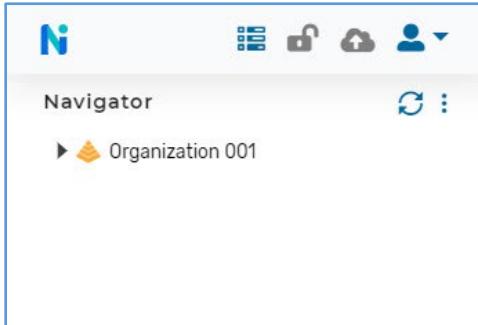
**Note:** If configured, multiple repeating library components with matching criteria will be inserted into the document. See [Section 1.4](#) for detailed instructions on adding new library components to a document while authoring.

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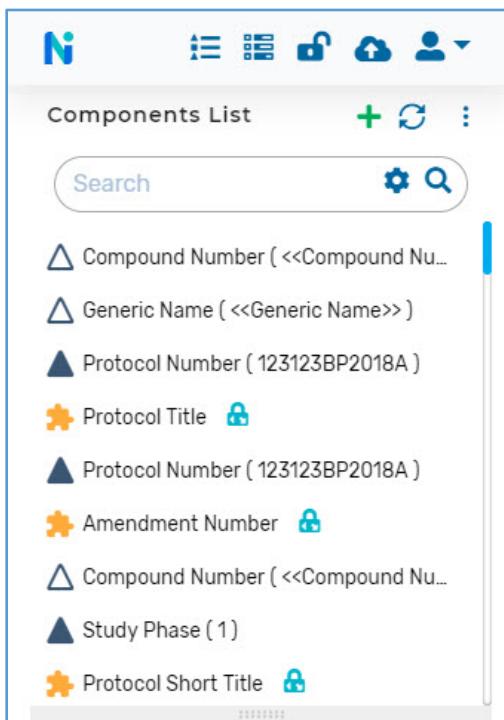
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5. On the right-hand side, the *InteliNotion Word App* displays the **Navigator** view by default. Refer to [Module 3, Section 1](#) for an overview of various icons and views displayed at the top of the *InteliNotion Word App*.



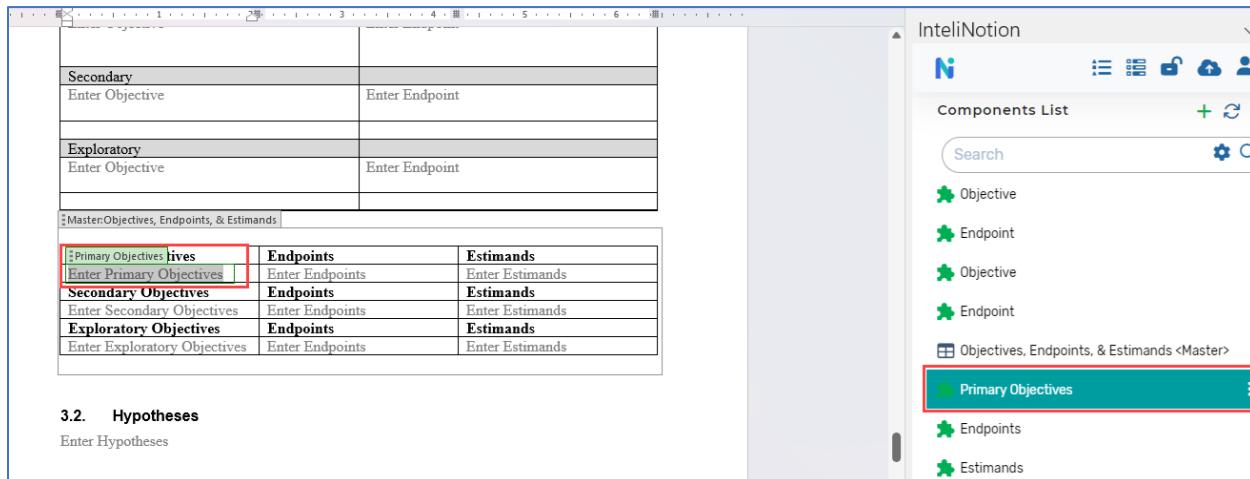
6. All the editable components (ie, de novo or repurpose reused) will be checked out along with the document and a **lock icon**  displayed next to their name in the **Components List**.



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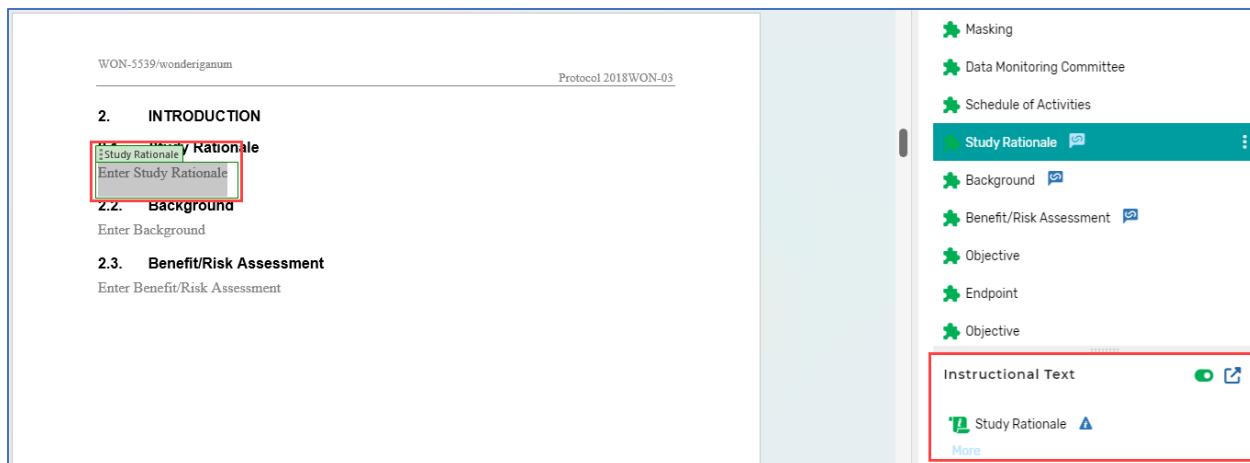
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7. Variables will not be checked out, since their value cannot be edited within the document's context. The source value being used to populate the variable in the document will be displayed in parentheses next to the variable's name.
8. As a user clicks into various components throughout the document when editing it, the focus in the **Components List** changes to that specific component.



The screenshot shows the InteliNotion Word App interface. On the left, there is a Microsoft Word document window displaying a table with columns for Secondary, Enter Objective, Enter Endpoint, Exploratory, Enter Objective, and Enter Endpoint. Below the table, there is a section titled "3.2. Hypotheses" with the sub-section "Enter Hypotheses". On the right, the InteliNotion sidebar is visible, featuring a "Components List" section with a search bar and a list of items: Objective, Endpoint, Objective, Endpoint, and "Objectives, Endpoints, & Estimands <Master>". A red box highlights the "Primary Objectives" item in the list, which is also selected. Below the sidebar, the "Instructional Text" area contains the text "Study Rationale" with a red box around it.

9. If available, related instructional text will display in an **Instructional Text** area at the bottom of the *InteliNotion Word App* pane.

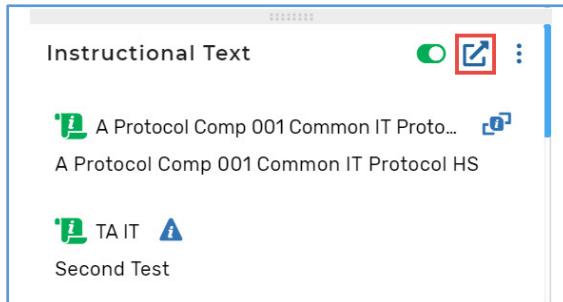


The screenshot shows the InteliNotion Word App interface. On the left, there is a Microsoft Word document window displaying sections 2. INTRODUCTION, 2.1. Study Rationale, 2.2. Background, and 2.3. Benefit/Risk Assessment. The "Study Rationale" section is highlighted with a red box. On the right, the InteliNotion sidebar is visible, showing a list of components: Masking, Data Monitoring Committee, Schedule of Activities, Study Rationale, Background, Benefit/Risk Assessment, Objective, Endpoint, and Objective. Below the sidebar, the "Instructional Text" area contains the text "Study Rationale" with a red box around it.

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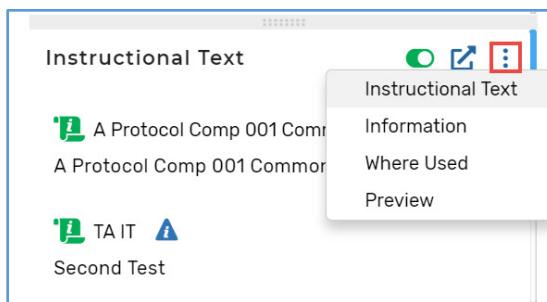
- a. The Related instructional text will display in the **Instructional Text** area in both the **Components List** or **Libraries** views of the *InteliNotion Word App*.
- o The user can pop out the instructional text area into a separate window by clicking the arrow button located at the top-right corner.



- b. The type of instructional text that may be displayed includes:
- i. Element ( $\Delta$ ): This type of instructional text is specific for the single component.
  - ii. Common ( $\square \text{?}$ ): This type of instructional text is not specific and may be related to/relevant for multiple components.
  - iii. Library ( $\square \text{!}$ ): This type of instructional text is specific for a given library component and only displays if either the library component has already been reused/inserted in the document (which the user's cursor is clicked in) or the user clicks on a library option displayed in the Libraries view (eg, before the library component is selected for reuse and inserted into the document).
- c. The user can click the **Library instructional text toggle button** to either enable (display) or disable (do not display) the 'library' instructional text.



- d. The user can also activate another type of informational display (eg, [content] Preview) by clicking the **vertical ellipsis**  $\vdots$  and then selecting the appropriate option.



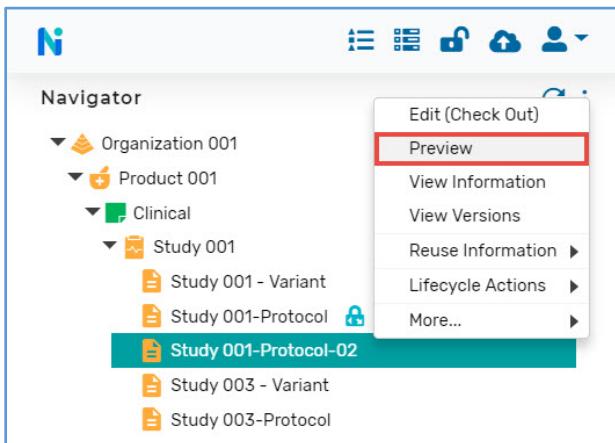
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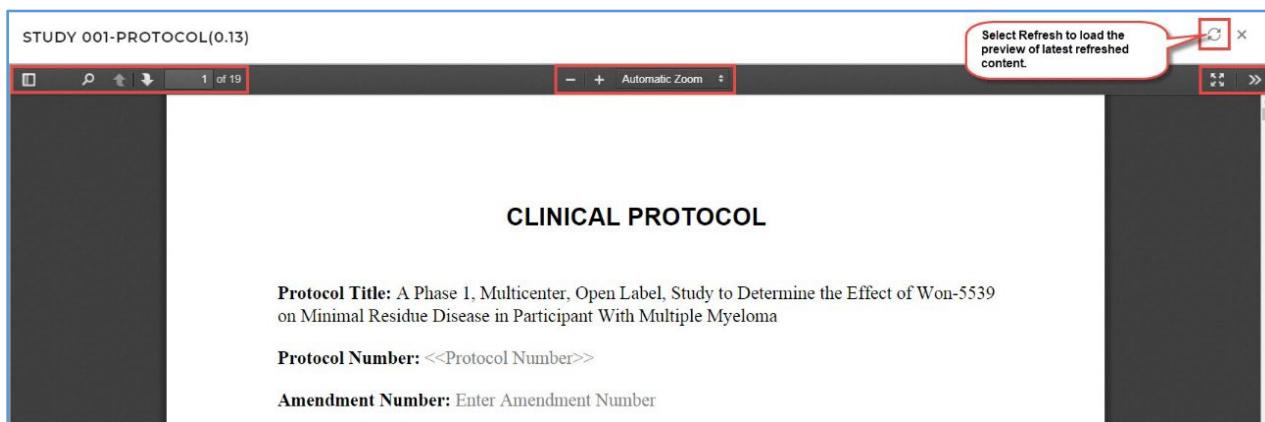
10. While authoring a document or a component, all the built-in *MS Word* features such as **Fonts, Styles, Track Changes, Commenting**, etc. can be used.

**Note:** To maintain style consistency when authoring documents, in some cases, an extra paragraph mark may be needed at the end of the content within a component to ensure there is no style/formatting change when it is reused. This is especially important given certain conditions such as if a table is at the end of the component's content *OR* if the style applied to the target component (ie, the one in the document intended for reuse) is expected to be different than the style applied to the current component.

11. A user can also preview a document (or an individual component) in PDF format online with navigation of pages available. To do so a user would right-click on the document (or component listed in the Component Status Report) they want to preview and choose **Preview** from the menu (See [Module 8, Section 2.4.3](#)).



12. The user can navigate through pages using next/previous page and can zoom in and out.



STUDY 001-PROTOCOL(0.13)

1 of 19      - + Automatic Zoom      Select Refresh to load the preview of latest refreshed content.

**CLINICAL PROTOCOL**

**Protocol Title:** A Phase 1, Multicenter, Open Label, Study to Determine the Effect of Won-5539 on Minimal Residue Disease in Participant With Multiple Myeloma

**Protocol Number:** <<Protocol Number>>

**Amendment Number:** Enter Amendment Number

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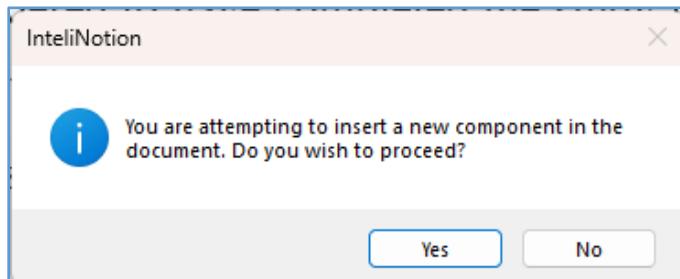
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## 1.1 ADDING CONTENT TO THE DOCUMENT: DE NOVO

De novo (new) content may be added to the open document by entering content (text, tables, figures, etc.) into the content control boxes provided for the component; content can be entered by clicking onto or into the box and typing in free text, inserting a new table, figure, etc., or by copy/pasting content from another document.



A new or 'ad hoc' component can also be added by placing the cursor at the desired location within the document, ie outside of any content controls, and then inserting/reusing a selected component from search, an existing document or library, as described in respective sections below. Note that when reusing a new or 'ad hoc' component in this manner, the user will receive the following warning message and must click Yes to proceed with inserting/reusing the component.



## 1.2 ADDING CONTENT TO THE DOCUMENT: VARIABLE INSERTION

Variables are elements configured to source their value from a predefined property on a given object (eg, document, study). When the variable is inserted in a component included in that same type of document, its value will populate as expected. Additionally, when the component is reused into a different type of document, its value will be refreshed (the default behavior) to reflect its new document's context.

Metadata sourced variables (MSV) are a type of variable wherein the value is not prepopulated, but selected by a user from a list of values that is sourced within the system's metadata catalog. MSVs can be configured as an element, then inserted into a template. Multiple instances of MSVs can be inserted into a document from the Components List in the IN Word app.

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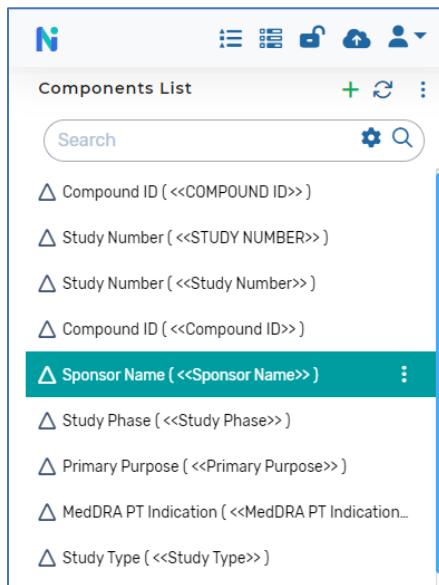
**Notes:**

- All types of formatting including Font Type, Font Color, Font Size, and Highlight associated with any content (pre-existing or newly added) inside a component can be edited using the various formatting features provided by *MS Word* or can be removed and set to the default format setting using the Clear All Formatting feature provided by the *InteliNotion Word app*.
- If instructional text is added within a specific component of the template, it can be deleted from within the generated document by selecting and removing it using typical *MS Word* functionality (eg, use the Delete or Backspace button on the keyboard). Alternately, if the instructional text was formatted in a specific *MS Word* style, the *InteliNotion Text Tools* functionality may be used to remove it automatically.
- Adding comments to locked components is supported if the component is not locked for deletion.

Follow the steps listed in the sections below to insert either a variable or MSV.

### 1.2.1 Insert Additional Instance or New (Property-Sourced) Variable

1. Place the cursor in an existing component or elsewhere in the document itself where the variable is to be inserted (eg, directly in the document outside of any component).
2. Switch to the **Components List** in the *InteliNotion Word App*.
3. To insert another instance (ie, copy) of a variable already inserted in the document:
  - Click the **Search Configuration** button (**gear icon** ) and select **Show Variables** to filter the list, if needed. Click outside of the **Filter Configuration** pop-up window to close it.

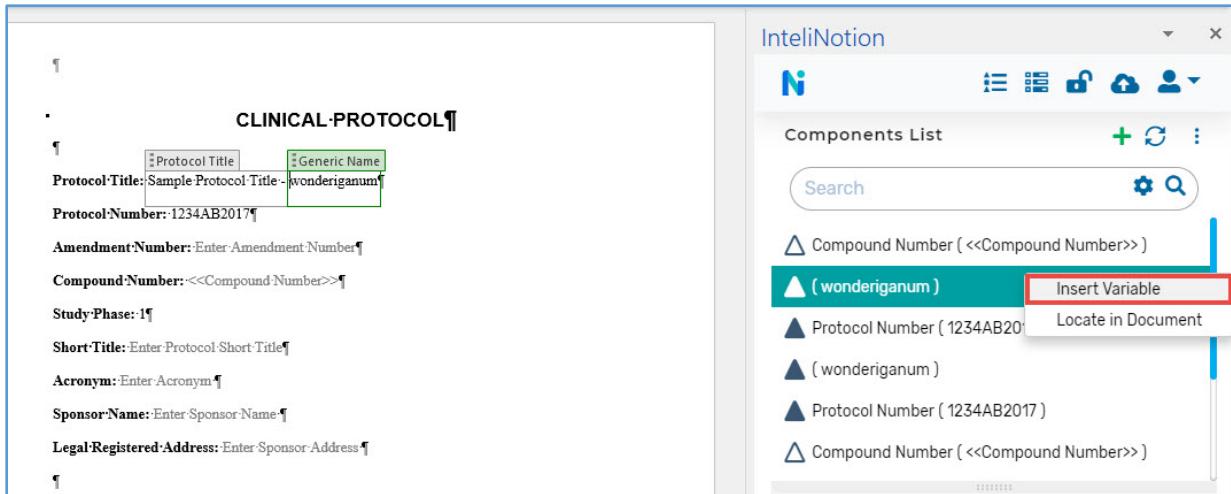


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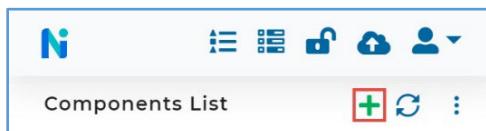
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- Click the vertical ellipsis next to the relevant and then select **Insert Variable**.

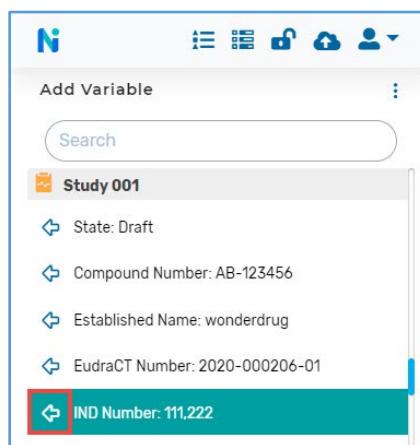


- To insert a new variable that has not yet been inserted in the document:

- Click the **plus sign icon**  . An **Add Variable** view will appear and list the current document's properties along with the properties for other related 'parent' objects (eg, Study ABC) per the document's location in the **Navigator**.



- Locate the relevant object's property to be used as a variable, and then click the arrow next to its name.

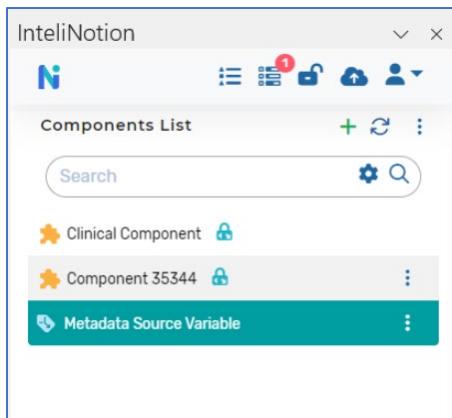


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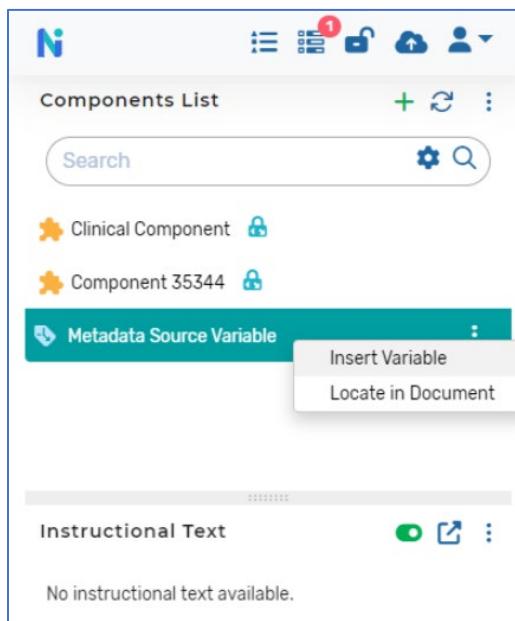
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## 1.2.2 Insert Additional Instance of a Metadata Sourced Variable

1. Place the cursor in a blank space in the document where the MSV is to be inserted (ie, outside of any component).
2. Switch to the **Components List** in the *InteliNotion Word App*.
3. Navigate to an existing MSV to be inserted into the document.



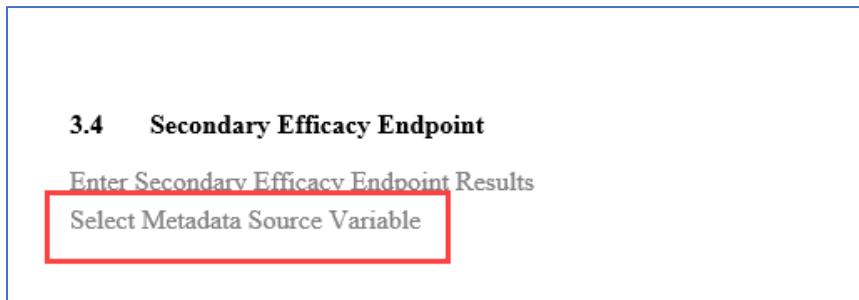
4. Right click and select **Insert Variable**.



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5. A blank instance of the MSV will be inserted into the document at the cursor location.

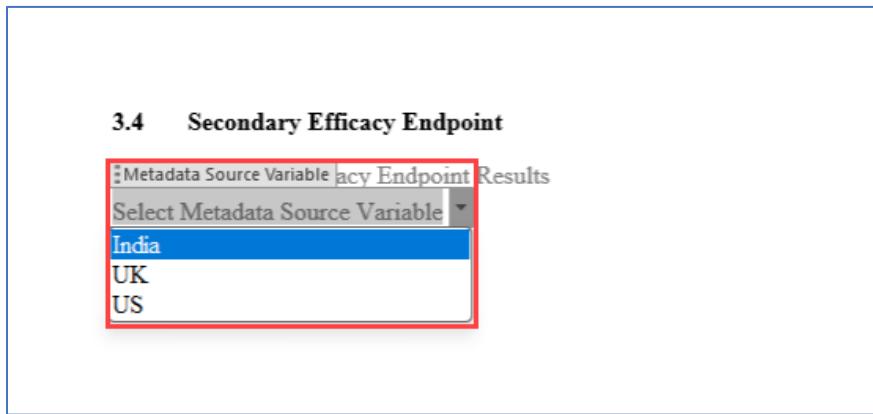


3.4 Secondary Efficacy Endpoint

Enter Secondary Efficacy Endpoint Results

Select Metadata Source Variable

6. Select the desired value from the drop-down menu.



3.4 Secondary Efficacy Endpoint

Metadata Source Variable Secondary Endpoint Results

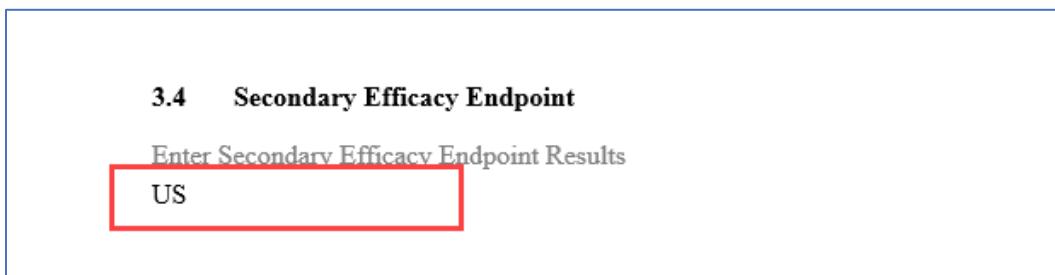
Select Metadata Source Variable ▾

India

UK

US

7. The MSV will be populated with the selected value, with any existing MSVs remaining unaffected (ie, previously selected values, if any, remain as is).



3.4 Secondary Efficacy Endpoint

Enter Secondary Efficacy Endpoint Results

US

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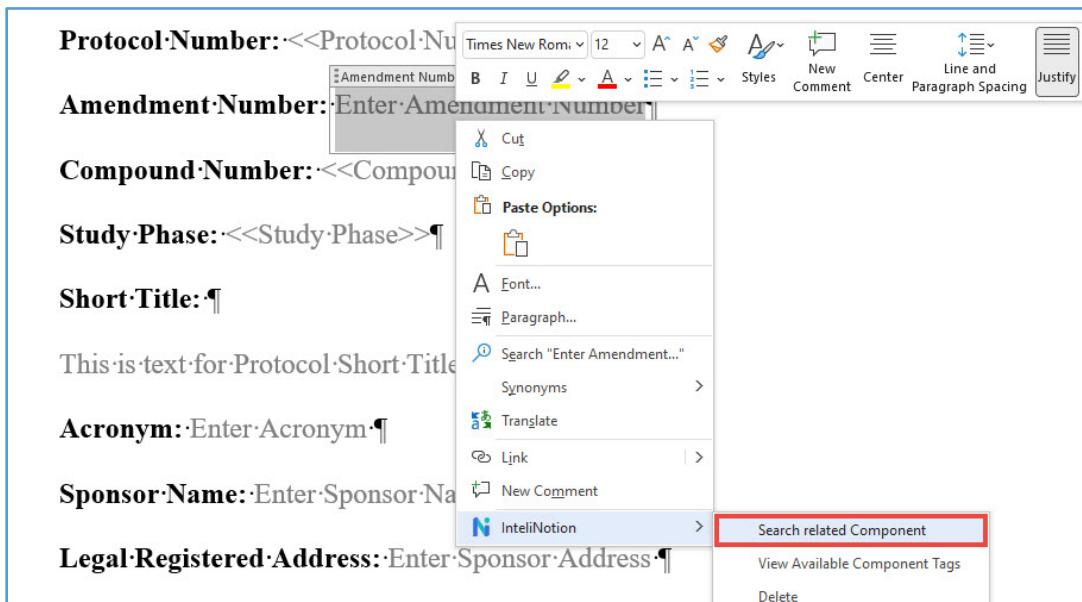
## 1.3 ADDING CONTENT TO THE DOCUMENT: VIA SEARCH FOR RELATED COMPONENTS IN THE SYSTEM

A user can search existing components in the system for reuse within a document while authoring. Components may be found by either matching related properties (eg, name, alias, study phase, lifecycle state, etc.) or selected text within the component itself.

**Note:** When adding a component with a tag already applied, a pop-up will display prompting the user to retain or discard that tag. Choose **Yes** or **No** as applicable. If new content tags need to be applied, see [Module 11](#) for detailed instructions.

### 1.3.1 Searching by Property Match

1. Right-click on the component in the document, hover over the **InteliNotion** option and click **Search Related Component**.

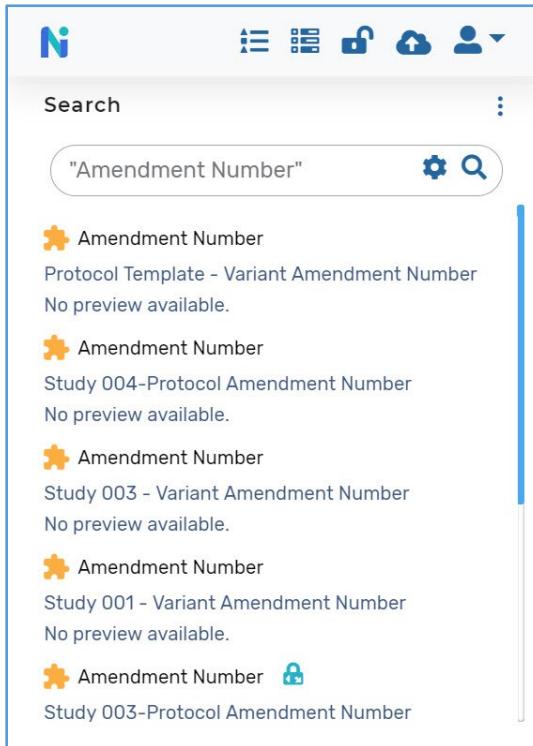


**Note:** Searching via property match includes searching via both **Name** and **Alias**. The **Alias** field can be used to track reuse of components over time as names of components evolve. Best practice for this field is for previous names of the element to be entered as aliases, separated by the pipe “|” symbol. This allows the search for related component function to find previous iterations of the component name, as this function operates by searching both the name and alias fields. See the [InteliNotion Authoring Configurations Guide](#) for detailed instructions on configuring **Name** and **Alias** fields.

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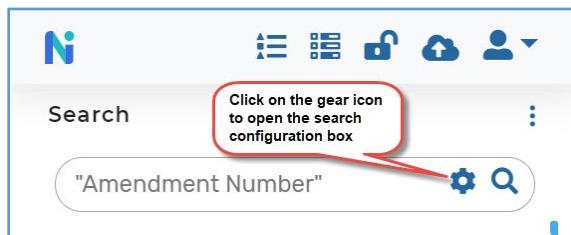
2. The *InteliNotion Word App* will automatically switch to the **Search** view and display a list of matching search results that have the same name as the component in the document, as shown below.



The screenshot shows the InteliNotion Word App interface in Search mode. The search bar at the top contains the text "Amendment Number". Below the search bar, there is a list of search results:

- Amendment Number  
Protocol Template - Variant Amendment Number  
No preview available.
- Amendment Number  
Study 004-Protocol Amendment Number  
No preview available.
- Amendment Number  
Study 003 - Variant Amendment Number  
No preview available.
- Amendment Number  
Study 001 - Variant Amendment Number  
No preview available.
- Amendment Number  
Study 003-Protocol Amendment Number

3. The search results can be filtered by clicking the **Search Configuration** button (gear icon ).

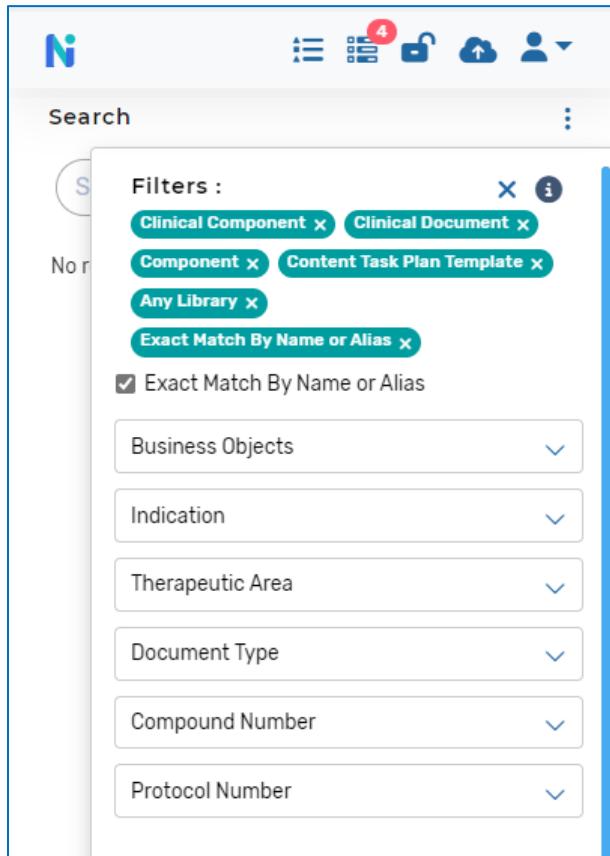


The screenshot shows the InteliNotion Word App interface in Search mode. A red callout box points to the gear icon in the search configuration box. The text inside the callout box reads: "Click on the gear icon to open the search configuration box".

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4. A **Filters** pane will open. By default, the search results will be filtered to include components of the same business object type (eg, **Clinical Component**) and the default search library for that object type, if configured by the admin. The search results can also be configured to show only those that can be reused (ie, components that have the same name value as the component in the document). The user can also unfilter the list of search results so that all matching components (eg, based on name value, property value, text-based content match, etc.) are shown.



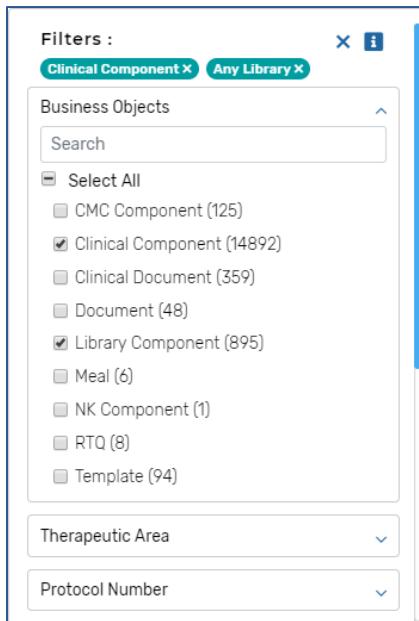
#### **Notes**

- All the business objects configured as **Searchable** by the admin are listed under the **Business Objects** filter. While authoring, however, only the Component business object, and its related subtypes (eg, **Clinical Component**) can be reused in the document.
- If there is no default search library set for the selected business object, the selected filter at the top will show **Any Library**.

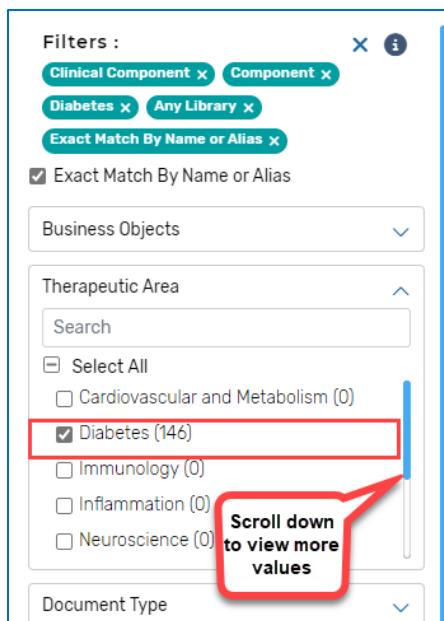
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5. Select additional object types to search against, if needed, then close the **Business Objects** filter.



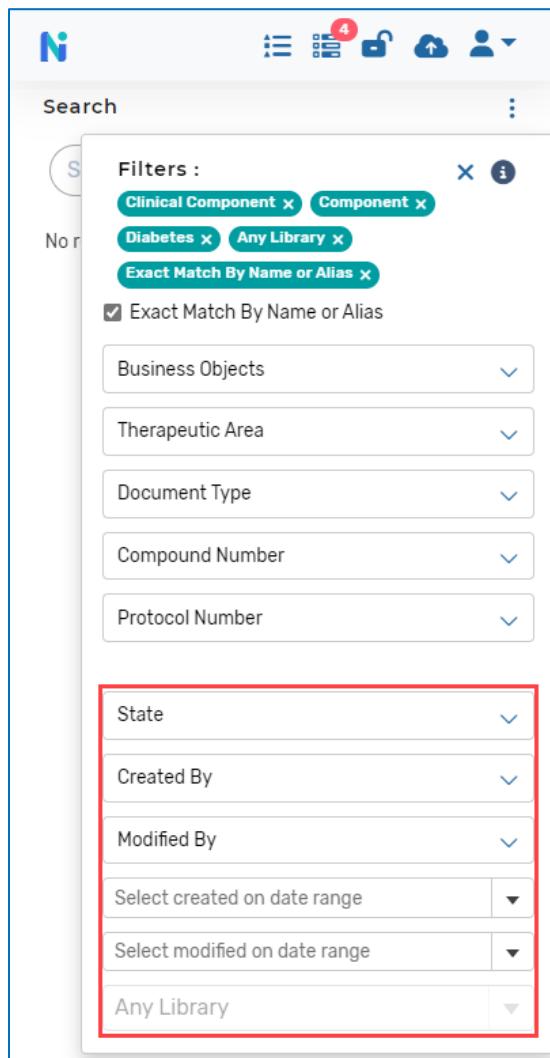
6. Related properties of the business objects selected above, which are also configured as **Faceted** (ie, may be used as a filter) by the admin, may be used to further refine the search results. If/when a property value is selected, the number of matching results (shown parenthetically) dynamically changes to indicate an approximate number based on the user's permission level in the system.



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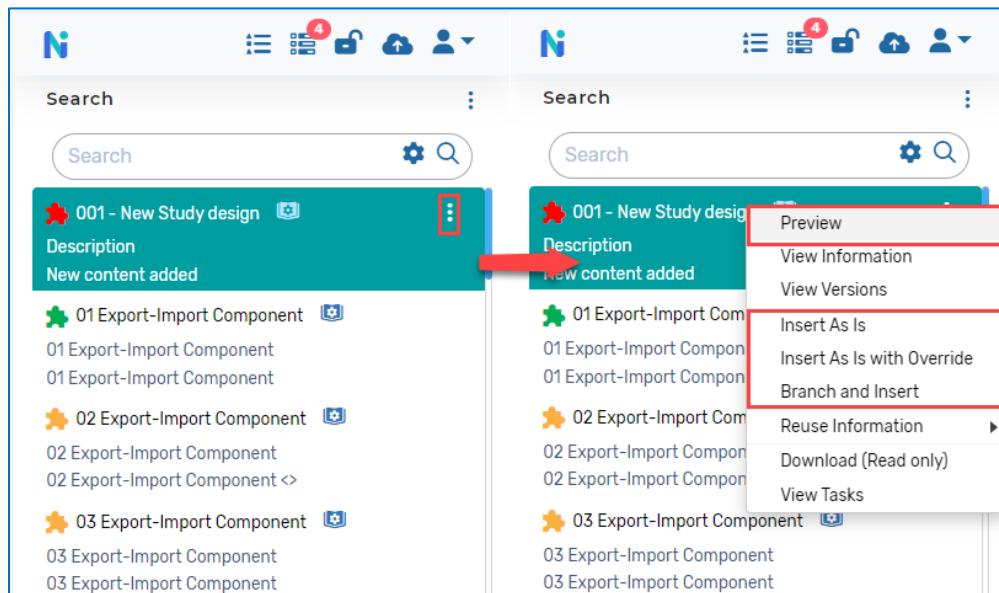
7. Additional filtering by system-generated properties may also be applied, including:
  - **State** - To select and apply a lifecycle state filter (eg, **Draft**, **Approved**)
  - **Created By** - To select specific users who created the component
  - **Modified By** - To select specific users who last modified the component
  - **Select created on date range** - To select a date range within which a component was created
  - **Select modified on date range** - To select a date range within which a component was last modified
  - **Any Library** - To select a specific library, if configured to allow searching against, for the specific Component business object type. This filter is only enabled if a single business object is selected



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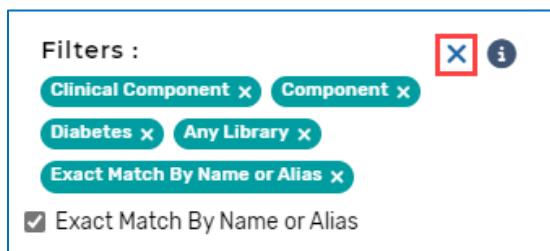
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8. After selecting the appropriate filters, click outside of the **Filters** window to view the updated list of results.
9. Locate the component of interest, click the vertical ellipsis  displayed by the result, and then click the following, as applicable:
  - **Preview** - To preview the component's content
  - **Insert As Is** - To reuse the component as-is (the content will not be editable)
  - **Insert As Is with Override** – To reuse the component as-is (the content will be editable)
  - **Branch and Insert** - To repurpose reuse the component (the content will be editable)



### Notes

- To remove a single filter, click the **white X** next to the filter's name or uncheck the relevant checkbox in the appropriate filter's drop-down list.
- To remove all filters, click the **blue X** at the top-right corner of the **Filters** window.

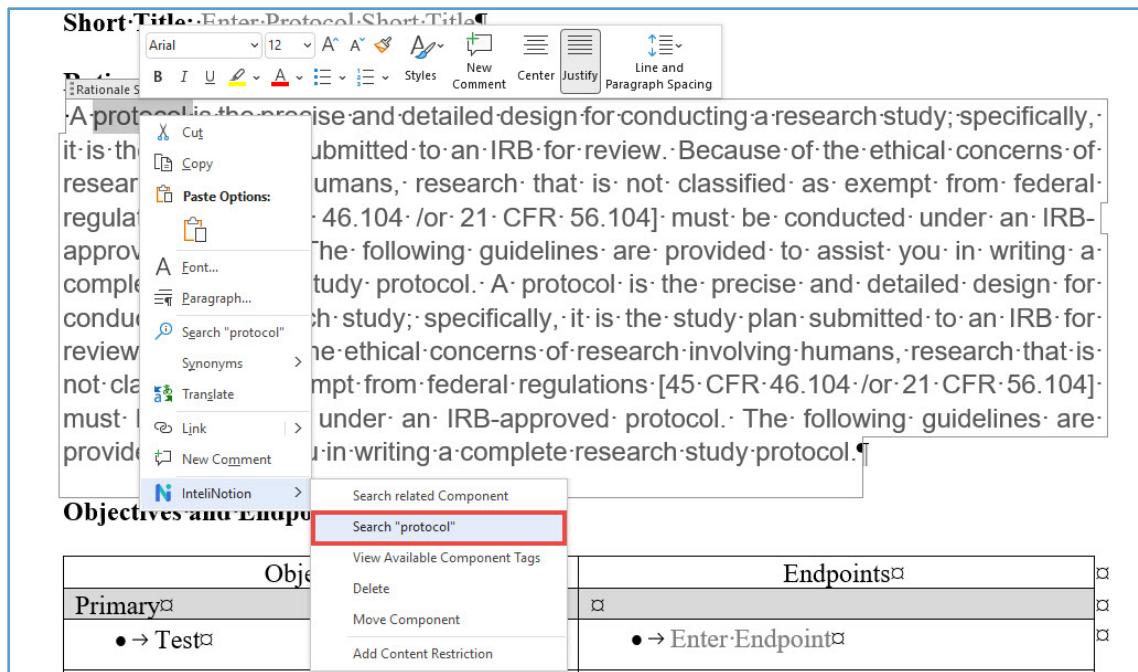


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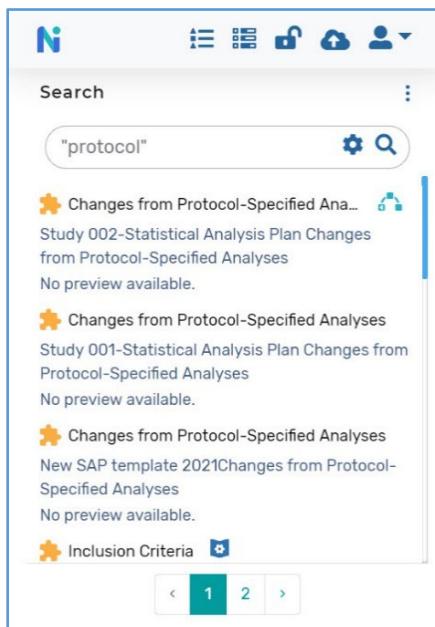
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### 1.3.2 Searching by Selected Text Match

1. Highlight/select text within a component in the document, right-click on the component, hover over the **InteliNotion** option, and click **Search “[Text]”**.



2. The *InteliNotion Word App* will automatically switch to the **Search** view and display a list of matching search results based on the selected text, as shown below.

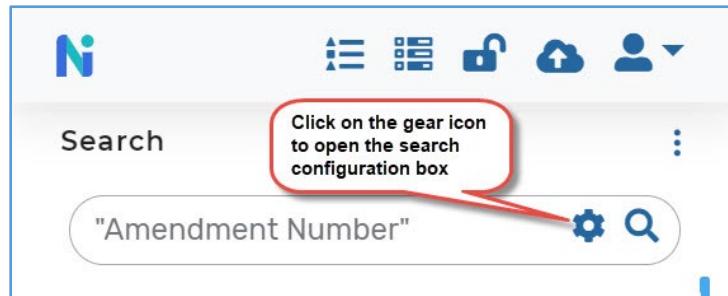


A screenshot of the InteliNotion Search view. The search bar contains the query "protocol". Below the search bar, there are three search results, each preceded by a yellow star icon and a link to a document titled "Changes from Protocol-Specified Analyses". The results are paginated at the bottom with page numbers 1, 2, and 3.

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3. The search results can be filtered by clicking the **Configuration button gear icon**  then following steps 1-2 outlined above.

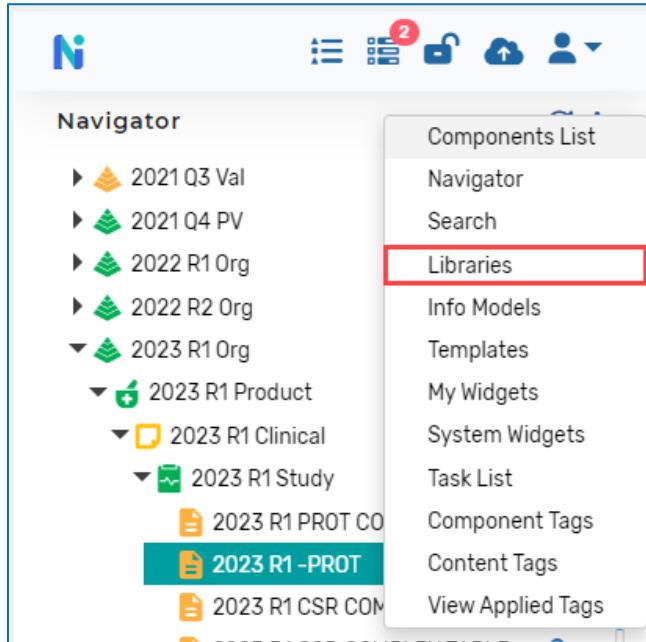


## 1.4 ADDING CONTENT TO THE DOCUMENT: VIA A LIBRARY

Some components are added to a library within the system by an authorized user (eg, admin) so they can be made readily available for reuse by users while authoring a document. The reuse policy for these library components is set at the library level. Unlike reusing a component located via **Search**, the user cannot decide how he/she wants to reuse the library component but instead must adhere to the reuse policy already applied.

**Note:** When adding a component with a tag already applied, a pop-up will display prompting the user to retain or discard that tag. Choose **Yes** or **No** as applicable. If new content tags need to be applied, see [Module 11](#) for detailed instructions.

1. Click on the **vertical ellipsis**  in the *InteliNotion Word App* and click **Libraries**.

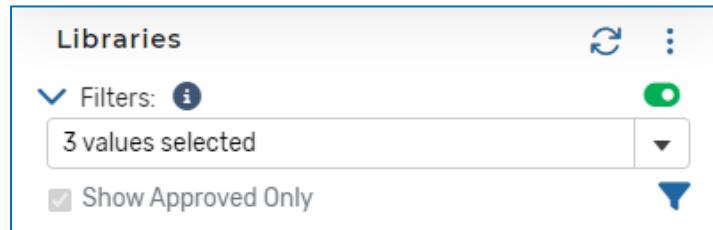


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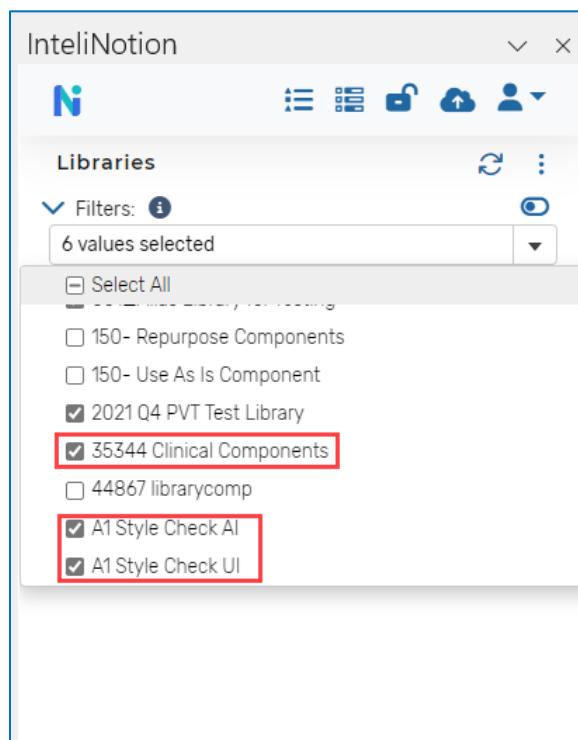
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## Notes:

- In a document open for editing, when switching the *InteliNotion Word App* to the **Libraries View**, libraries relevant to the document will be pre-selected.
- If a library has been configured to be pre-selected based on a prespecified matching property value (eg, Therapeutic Area = Diabetes), that library will be pre-selected for the user in the filter.



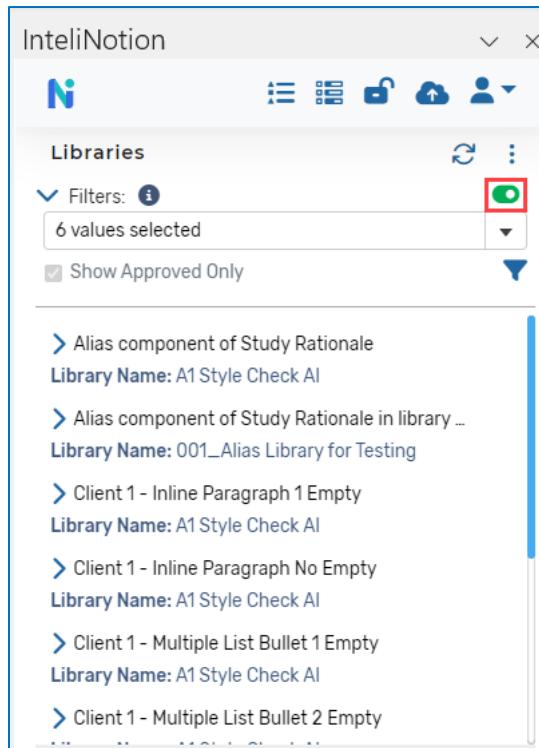
2. Select the desired library or libraries to match against by clicking on the search filter arrow and check the appropriate options. Click off the dropdown list.



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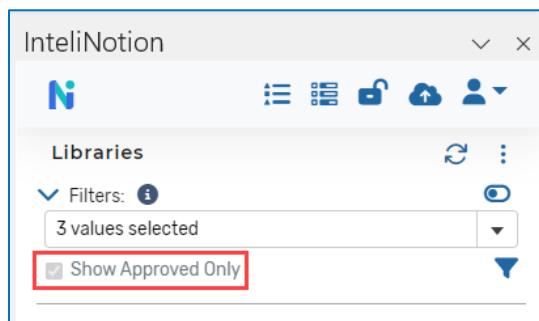
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3. Click the **Show all** components toggle to the on position to display matching library components.



#### **Notes:**

- The **Show Approved Only** checkbox is checked by default and disabled for a typical user. Only an authorized user can uncheck the box so that draft library components can be previewed/tested.

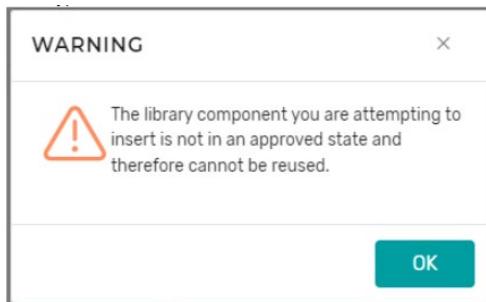


- Clicking refresh will clear the selection of libraries – even if previously pre-selected. Closing and reopening Word will clear all library selection except for those that were pre-filtered. However, if the document was saved and checked in, but Word was left open, the prior library selections will be retained.

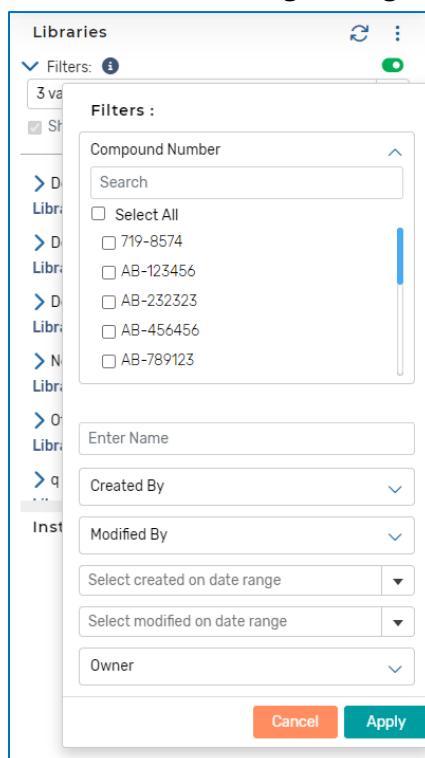
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- To ensure the style and any formatting applied to the content in the (library) component remains unchanged after it is reused, either via auto-insertion during document generation, or user-insertion while authoring, the same style(s) should be imported/available in the document or template itself.
- If the user attempts to add a component that is still in a draft state, a pop-up will display informing the user that the draft component cannot be reused into the document.



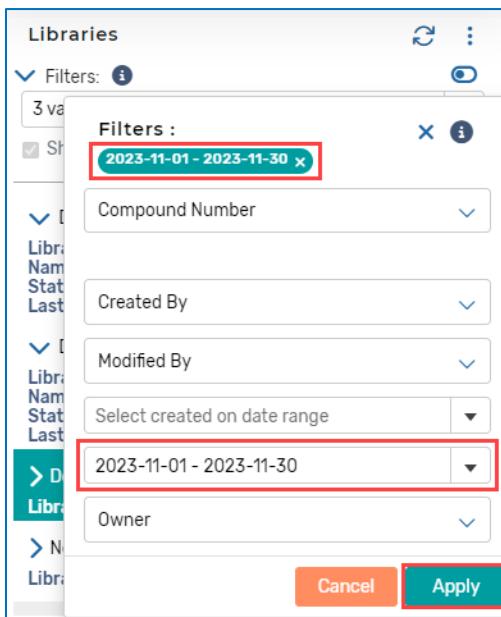
4. The components will display based on the **Description** first, then by the **Created On Date**. To filter the components by property, click the **filter** icon. The **Filters** list will display with the available properties for the selected libraries, based on the configuration (see **InteliNotion Authoring Configurations Guide, Section 6.3**).



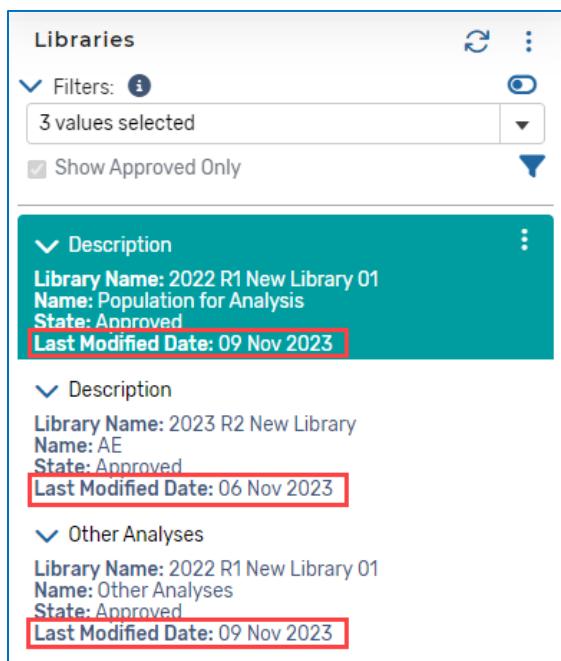
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5. Select the desired filters from the available choices. The selected filters will display at the top of the **Filters** menu. Click **Apply** to filter results.



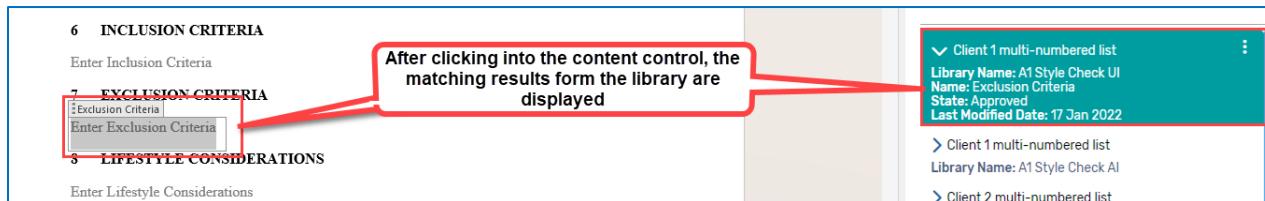
6. The **Libraries** sidebar will update to show only those components which match the filtering criteria. This can be confirmed by clicking on the components and verifying the information displayed. These components can then be added to the document as desired.



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7. Click in a component within the document, and the result dynamically updates to display matching components from the library, if available.



6 INCLUSION CRITERIA  
Enter Inclusion Criteria

7 EXCLUSION CRITERIA  
Enter Exclusion Criteria

8 LIFESTYLE CONSIDERATIONS  
Enter Lifestyle Considerations

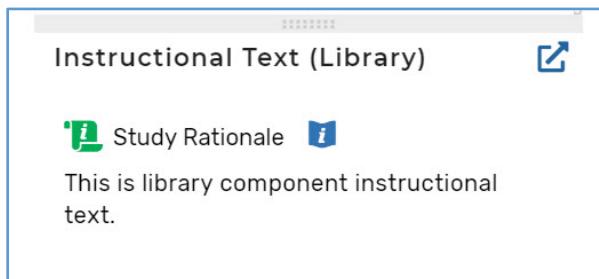
After clicking into the content control, the matching results form the library are displayed

Client 1 multi-numbered list  
Library Name: A1 Style Check UI  
Name: Exclusion Criteria  
State: Approved  
Last Modified Date: 17 Jan 2022

> Client 1 multi-numbered list  
Library Name: A1 Style Check AI

> Client 2 multi-numbered list

8. After selecting/highlighting a matching result, the library component-specific instructional text  is also displayed in the **Instructional Text** pane.

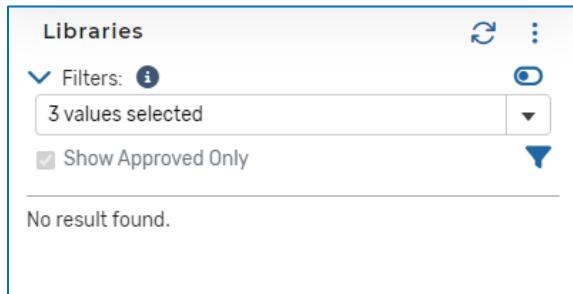


Instructional Text (Library)

 Study Rationale 

This is library component instructional text.

**Note:** The dynamic results from the **Libraries** view displays **only** if the selected document component has at least one matching component within the selected library or libraries. If there are no matches, then **No result found** is displayed.



Libraries

Filters: 

3 values selected

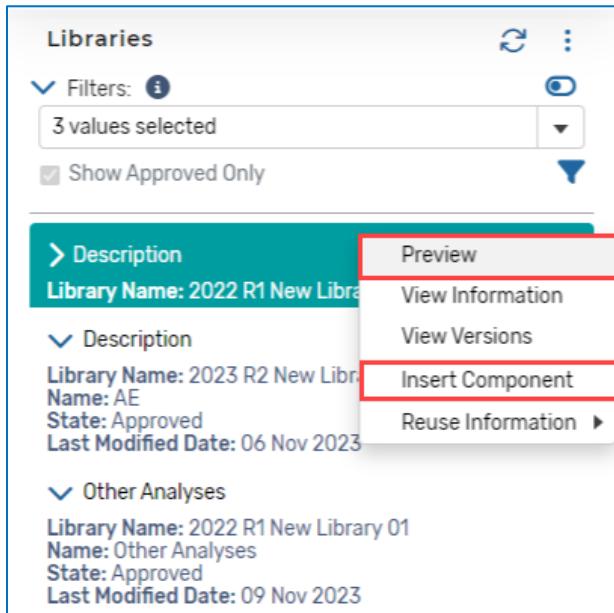
Show Approved Only

No result found.

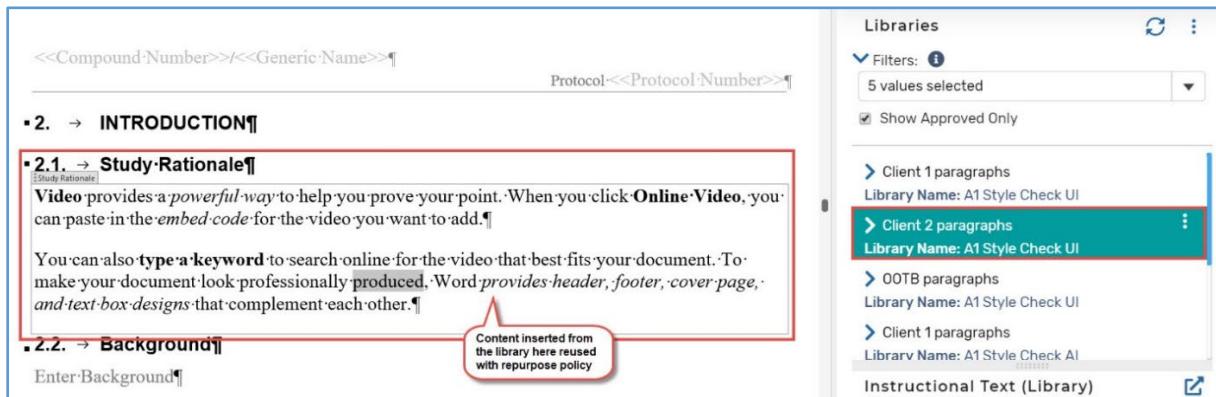
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9. The user can preview a component's content or insert the component by using the applicable option available after clicking on the **vertical ellipsis** ⏮ displayed beside the component.



10. After inserting the component, the content appears in the content control box as shown below.



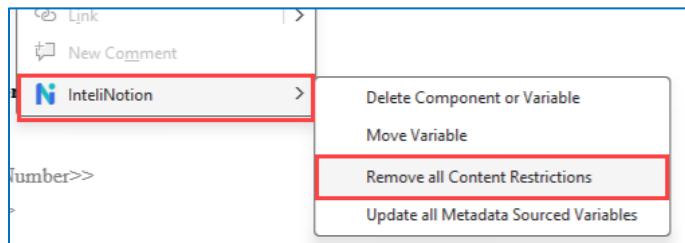
The screenshot shows the content control box with inserted library content. A callout bubble points from the inserted content back to the 'Insert Component' option in the Libraries menu.

**Note:** The content gets inserted according to the reuse policy specified when configuring the library. Therefore, the user will not see options to select the type of reuse unless the **Allow Override** checkbox was checked during the configuration process. If the **Allow Override** checkbox is checked, users with the appropriate override permission can use the right click menu option to override the reuse policy of inserted components. See **InteliNotion Authoring**

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**Configurations Guide, Section 5.1** for instructions on steps to configure override permissions.



## 1.5 ADDING CONTENT TO THE DOCUMENT: EXISTING COMPONENT FROM ANOTHER DOCUMENT (VIA NAVIGATOR)

By browsing the **Navigator** view in the *InteliNotion Word App*, an existing component from another document can be located and reused. If a non-matching component is selected for reuse (ie, one that has a different name than the component in the document), the user may be able to reuse the content only from the selected component. Details for each type of reuse are provided in the subsections below.

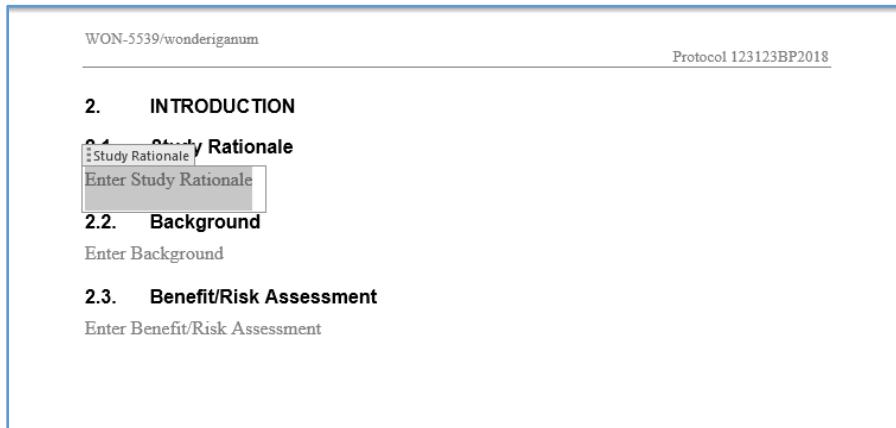
### **Notes:**

- When adding a component with a tag already applied, a pop-up will display prompting the user to retain or discard that tag. Choose **Yes** or **No** as applicable. If new content tags need to be applied, see [Module 11](#) for detailed instructions.

When adding a reused component of any type, follow the steps listed below

### 1.5.1 Component with a Matching Name

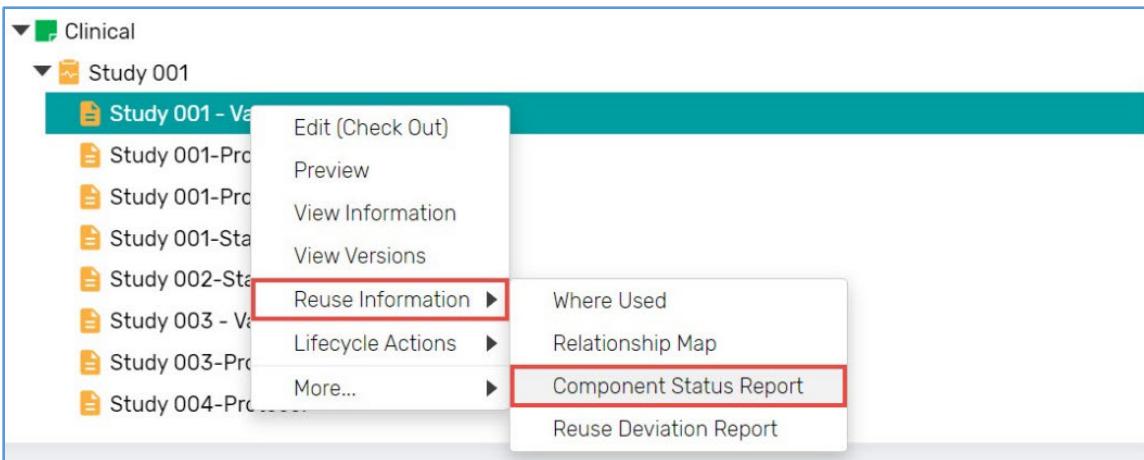
- Within the open document, click on the content component to be populated with a reused component (eg, **Study Rationale**).



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2. In the **Navigator**, expand the relevant business objects (eg, product, study) to locate the document of interest. Right-click on the document, navigate to **Reuse Information** and then select **Component Status Report**.



**Note:** Users can also double-click the relevant document to open its **Component Status Report**.

3. The Component Status Report will list all the components within the selected document.
4. Locate the component to Reuse.

Component Status Report: Statistical Analysis Plan Document							
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action	
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Objective Test text for script 1...	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Objective	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Objectives, Endp...							
Primary Objecti...	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Endpoints	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Estimands	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Secondary Obj...	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Endpoints	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Estimands	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Exploratory Obj...	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Endpoints	Use As Is	Draft	0.1	2024-11-07 8:57 PM			
Estimands	Use As Is	Draft	0.1	2024-11-07 8:57 PM			

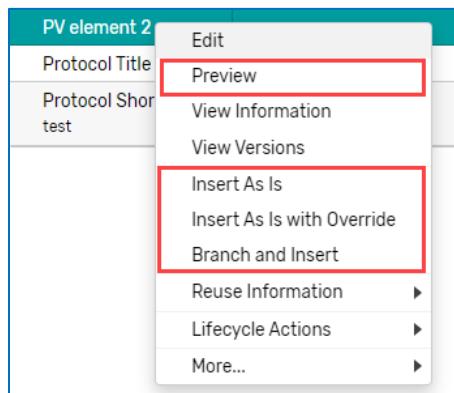
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**Notes:**

- The components can be filtered and sorted by clicking on the column heading.
- Some components may be repeated in the list because they have multiple instances (eg, objective, endpoint).
- If a user edits/checks out a document's component individually (i.e., via the document's Component Status Report), the user will no longer be able to check out the document itself.
- See [Section 1.9.2](#) for further details on reusing an existing component set from another document via its Component Status Report.

- Right-click on the component name. Either preview the component and/or insert it into the document by clicking either **Insert As Is**, **Insert As Is with Override**, or **Branch and Insert**.



- The selected component's content will insert into the specified component in the open document (Step 1), as shown below in this example of a repurpose reused (ie, **Branch and Insert** option) component from another document:

The screenshot shows a Microsoft Word document with the following content:

- Section 2.1.:** **INTRODUCTION**  
Video provides a powerful way to help you prove your point. When you click Online Video, you can paste in the embed code for the video you want to add.
- Section 2.2.:** **Background**  
Enter Background
- Section 2.3.:** **Benefit/Risk Assessment**  
Enter Benefit/Risk Assessment

The **Navigator** panel on the right shows the following hierarchy:

- 2021 Q3 Val
- Organization 001
  - Product 001
    - Clinical
      - Study 001
        - Study 001 - Variant
          - Study 001-Protocol
          - Study 001-Protocol-02
          - Study 003 - Variant
          - Study 003-Protocol
          - Study 004-Protocol

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### 1.5.2 Component with a Non-Matching Name

- Within the open document, click on the content component to be populated with a reused component (eg, **Protocol Short Title**).

**CLINICAL PROTOCOL**

**Protocol Title:** Enter Protocol Title

**Protocol Number:** 2018WON-02

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2

**Short Title:**  Protocol Short Title

**Acronym:**

- In the **Navigator**, expand the relevant business objects (eg, product, study) to locate the document of interest. Double-click on the document to open its Component Status Report, and then locate the component that has a different name (eg, **Protocol Title**) to reuse.

Component Status Report: Statistical Analysis Plan Document

Component Name	Reuse Type	State	Version	Modified On	Action
<b>▲ Status: Not Modified (41 items)</b>					
Status		Draft	0.1	2024-11-07 8:59 PM	
SAP Date		Draft	0.1	2024-11-07 8:59 PM	
<b>Protocol Title</b>	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Protocol Short Title	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Acronym	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Sponsor Name	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Sponsor Address	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Abbreviations	Repurpose	Draft	0.1	2024-11-07 8:59 PM	
Objective	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Objective Test text for script 10/2	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Objective	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Endpoint	Use As Is	Draft	0.1	2024-11-07 8:57 PM	
Objectives, Endpoi...					
Primary Objectives	Use As Is	Draft	0.1	2024-11-07 8:57 PM	

Close Update

**Note:** The components can be filtered and sorted by clicking on the column heading.

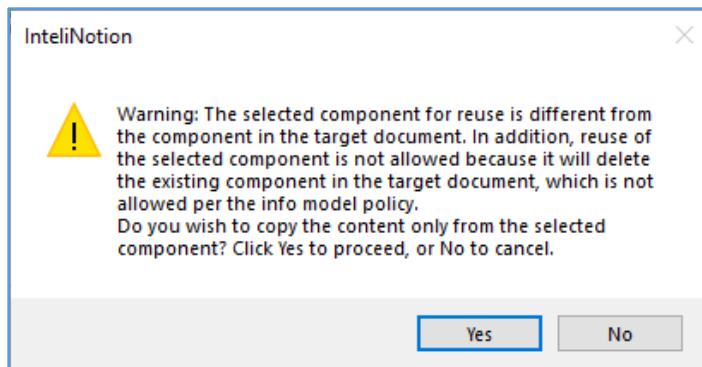
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3. Right-click on the component name. Either preview the component and/or attempt to insert it into the document by clicking either **Insert As Is**, **Insert As Is with Override** OR **Branch and Insert**.

Component Name	Reuse Type	State
<b>▲ Status: Not Modified (41 items)</b>		
Status		Draft
SAP Date		Draft
Protocol Title	Preview	Draft
Protocol Short Title	View Information	Draft
Acronym	View Versions	Draft
Sponsor Name	View Tasks	Draft
Sponsor Address	Insert As Is	Draft
Abbreviations	Insert As Is with Override	Draft
Objective	Branch and Insert	Draft
Endpoint	Reuse Information	Draft
Objective Test text for script 10/2	Manage Notifications View Audit Logs	Draft
Endpoint	Use As Is	Draft

4. Unless **Insert As Is with Override** was chosen, allowing the user to override any content restrictions on the reused component, depending on the delete policy configured for the component in the document, one of the following actions will occur:
  - a. If deletion of the component in the document is **not allowed** per the info model or template policy, this message will display:



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- i. In this case, the user can either choose to copy the content **only** from the selected component, with no reuse relationship maintained, or cancel the operation (ie, click **No**).
- ii. If the user clicks **Yes**, the content of the non-matching component will be copied into the component in the document.

## CLINICAL PROTOCOL

**Protocol Title:** Enter Protocol Title

**Protocol Number:** 2018WON-02

**Amendment Number:** Enter Amendment Number

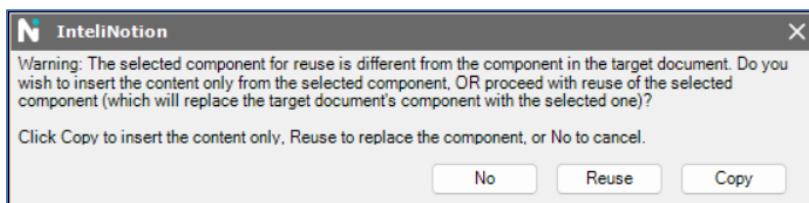
**Compound Number:** WON-5539

**Study Phase:** 2

**Short Title:**  A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus testinib for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy

**Acronym:** Enter Acronym

- b. If deletion of the component in the document is **allowed** per the info model or template policy, this message will display:



- i. In this case, the user can either choose to: 1) copy only the content from the selected component, with no reuse relationship maintained; 2) reuse the selected component by replacing the existing component in the document with it; or 3) cancel the operation (ie, click **No**).
- ii. If the user clicks **Copy**, only the content of the non-matching component will be copied into the component in the document.

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## CLINICAL PROTOCOL

**Protocol Title:** Enter Protocol Title

**Protocol Number:** 2018WON-02

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2

**Short Title:** Enter Protocol Short Title

**Acronym:**

**Acronym:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus testinib for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy

- iii. If the user clicks **Reuse**, the component in the target document is replaced by the one being reused; editing of the new component will be based on the type of **Reuse** (ie, it will depend if **Insert As Is**, **Insert As Is with Override** or **Branch and Insert** is selected). Because the component from another document was reused into the open document, instead of only its content being copied, a reuse relationship will be maintained.

## CLINICAL PROTOCOL

**Protocol Title:** Enter Protocol Title

**Protocol Number:** 2018WON-02

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2

**Short Title:** Enter Protocol Short Title

**Protocol Title:**

**Acronym:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus testinib for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy

### 1.5.2.1 Updating Component Name to Match Alias

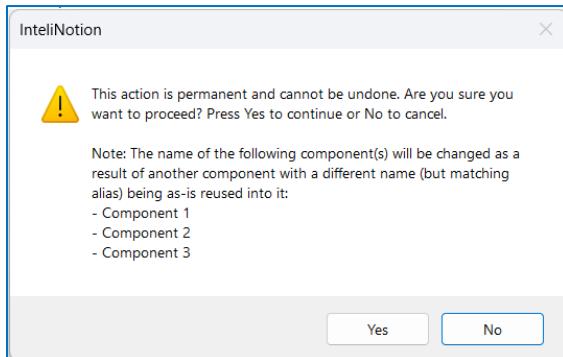
An author replacing a component into a document using the **Insert As Is** option will receive an informational pop-up with information concerning the name change of the component, depending on the scenario. See the paragraphs below for the information message parameters.

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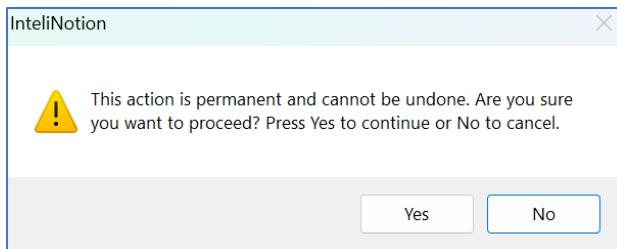
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- When the component's name is different but one of the aliases of the component in the document matches with the searched component's name, an info message will display informing the user that the name of the component in the document will change.



- When the replaced component is further reused in a downstream document, if the user edits/checks out the downstream document, opens the component status report when prompted, there will be an option to **View/Accept** the change. An info message informing the user that changing the name of the component in the downstream document is a permanent action that cannot be undone.



- When the replaced component is further reused in a downstream document, if the user edits/checks out the downstream document and opens the component status report and selects multiple components with selection includes at least one change type as **Component** and **View/Accept** the change and Update, a "Permanent action's" existing message pops-up and the user is notified with a message that the name of the component in the downstream document will change.

Component Status Report: Test 53897-CSR_1						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Modified (4 items)</b>						
Short Title	Use As Is	Draft	0.2	2024-03-05 4:42 PM	Component	<a href="#">View / Accept</a>
Study Rationale	Use As Is	Draft	0.1	2024-03-05 4:42 PM	Component	<a href="#">Ignore</a>

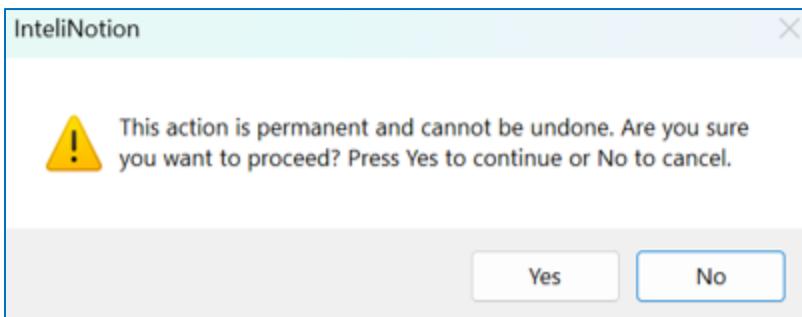
- When the replaced component is further reused in a downstream document, if the user edits/checks out the downstream document, opens the component status report when prompted, and selects multiple components with change type NOT a component and

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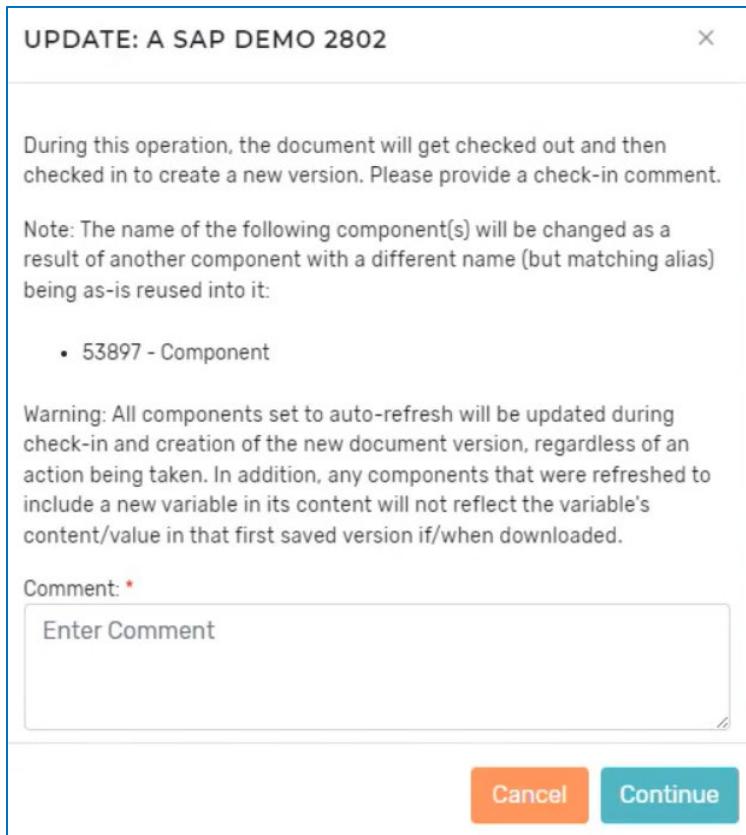
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View/Accept the change and Update, a message informing the user that this is a permanent action that cannot be undone will display.



- When the user opens the component status report from a navigator of a closed document and selects multiple components with at least 1 change type as **Component** and completes the **View/Accept** action updating the component, an **Update** message will display.

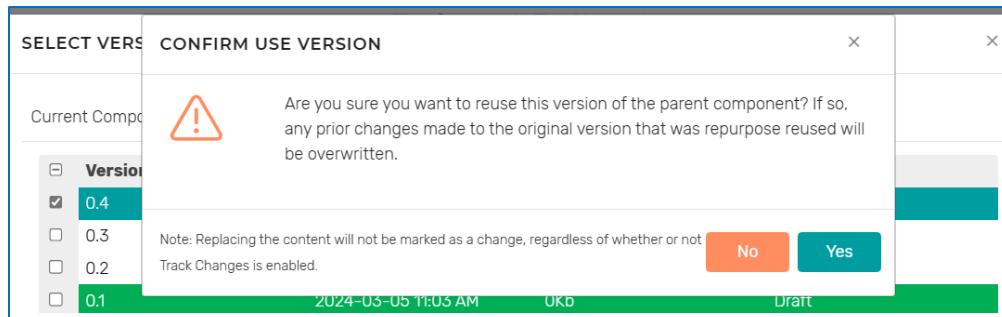


- When the user opens the component status report from a navigator of a closed document and selects multiple components with none of the component change type selection as

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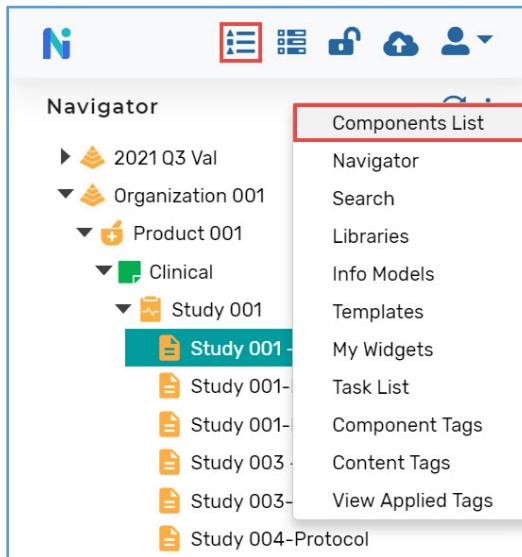
**Component** and **View/Accept** the change and update, an **Update** message pops-up without a note mentioned in existing message.



## 1.6 ADDING CONTENT TO THE DOCUMENT: EXISTING COMPONENT FROM OPEN DOCUMENT

An existing component in the document may be reused elsewhere as described below.

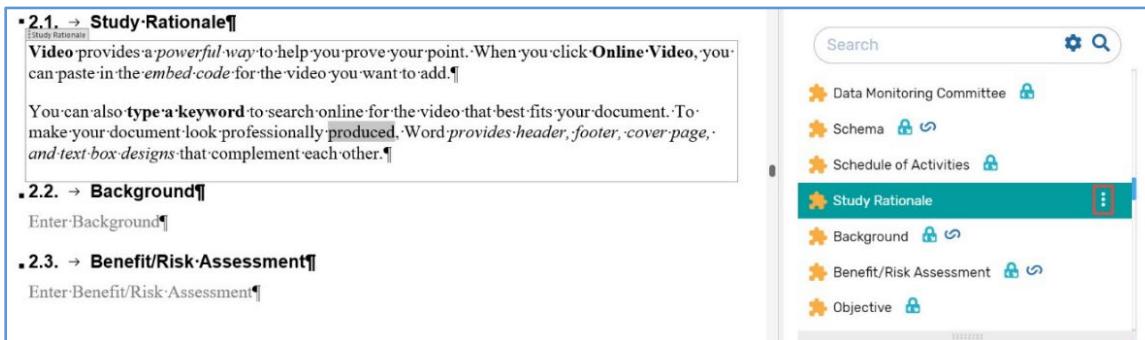
1. If needed, click on the **vertical ellipsis** ⏮ in the *InteliNotion Word App* and click the **Components List** option or click on the **Components List icon** .



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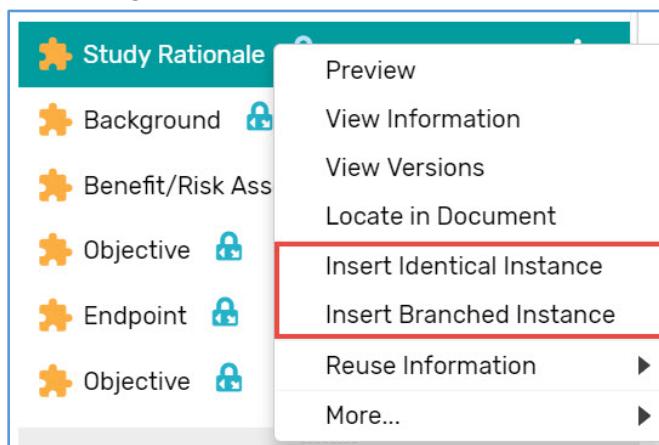
2. Place the cursor in the location of the document where the reused component is to be inserted. Then, locate the component to be reused in the **Components List**, and click on the **vertical ellipsis** ⏮ beside its name.



The screenshot shows the Intelinotion software interface. On the left, a document view displays three sections: '2.1. → Study-Rationale', '2.2. → Background', and '2.3. → Benefit/Risk-Assessment'. Each section contains a brief description and an input field. On the right, a 'Components List' sidebar shows a search bar and a list of components: Data Monitoring Committee, Schema, Schedule of Activities, Study Rationale (selected), Background, Benefit/Risk Assessment, and Objective. Each component has a lock icon and a vertical ellipsis (⋮) icon.

3. Click on one of the following **Reuse** options:

- **Insert As Is** – To insert an identical copy of the component (ie, intra-document reuse); any edits made to the component will be propagated to the other locations, and vice versa.
  - If working with a split-screen, be cautious when editing an intra-document reused component. If one instance is edited on the top screen view, do not immediately click in the bottom screen view, as this may lead to a synching issue between the 2 locations.
- **Insert Branched Instance** – To insert a branch of the component (ie, derivative) that maintains a relationship with its source; any edits made to the component will not be propagated to the other locations.

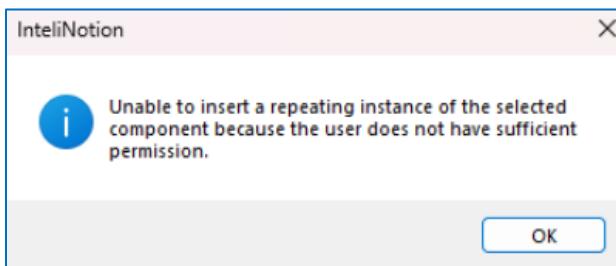


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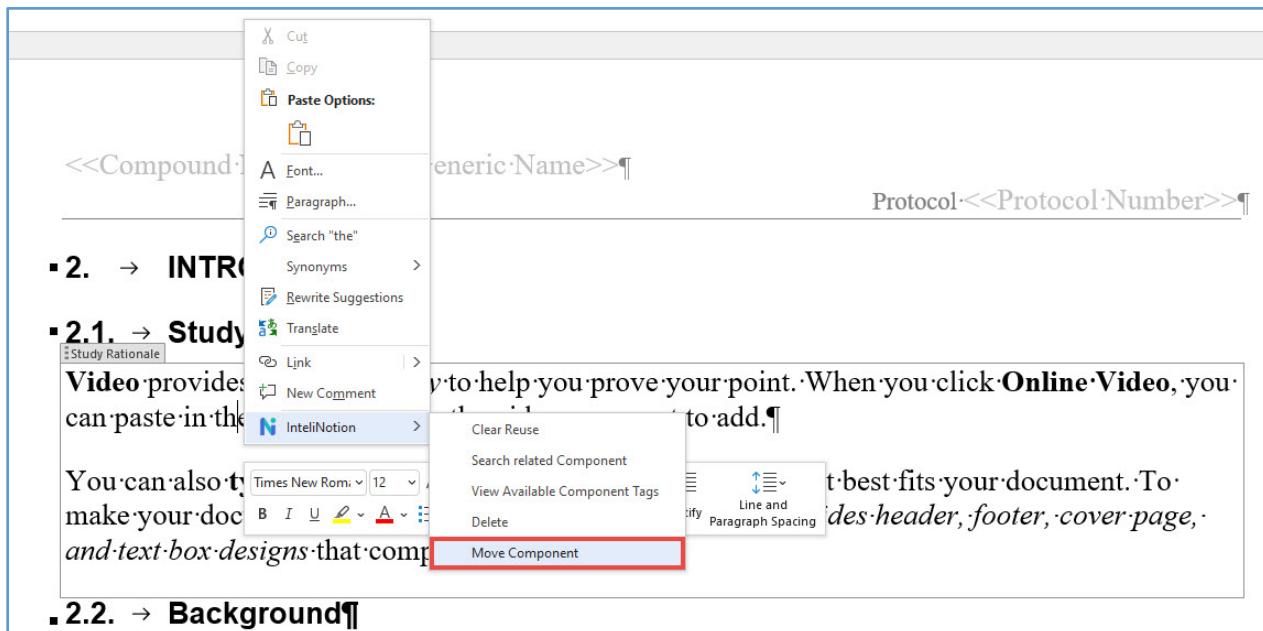
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## Notes:

- The **Insert Branched Instance** option appears for a component only after it is saved to the system at least 1 time.
- The new component will immediately show in the **Components List**; however, it will not show as checked out to the user until the document is saved. It is recommended to save the document after performing one of the reuse options.
- The following error message will display if the user does not have sufficient permissions to add the desired component to the document. This message will differ depending on the type of component the user is attempting to add.



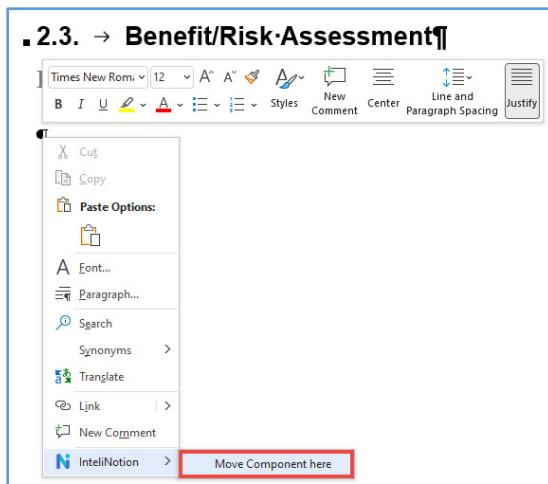
- If the newly inserted component needs to be moved in the document:
  - Right-click on it, hover over the **InteliNotion** option and click **Move Component**.



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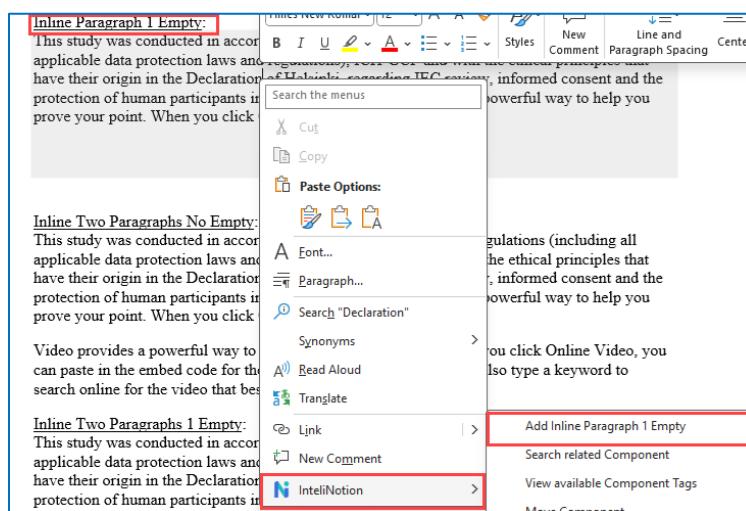
- b. Place the cursor in the appropriate location of the document, right-click, hover over the **InteliNotion** option, and click **Move Component Here**.



## 1.7 ADDING CONTENT TO THE DOCUMENT: VIA ADDITION OF REPEATED COMPONENTS

Certain content components may be configured to allow for repeating (ie, the addition of multiple unique instances of the same type of component); examples include study objectives, endpoints, inclusion/exclusion criteria, and personnel names.

- In the open document, locate the applicable component configured as a repeating component and right-click inside the content control. This will bring up the menu. Hover over the *InteliNotion* option and click the insert repeating component option, which will always appear as Add + the applicable component name.



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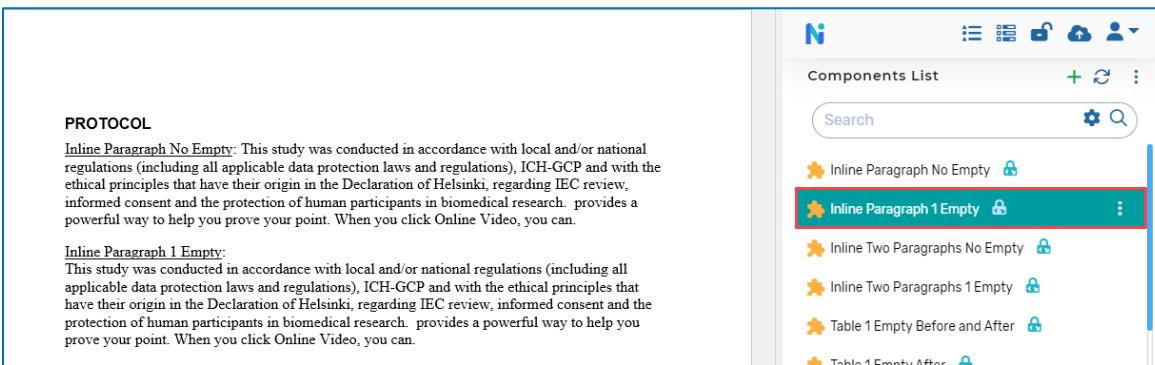
2. The new repeating instance of the component will appear below the original instance.

**Inline Paragraph 1 Empty:**  
 This study was conducted in accordance with local and/or national regulations (including all applicable data protection laws and regulations), ICH-GCP and with the ethical principles that have their origin in the Declaration of Helsinki, regarding IEC review, informed consent and the protection of human participants in biomedical research. provides a powerful way to help you prove your point. When you click Online Video, you can.

Enter Inline Paragraph 1 Empty

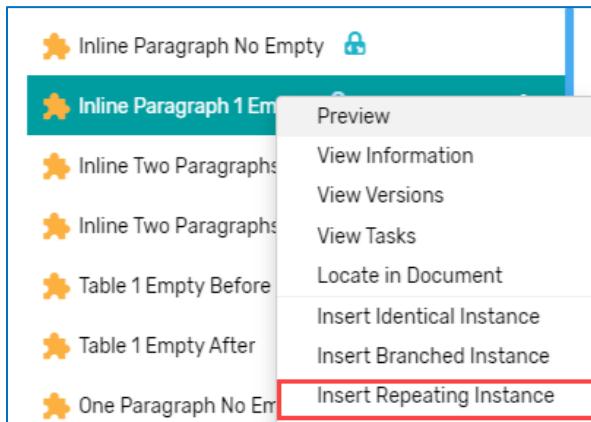
OR

1. Place the cursor where the repeating component should be inserted and click on the components list  icon.
2. A list of components will display in the *InteliNotion* sidebar. In the document, click on the applicable component configured as a repeating component. This will highlight the component in the components list.



The screenshot shows the InteliNotion software interface. On the right, the 'Components List' sidebar is open, displaying a list of components. One component, 'Inline Paragraph 1 Empty', is highlighted with a teal background and a red border around its icon and name. The main document area contains two instances of this component. The first instance has its content visible: 'This study was conducted in accordance with local and/or national regulations (including all applicable data protection laws and regulations), ICH-GCP and with the ethical principles that have their origin in the Declaration of Helsinki, regarding IEC review, informed consent and the protection of human participants in biomedical research. provides a powerful way to help you prove your point. When you click Online Video, you can.' The second instance is empty, represented by a red rectangular box.

3. Click the ellipses next to the applicable component and select **Insert Repeating Instance**.



The screenshot shows the InteliNotion sidebar with a context menu open over the 'Inline Paragraph 1 Empty' component. The menu items are: Preview, View Information, View Versions, View Tasks, Locate in Document, Insert Identical Instance, Insert Branched Instance, and Insert Repeating Instance. The 'Insert Repeating Instance' option is highlighted with a red border.

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**Note:** The new component will immediately show in the **Components List**; however, it will not show as checked out to the user until the document is saved.



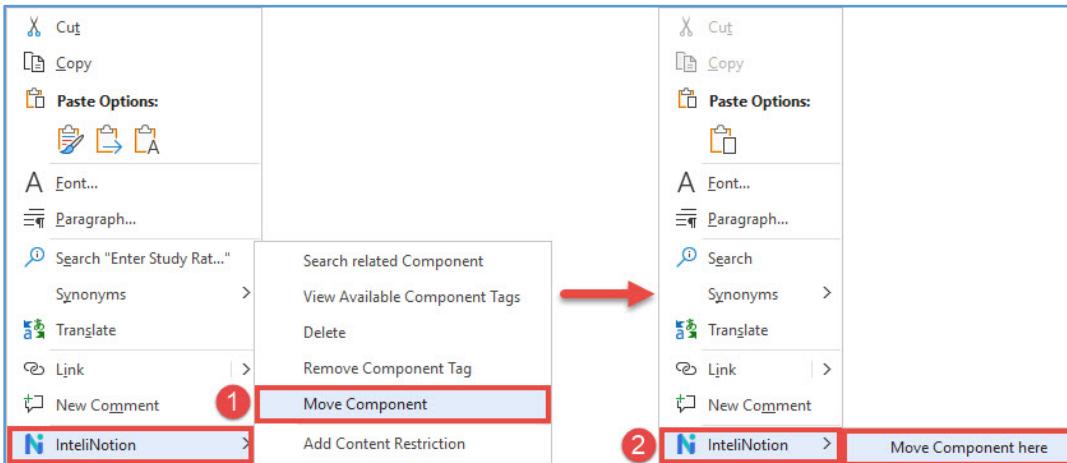
4. The repeated component will be inserted in the open document where the user placed the cursor.

Inline Paragraph 1 Empty:

This study was conducted in accordance with local and/or national regulations (including all applicable data protection laws and regulations), ICH-GCP and with the ethical principles that have their origin in the Declaration of Helsinki, regarding IEC review, informed consent and the protection of human participants in biomedical research. provides a powerful way to help you prove your point. When you click Online Video, you can.

Enter Inline Paragraph 1 Empty

5. After insertion of the repeated component, if the component needs to be moved, right click on the newly inserted component, hover over the **InteliNotion** option, and click **Move Component**. Place the cursor where the item needs to be relocated, and click **Move Component Here**.



**Note:** If an element is configured as repeating, the option to add a repeating component after reuse (regardless of as-is/repurpose reuse) is still available to the user.

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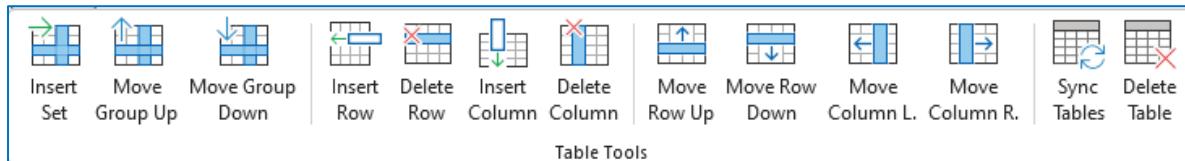
## 1.8 MANAGING COMPLEX TABLES

The elements in a complex table are called sets. Two types of complex tables can be managed in an *InteliNotion* Document:

- **Hierarchical** - hierarchical tables are organized in order of rank, and are presented in rows, eg, an Objectives and Endpoints table where an objective can have one or many endpoints.
- **Set in Relation** - set in relation tables are organized to display sets that have a relation between them. These sets can be presented in rows or in columns, eg, the table of Study Interventions Administered.

Complex tables that have been inserted into a document, (created from a template that was configured accordingly), can be managed through the Table Tools from the InteliNotion Ribbon.

The complex table ribbon will appear once the cursor is placed inside a complex table and the user clicks the drop-down arrow next to Table Tools:



### Notes:

- If the table was configured with a footnote type element (see **InteliNotion Authoring Configuration Guide, Section 2.2.7**), it will appear at the bottom of the table.
- Apart from **Sync** and **Delete Table**, actions taken via the table tools ribbon cannot be undone. The user will receive the following confirmation pop-up:



### 1.8.1 Inserting a Set

All complex tables in a document will have at least one row or one column populated with the initial components.

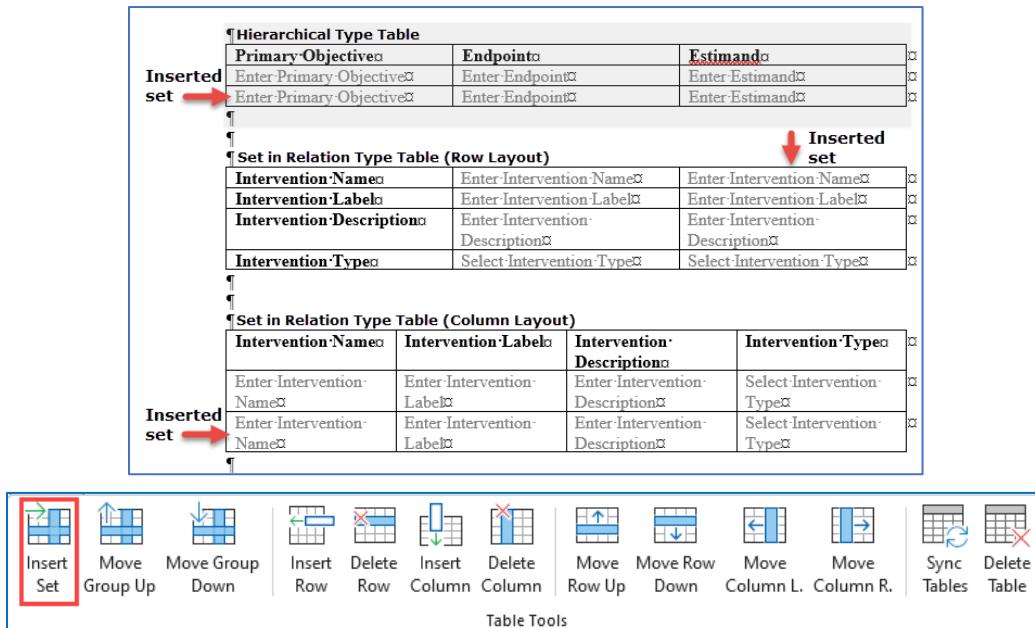
Adding a new set in a complex table can include a new row (hierarchical and column layout set in relation tables) or a new column (only in row layout set in relation tables). Placing the cursor in

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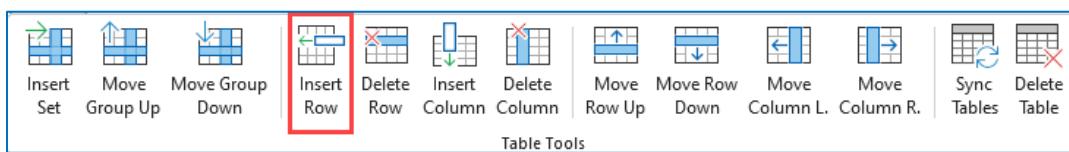
any cell where the initial or previous component exist and clicking **Insert Set** on the ribbon will add a new row below (or column to the right) populating all the new corresponding components.



### 1.8.2 Inserting an Empty Row

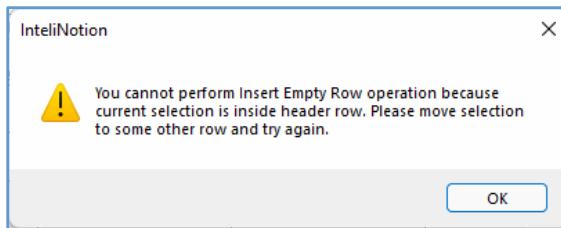
A blank or empty row can be inserted in a master complex table.

To insert a blank row below the row where the active cursor is located, click on the **Insert Row** on the *InteliNotion* ribbon.



#### Note:

- It is not possible to insert an empty row on a row layout set in relation table.
- Trying to insert a row on either type of complex table when the cursor is positioned on a heading row will cause a warning:



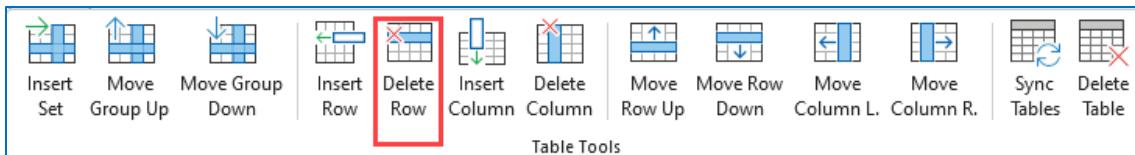
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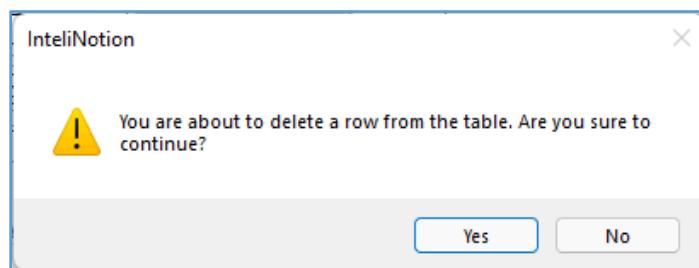
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### 1.8.3 Removing a Row

A populated or empty row in a complex table can be removed by clicking **Delete Row** on the *InteliNotion* ribbon.



All content or variables in that row will be removed after clicking **Yes** on the warning message.



#### **Notes:**

- Header rows cannot be removed from Set in Relation tables.
- A row cannot be removed in a master table if the same row also exists in non-master table.
- This operation cannot be undone.

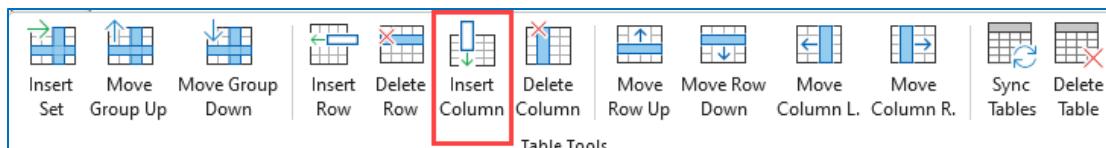
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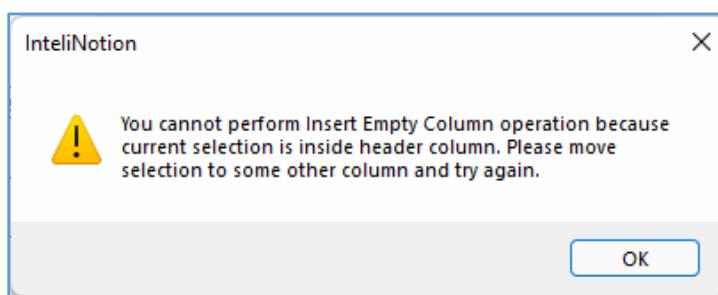
#### 1.8.4 Inserting an Empty Column

A blank or empty column can be inserted in a master complex table.

To insert a blank column to the right of the one where the cursor is positioned, click **Insert Column** on the *InteliNotion* ribbon.

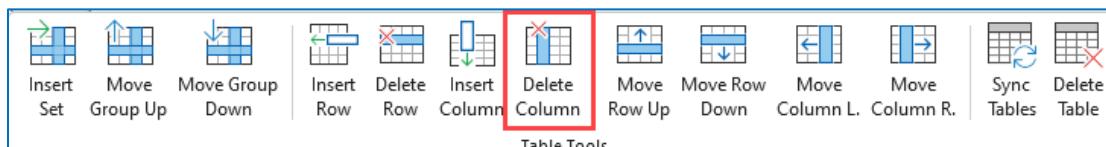


**Note:** Trying to insert a column on a row layout Master Set in Relation table will cause a warning when the cursor is positioned on a heading column:

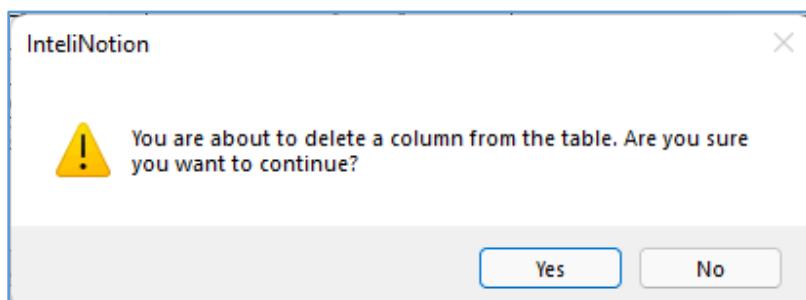


#### 1.8.5 Removing a Column

In either type of complex table, a populated or empty column can be removed by clicking **Delete Column** on the *InteliNotion* ribbon.



All content or variables in the column will also be removed after clicking **Yes** on the warning message.



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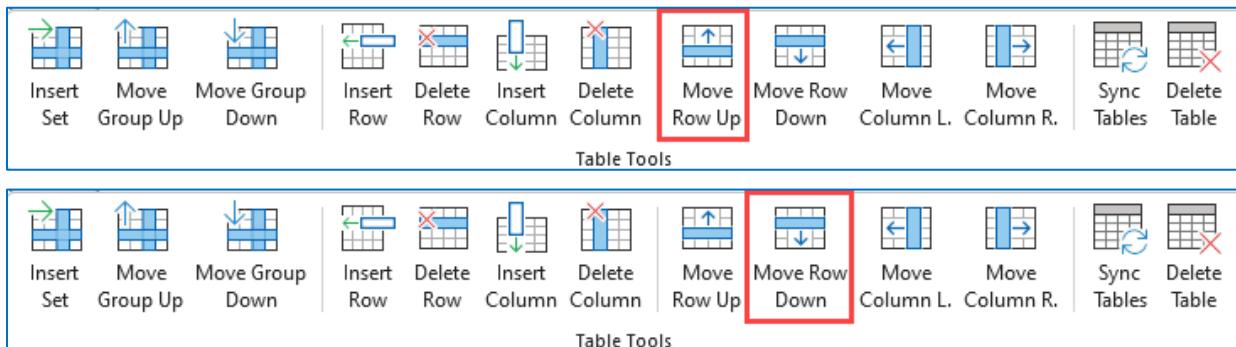
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**Notes:**

- Header rows cannot be removed.
- A column cannot be removed in a master table if the same column also exists in non-master table.
- This operation cannot be undone.

### 1.8.6 Moving a Row

In either type of complex table, a row with all its content can be moved up or down using the **Move Row Up** and **Move Row Down** buttons on the *InteliNotion* ribbon.



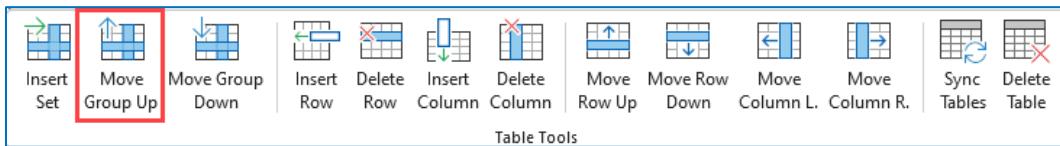
**Note:** In a hierarchical table or a column layout set in relation table the first row under a heading row cannot be moved from its place and the second row cannot be moved into the first place either.

### 1.8.7 Moving a Group

As full-control admin user *OR* authorized user with both Templates and Info Models functional permission, the user has the option to move an inserted set within a hierarchical type complex table.

After a new/additional set of elements is inserted into a table within either a template or document the following actions can be taken:

A set of elements, including its corresponding header row, can be moved up within the table, by using a **Move Group Up** command on the table tools ribbon.

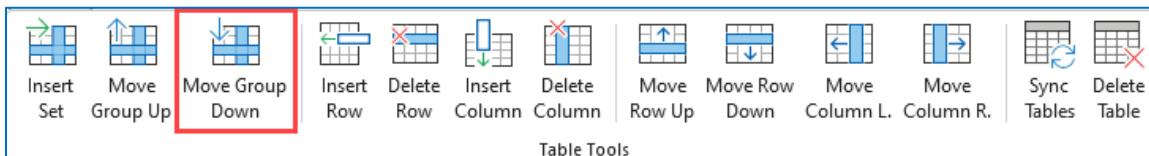


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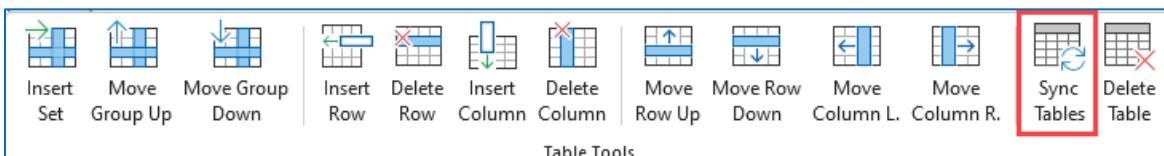
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After moving a set of elements with header row up, they can be moved back down by using the **Move Group Down** command on the table tools ribbon.

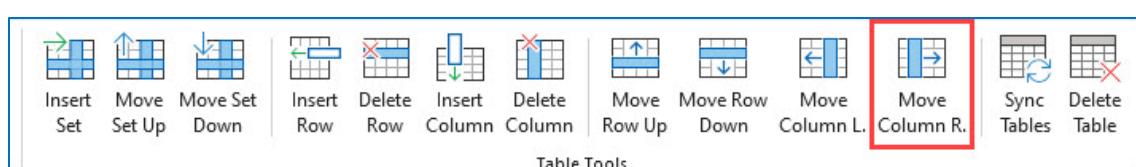
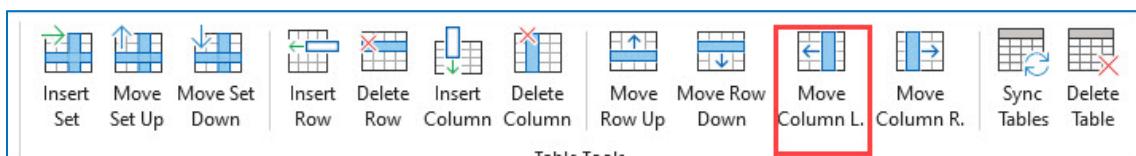


Changes can be synched to the non-master table instance(s) - these will include content changes and any additional sets added in master and not reordered groups.



### 1.8.8 Moving a Column

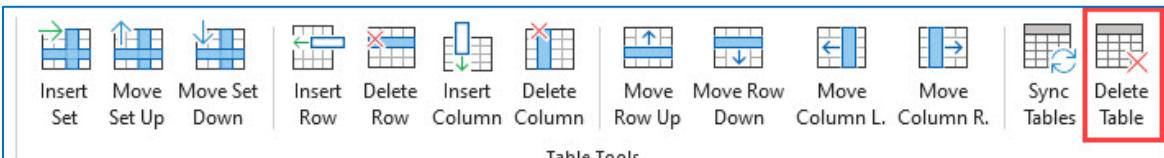
In either type of complex table, a column with its content can be moved left or right using the **Move Column L.** and **Move Column R.** buttons on the *InteliNotion* ribbon.



**Note:** The first column next to the header column in a row layout Set In Relation table, cannot be moved from its place and the second column cannot be moved into the first place either.

### 1.8.9 Removing Tables

Complex tables can be removed from a document by placing the cursor inside the table and clicking the **Delete Table** button in the *InteliNotion* ribbon.



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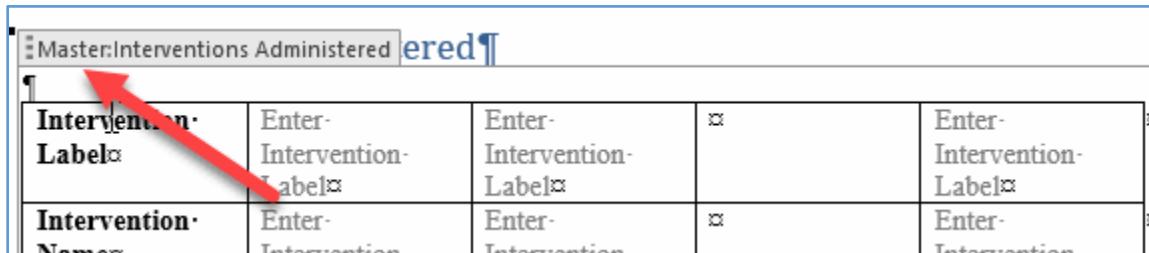
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**Note:**

- Master Tables can only be removed if all the child tables are removed first.
- This operation cannot be undone.

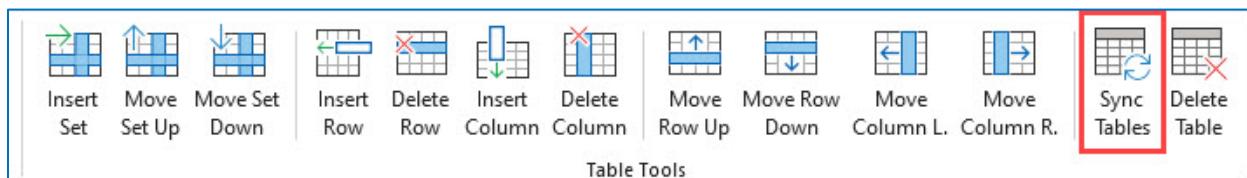
## 1.8.10 Synchronizing Tables

A document can have multiple instances of a complex table with different layouts, but the first instance inserted will be the master; this can be identified by clicking on the table and observing the content control title as shown in the figure below.

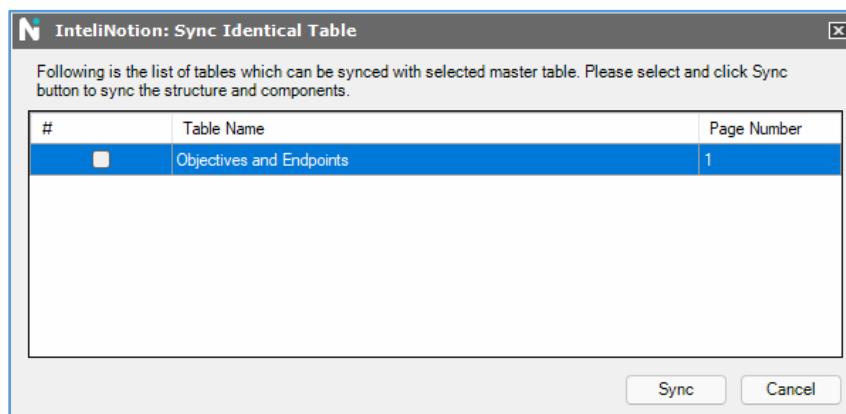


Intervention- Label	Enter- Intervention- Label	Enter- Intervention- Label		Enter- Intervention- Label
Intervention- Name	Enter- Intervention-	Enter- Intervention-		Enter- Intervention-

When changes are made to the master table, those changes will be reflected in the other copies contained in the document only after using the **Sync Tables** button on the *InteliNotion* ribbon.



When working in a master table, clicking on the **Sync Tables** button will bring up a list of all the child tables in the document that can be synchronized. Only components that are present in both child and master tables will be updated.



**Note:** This operation cannot be performed while the document is in co-authoring.

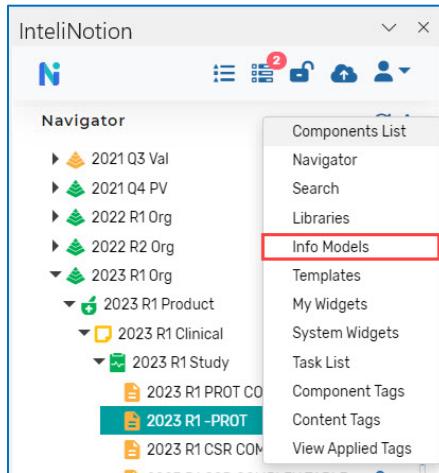
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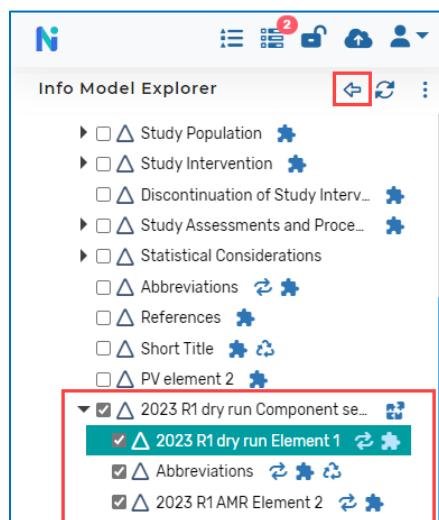
## 1.9 ADDING CONTENT TO THE DOCUMENT: COMPONENT SETS

Some components within the system are grouped, forming component sets. These component sets, once inserted into a document, are contained within one content control box. To add a component set, follow the steps listed below.

1. In the open document, place the cursor where the component set is to be inserted. Click on the ellipses in the *IN Word app* and select **Info Models**.



2. Navigate to the component set to be added, check the checkbox next to the applicable component set and click on the **Insert Selected Element** icon at the top right.



**Note:**

- If necessary, elements within the component set can be reordered via drag and drop before insertion into the document.

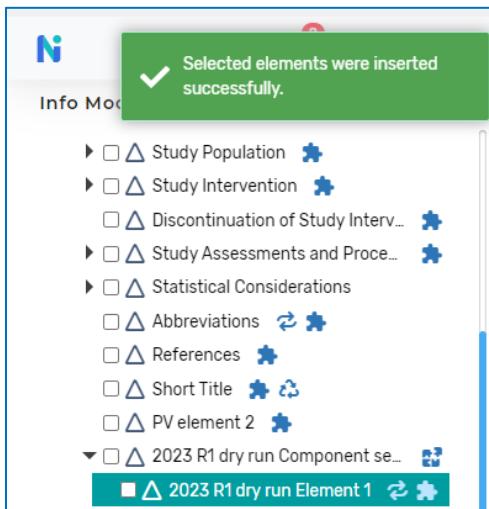
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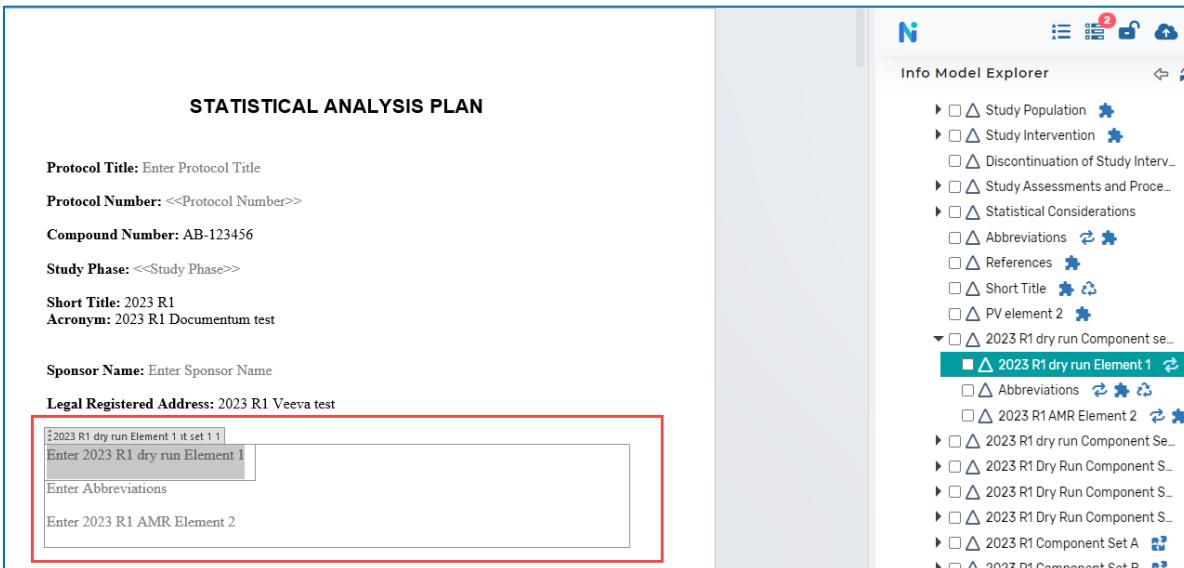
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- It is possible to select all elements within a component set by checking the checkbox next to the parent component set, or to select each element individually, as needed, by checking the checkboxes next to the desired elements within the component set.
- If needed, additional elements from the same component set can be added following steps 1-2 above, and when the document is refreshed, the additional elements will appear within the same content control.
- It is possible to insert only one component from a component set if desired.

3. Selected elements added successfully message will display.



4. Component set will appear at the selected location in the document.



A screenshot of a Microsoft Word document titled "STATISTICAL ANALYSIS PLAN". The document contains several fields and text entries. On the left, there is a red rectangular box highlighting a section of the text. To the right of the document is the Info Model Explorer window, which shows the "2023 R1 dry run Element 1" component set expanded, with its contents listed below it.

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### 1.9.1 Adding an Additional Component Set

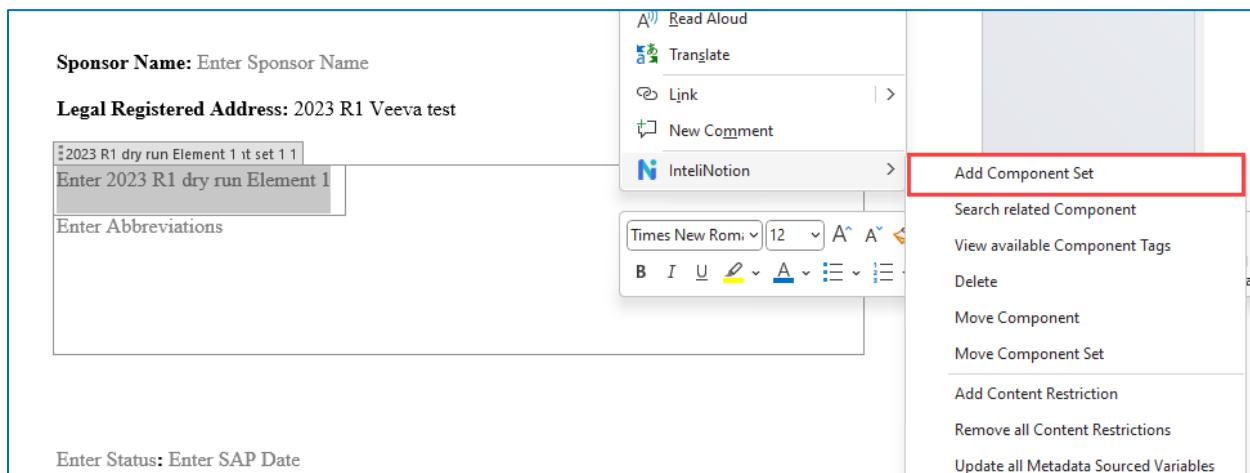
Once a component set has been added to the document, the user can add another instance of the component set with the following parameters:

- The newly inserted component set will include all the components in the existing set that was used to insert a repeating instance.
- The newly inserted set will have a suffixed number added at the end of the component set name; this number will always be sequentially increased based on the number of existing sets of the same type (eg, if the existing set name is 'Adverse Events 1' the new set name will be 'Adverse Events 2') regardless of its inserted order/position within the document.
- All the components in the newly inserted set will be empty.
- The Components List will refresh to show the newly inserted component set (with the up versioned suffix number) as well as each of its components.
- The user can enter content in any of the components included in the newly inserted set or outside the components but still within the outer content control.
- If a third component set is added using the newly generated component set, the extra content will not be included in the newly inserted set.
- After the document is saved, the components will now display in the document's Component Status Report

**Note:** When mapping individual components from a component set, only the components for that set are available for mapping. Components from different sets cannot be mapped from different source component sets.

Follow the steps listed below to add a repeating instance of a component set.

1. Right click on the component set to be duplicated, hover over **InteliNotion** and click **Add Component Set**.



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2. A duplicate component set with the up versioned number will be added to the document.

Enter 2023 R1 dry run Element 1

Enter Abbreviations

Enter 2023 R1 AMR Element 2

2023 R1 dry run Component set 1 2

Enter 2023 R1 dry run Element 1

Enter Abbreviations

Enter 2023 R1 AMR Element 2

**Note:** If a user attempts to add a duplicate component set via the info model, an error message will display. Component sets can only be duplicated from within the document.

### 1.9.2 Reusing a Component Set

When a user with at least C-R-U permissions is working on a document in single or co-authoring, it is possible to reuse an existing component set from another document via its Component Status Report. A component set can be reused into either an existing component set in the target document or 'freely' into the target document as a new/ad hoc set.

To reuse a component set into an existing component set in the target document:

1. Within the open document, click anywhere inside the component set to be populated with a reused component set from another document (eg, Related Adverse Events).

3 → ADVERSE·EVENTS¶

3.1 → Related·Adverse·Events¶

Related Adverse Events Message

Enter·Related·Adverse·Events·Message¶

Enter·Related·Adverse·Events·Findings¶

Enter·Related·Adverse·Events·Description¶

Enter·Related·Adverse·Events·Source¶

4 → SERIOUS·ADVERSE·EVENTS (3/4 REUSED)¶

Enter·Serious·Adverse·Events·Message¶

Enter·Serious·Adverse·Events·Findings¶

Enter·Serious·Adverse·Events·Description¶

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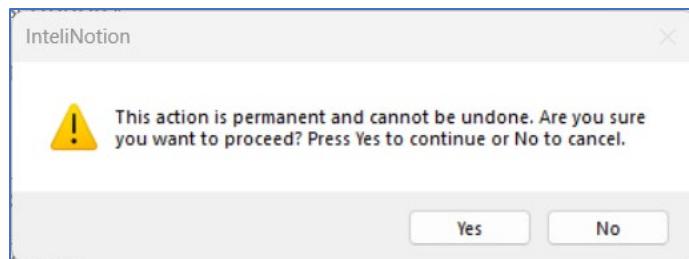
2. Open the Component Status Report of the source document.
3. Locate the component set that has the same type (eg, Related Adverse Events) to reuse within the 'Not Modified' section. (Note: Component sets are displayed with both a set row along with individual component rows in the 'Not Modified' section only.)
4. Right-click on the component set's name. Insert it into the document by clicking either **Insert As Is**, **Insert As Is with Override** OR **Branch and Insert**. All components in the selected set will be reused according to the selected reuse policy.

**Component Status Report: User Story 63046-CSR 03**

Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
Inclusion Criterion		Draft	0.4	2024-11-11 10:06 PM		
Exclusion Criterion		Draft	0.4	2024-11-11 10:06 PM		
<b>Related Adverse Events 1</b>						
Related Adverse Events Message		Draft	0.4	2024-11-11 10:06 PM		
Message Related adverse events CSR 03 up...						
Related Adverse Events Findings		Draft	0.4	2024-11-11 10:06 PM		
Findings Related adverse events CSR 03 up...						
Related Adverse Events Description		Draft	0.4	2024-11-11 10:06 PM		
Description Related adverse events CSR 03 ...						
Related Adverse Events Source		Draft	0.4	2024-11-11 10:06 PM		
Source Related adverse events CSR 03 upd...						
Related Adverse Events 3						
Related Adverse Events Message		Draft	0.1	2024-11-11 10:06 PM		
Related Adverse Events Findings		Draft	0.1	2024-11-11 10:06 PM		
Related Adverse Events Description		Draft	0.1	2024-11-11 10:06 PM		
Related Adverse Events Source		Draft	0.1	2024-11-11 10:06 PM		
Related Adverse Events 2						
Related Adverse Events Message		Draft	0.2	2024-11-11 10:06 PM		
Message Related adverse events CSR 03 up...						

**Close** **Update**

5. Selecting any option will display the following prompt:



6. Click **Yes**. Component set will be successfully reused into the document.

**Notes:**

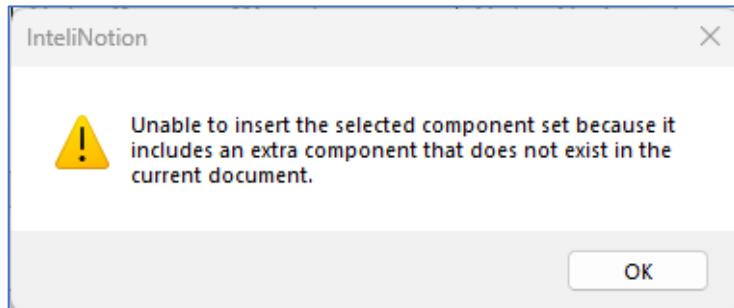
- After reuse, a component set will follow the component order/sequence that is defined per the target document's template. For example, if a component was reordered/moved within the existing component set, after it is reused into the

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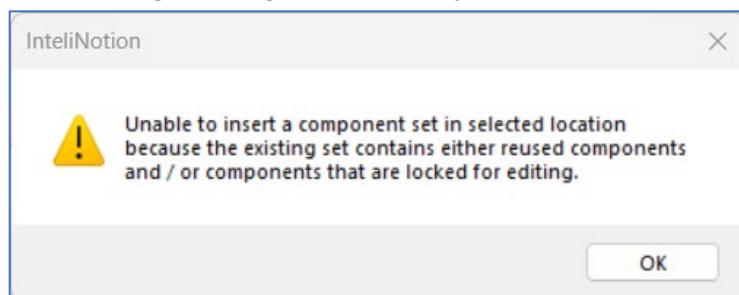
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target document, the components will revert to the original order (assuming the template configuration matched that of the original document).

- If a component set that is being reused contains an extra component that does not exist in the target document's template configuration, then this set will not be reused into the target document. The following warning will be displayed:



- It is not possible to reuse a component set from another document if the component set in target contains components that are reused or are locked for editing. The following warning will be displayed in this situation:



- Component sets cannot be reused into a non-matching component set (eg, attempt to reuse a 'Related Adverse Events' component set from another document into a 'Deaths' component set in target).
- A single component from a component set cannot be inserted/reused individually in the document if it was already inserted as part its set elsewhere in the document.

To reuse a component set 'freely' in the document as a new/ad hoc set from another document:

1. Place the cursor in an empty paragraph outside of a component.
2. Open the Component Status Report of the source document.
3. Locate the component set to be reused within the 'Not Modified' section.

**Note:** Component sets are displayed with both a set row along with individual component rows in the 'Not Modified' section only

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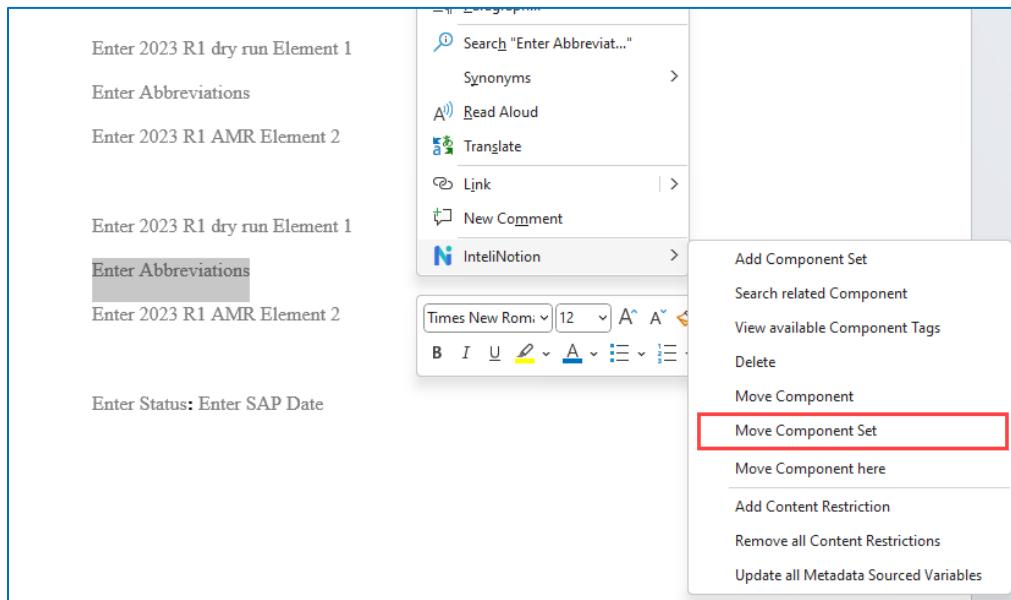
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4. Right-click on the component set's name. Insert it into the document by clicking either **Insert As Is**, **Insert As Is with Override** OR **Branch and Insert**.
5. Click 'Yes' when prompted and then the new set will be inserted into the document.

### 1.9.3 Moving a Component Set

To move an existing component set within the document, follow the steps listed below.

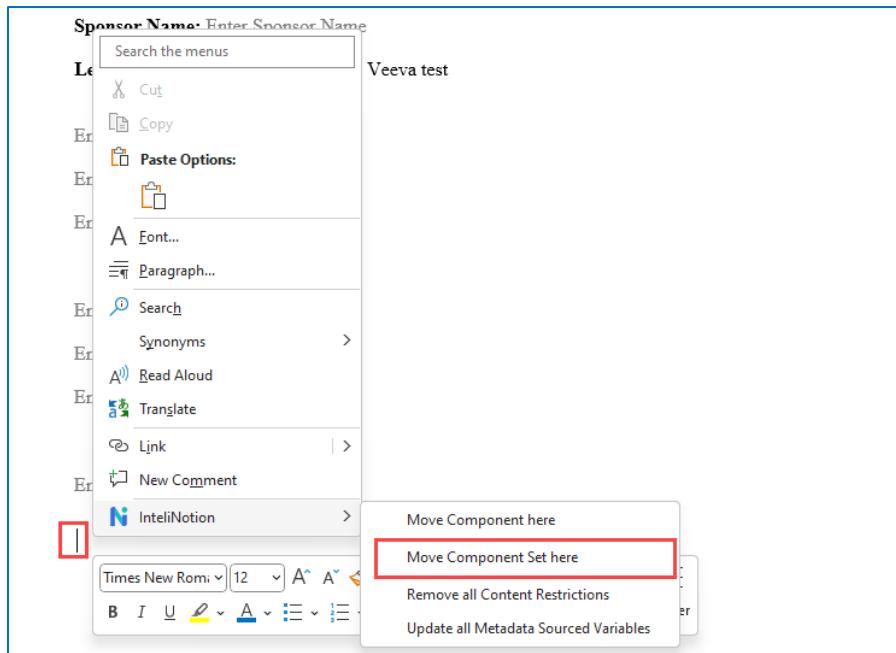
1. Right click on the component set to be moved, hover over **InteliNotion** and click on **Move Component Set**.



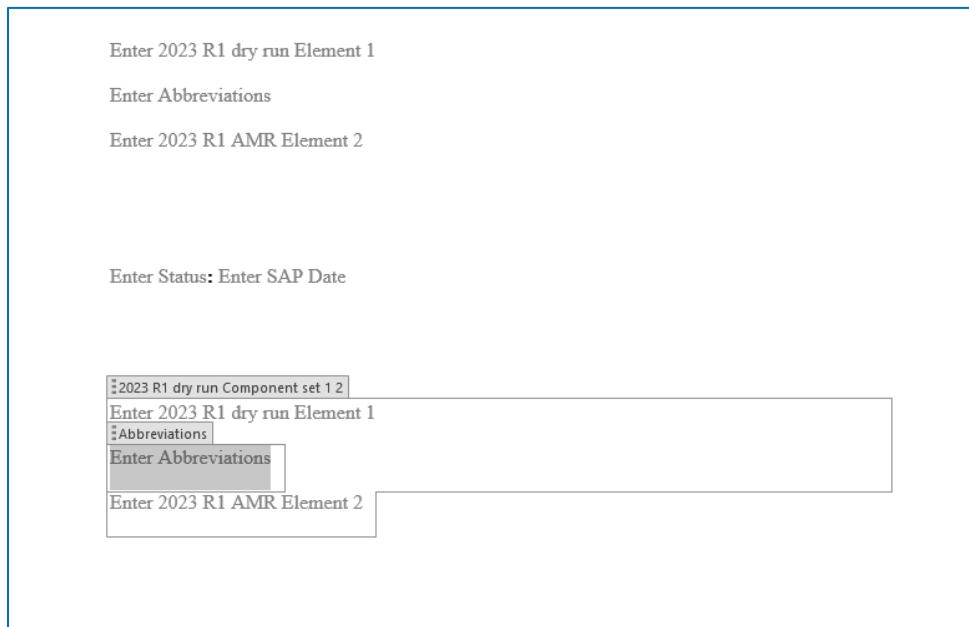
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2. Place the cursor in the desired new location, right click, hover over **InteliNotion** and click on **Move Component Set here**.



3. Component set will now display at the new location.

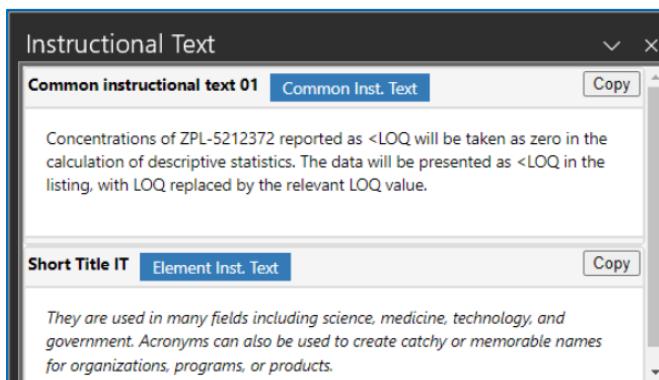


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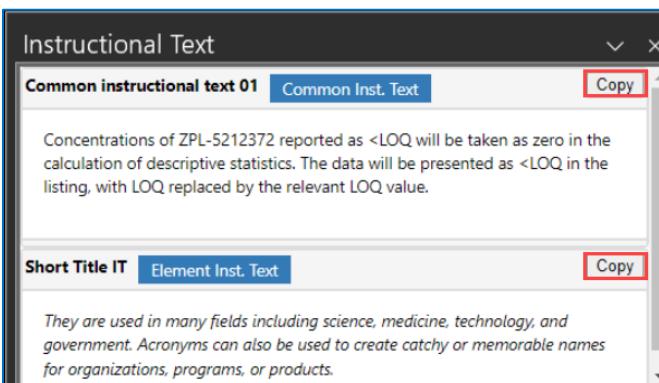
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## 1.10 ADDING CONTENT TO THE DOCUMENT: COPYING AND PASTING INSTRUCTIONAL TEXT

1. Click into a component's content control box and hover over the instructional text appearing in the **Instructional Text** pane and follow one of the two steps listed below:
  - Click on the **copy icon**  placed beside the instructional text name to copy the instructional text.
  - Pop-out the **Instructional Text** pane from the *InteliNotion Word App* by clicking on the **pop-out icon**  placed at the top-right corner of the **Instructional Text** pane.
2. The **Instructional Text** pane will pop-out on the screen.



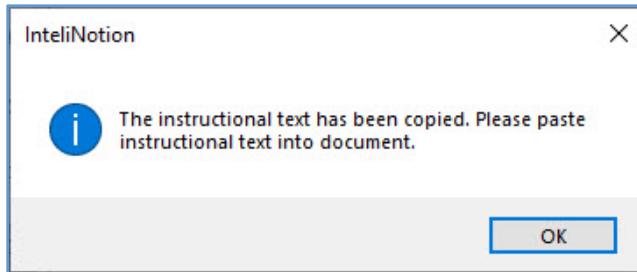
3. Click **Copy** at the top-right corner of the **Instructional Text** pane.



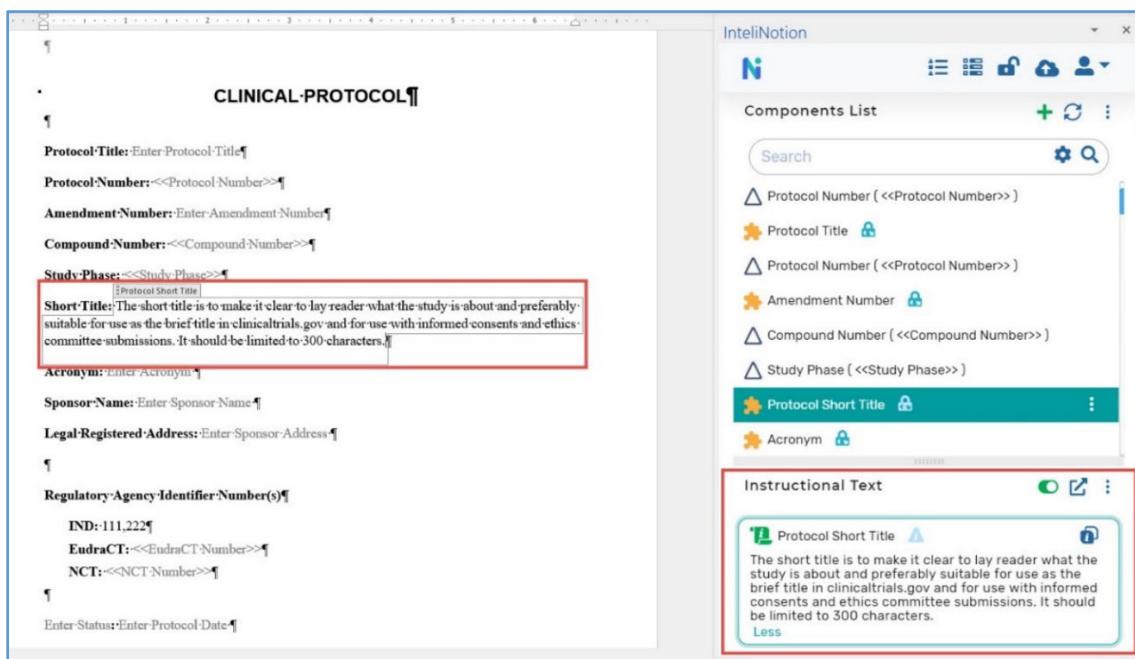
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4. The following message will appear on the screen. Click **OK**.



5. Click into the desired content control box and press **Ctrl + V** or right-click in the content control box and select **Paste Option-Keep Text Only** to paste the copied instructional text.



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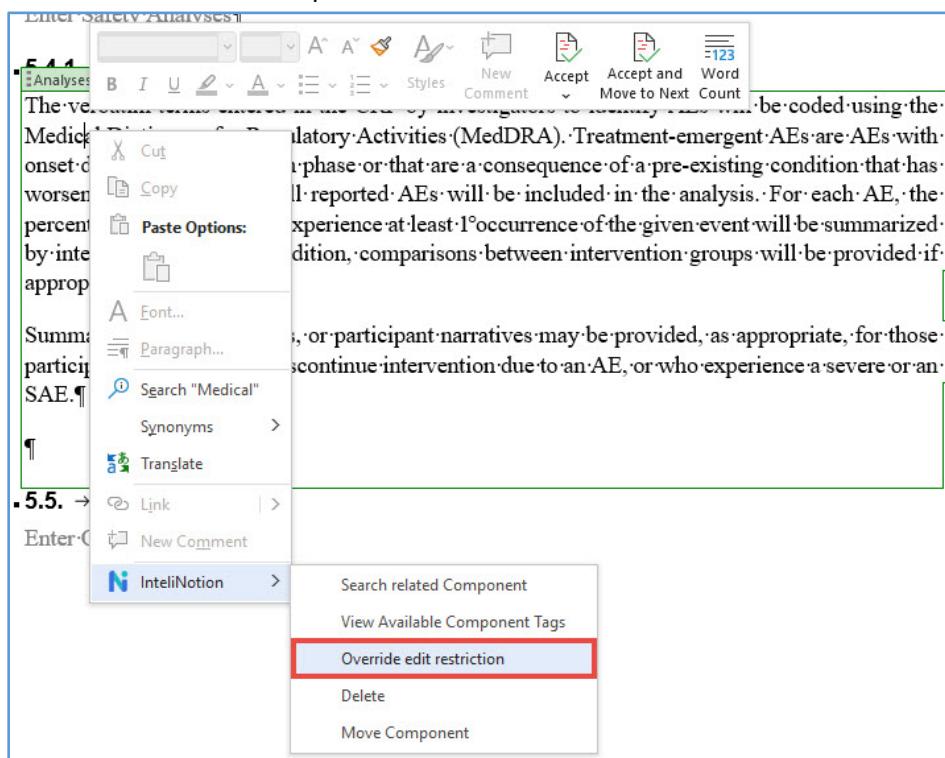
## 1.11 OVERRIDING AN AS IS REUSED COMPONENT OR LOCKED BASE COMPONENT

Certain components are configured to allow the user to override their editing restriction, including:

- A component that was **As Is** reused into a document during its generation (whether from a base document or library).
- A component in the template that had content added within it (referred to as a base component) and was then locked for editing.

To override the editing restriction for these types of components, follow the steps listed below.

1. Right-click on the **As Is** reused or locked base component in the open document, hover over the **InteliNotion** option and click **Override Edit Restriction**.



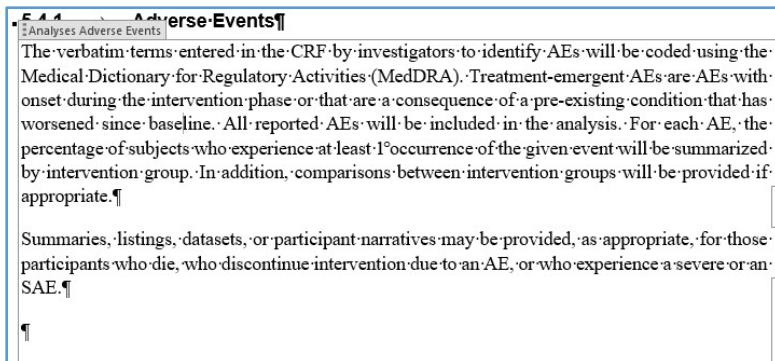
2. Enter a rationale for why the edit restriction needs to be overridden and click **Save**.



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3. After overriding its edit restriction, the component can now be edited, as needed.



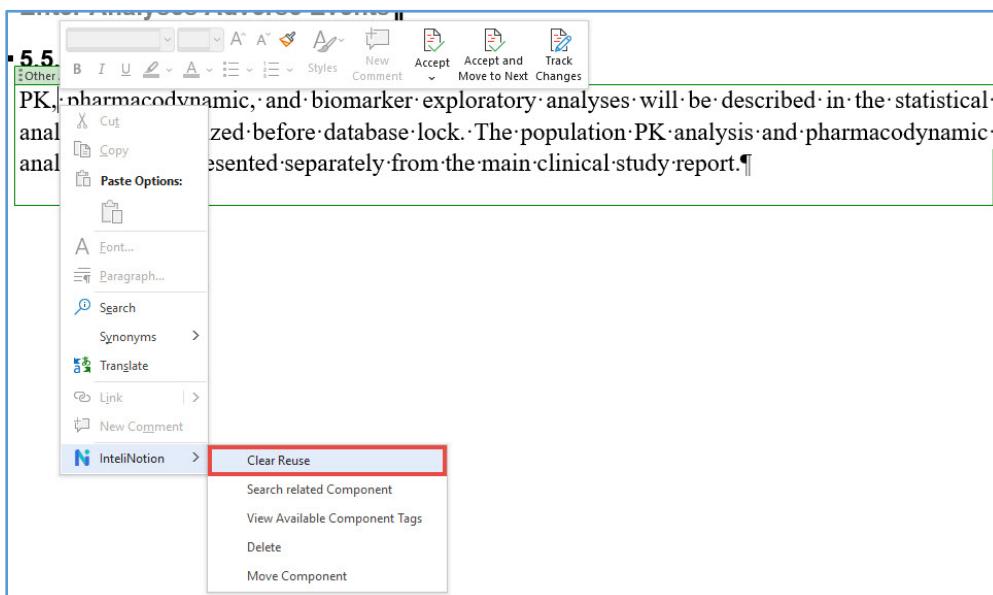
#### Notes

- After saving the document to the system, the component will show as checked out in the Components List, and the rationale is displayed in the relevant component's version history.
- When an **As Is** reused component's editing restriction is overridden, the newly created branch maintains a relationship with the reused source component.

## 1.12 REMOVING A REUSED COMPONENT

Any component that a user elects to **Reuse** while authoring – whether from a library, a search result, or an existing document located in the **Navigator** – can be removed from the document.

1. To remove a reused component, right-click on the component in the open document, hover over the **InteliNotion** option, and click **Clear Reuse**.

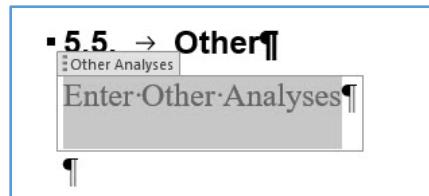


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2. The reused component will be removed, and an empty placeholder component is left in its place.

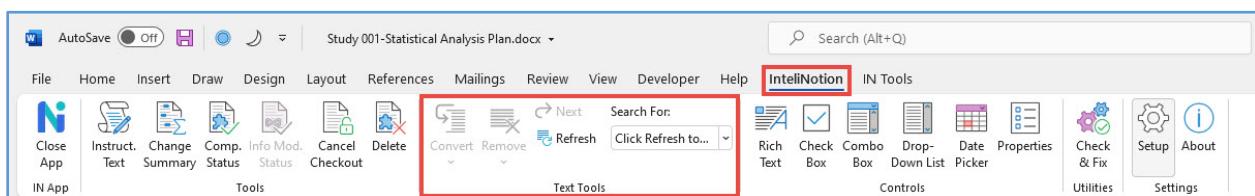


### **Notes**

- This action can be performed even if the document and component have been saved at least once after the initial reuse of the component.
- This action is available for variant documents for users with sufficient permissions.
- If a non-matching component has been reused (see [Section 1.5.2](#)), the empty placeholder will be for that component and not the original one that was replaced.

## **1.13 CONVERTING OR REMOVING STYLED TEXT**

The **InteliNotion ribbon** provides **Text Tools** to manage styled text within the document.



The following **Text Tools** are available for all users:

- **Search For** - The dropdown lists all the text styles (eg, **Heading 1**, **Heading 2**, **Strong**, etc.) applied to content within the document. Select the style to be searched for and then choose **Convert** or **Remove** to update the document accordingly.
- **Next** - This tool finds and highlights the next instance of content with the selected style.
- **Refresh** - This tool refreshes the **Search For** dropdown by adding new styles applied in the document and removing styles that have been removed from the document.
- **Convert** - This tool converts content with the selected style to *MS Word's Normal* style.
- **Convert All** - This tool converts all the content with the selected style to the *Normal* style in the document.
- **Remove** - This tool removes content with the selected content from the document.
- **Remove All** - This tool removes all the content with the selected style from the document.

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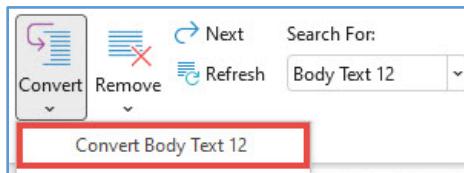
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## Notes

- If an expected style is not listed, click **Refresh**.
- Click **Refresh** to view all the styles applied in the document after generating/opening a document.
- When reusing components (component sets, legacy or repeating) from upstream documents, the system will only reuse the style from the header row for all the components. For example, if all the first-row cells have a different style, only the first cell of the first set style will be taken into consideration and will be applied to all the sets under that header. In the case of a hierarchical table set that has multiple headers, the style of each header only the first cell of the first set will be taken into consideration and will be applied to all the newly added set.

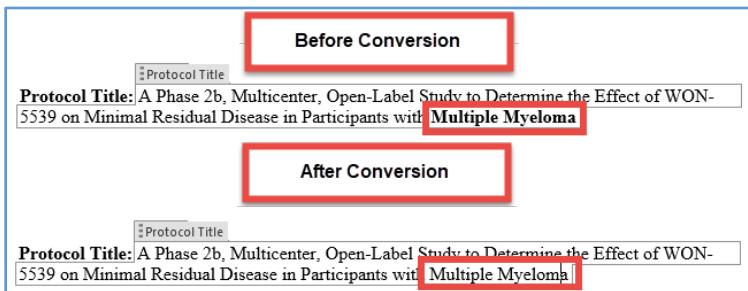
To convert content with a selected style, follow the steps listed below.

1. Under the **Convert** dropdown in the **InteliNotion** ribbon, click **Convert [Style name]**.

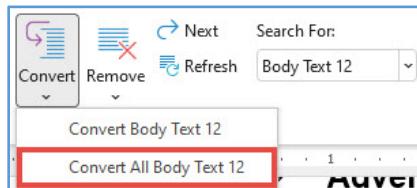


**Note** The **Style name** displayed in the **Convert [Style name]** action is the style selected in the **Search For** dropdown menu.

2. The highlighted or subsequently located content with the selected style will convert to the **Normal** style.



3. To convert all the content with a selected style, under the **Convert** dropdown in the **InteliNotion ribbon**, click **Convert All [Style name]**.



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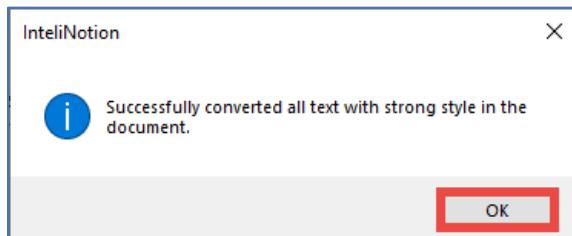
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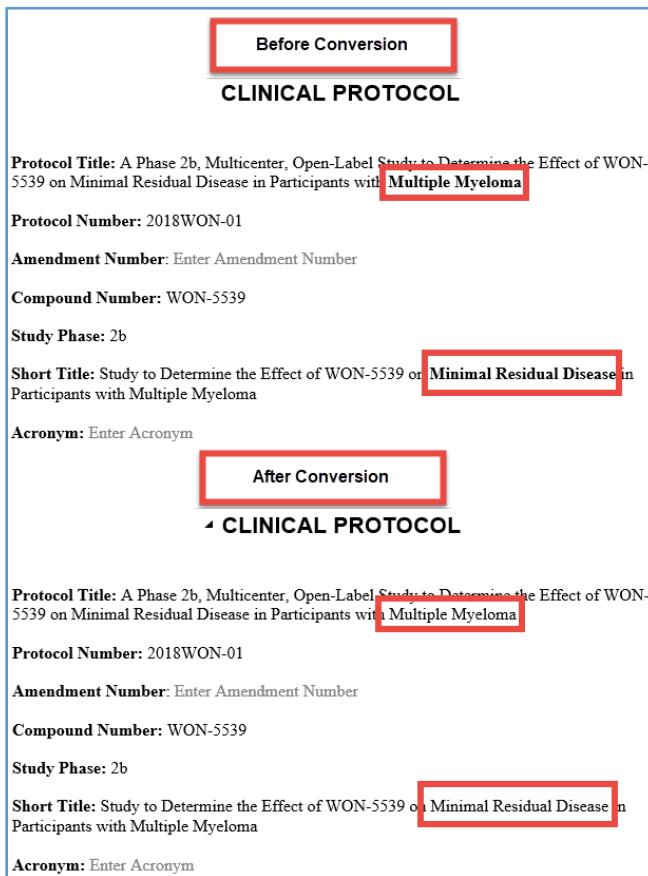
## Notes

- The **Style name** displayed in the **Convert [Style name]** action is the style selected in the **Search For** dropdown menu.
- If the content with the selected style is locked for editing in the document, or if the component with that content is checked out by another user, the content is not converted, and the system will notify the user accordingly.

4. The system will display a successfully converted message if the conversion is successful. Click **OK** to continue.



5. All the content with the selected style in the document will convert to **Normal** style.



**Before Conversion**

**CLINICAL PROTOCOL**

**Protocol Title:** A Phase 2b, Multicenter, Open-Label Study to Determine the Effect of WON-5539 on Minimal Residual Disease in Participants with **Multiple Myeloma**

**Protocol Number:** 2018WON-01

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2b

**Short Title:** Study to Determine the Effect of WON-5539 on **Minimal Residual Disease** in Participants with Multiple Myeloma

**Acronym:** Enter Acronym

**After Conversion**

**CLINICAL PROTOCOL**

**Protocol Title:** A Phase 2b, Multicenter, Open-Label Study to Determine the Effect of WON-5539 on Minimal Residual Disease in Participants with **Multiple Myeloma**

**Protocol Number:** 2018WON-01

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2b

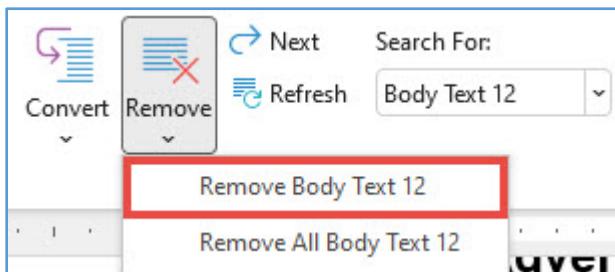
**Short Title:** Study to Determine the Effect of WON-5539 on **Minimal Residual Disease** in Participants with Multiple Myeloma

**Acronym:** Enter Acronym

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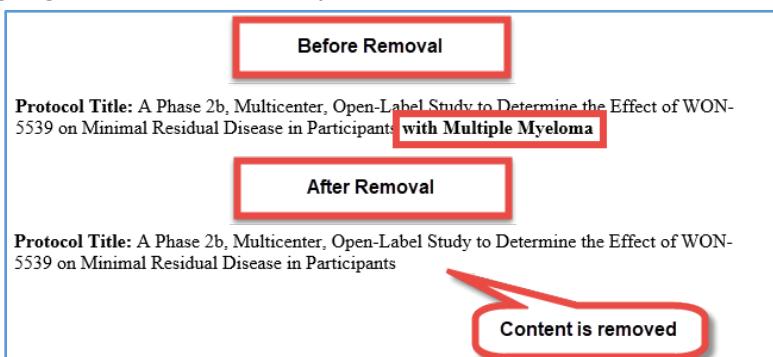
Confidential and proprietary to InteliNotion LLC. This is subject to non-disclosure or confidentiality agreement and must not be shared without prior written consent of InteliNotion LLC.

6. To remove content with a selected style, under the **Remove** dropdown in the **InteliNotion ribbon**, click on **[Style name]**.

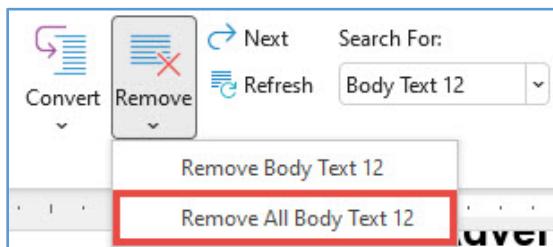


**Note:** The **Style name** displayed in the **Remove [Style name]** action is the style selected in the **Search For** dropdown.

7. The highlighted or subsequently located content with the selected style is removed:



8. To remove all the content with a selected style, under the **Remove** dropdown in the **InteliNotion ribbon**, click **Remove All [Style name]**.



#### Notes

- The **Style name** displayed in the **Remove All [Style name]** action is the style selected in the **Search For** dropdown.
- If the content with the selected style is locked for editing in the document, or if the component with that content is checked out by another user, the content is not removed, and the system will notify the user accordingly.

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9. The system will display a successfully removed message if the removal is successful. Click **OK** to continue.



10. All the content with the selected style in the document is removed.

**Before Removal**

**CLINICAL PROTOCOL**

**Protocol Title:** A Phase 2b, Multicenter, Open-Label Study to Determine the Effect of WON-5539 on Minimal Residual Disease in Participants **with Multiple Myeloma**

**Protocol Number:** 2018WON-01

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2b

**Short Title:** Study to Determine the Effect of WON-5539 **on Minimal Residual Disease** in Participants with Multiple Myeloma

**Acronym:** Enter Acronym

**After Removal**

**CLINICAL PROTOCOL**

**Protocol Title:** A Phase 2b, Multicenter, Open-Label Study to Determine the Effect of WON-5539 on Minimal Residual Disease in Participants

**Protocol Number:** 2018WON-01

**Amendment Number:** Enter Amendment Number

**Compound Number:** WON-5539

**Study Phase:** 2b

**Short Title:** Study to Determine the Effect of WON-5539 **in Participants with Multiple Myeloma**

**Acronym:** Enter Acronym

**Content is removed**

**Content is removed**

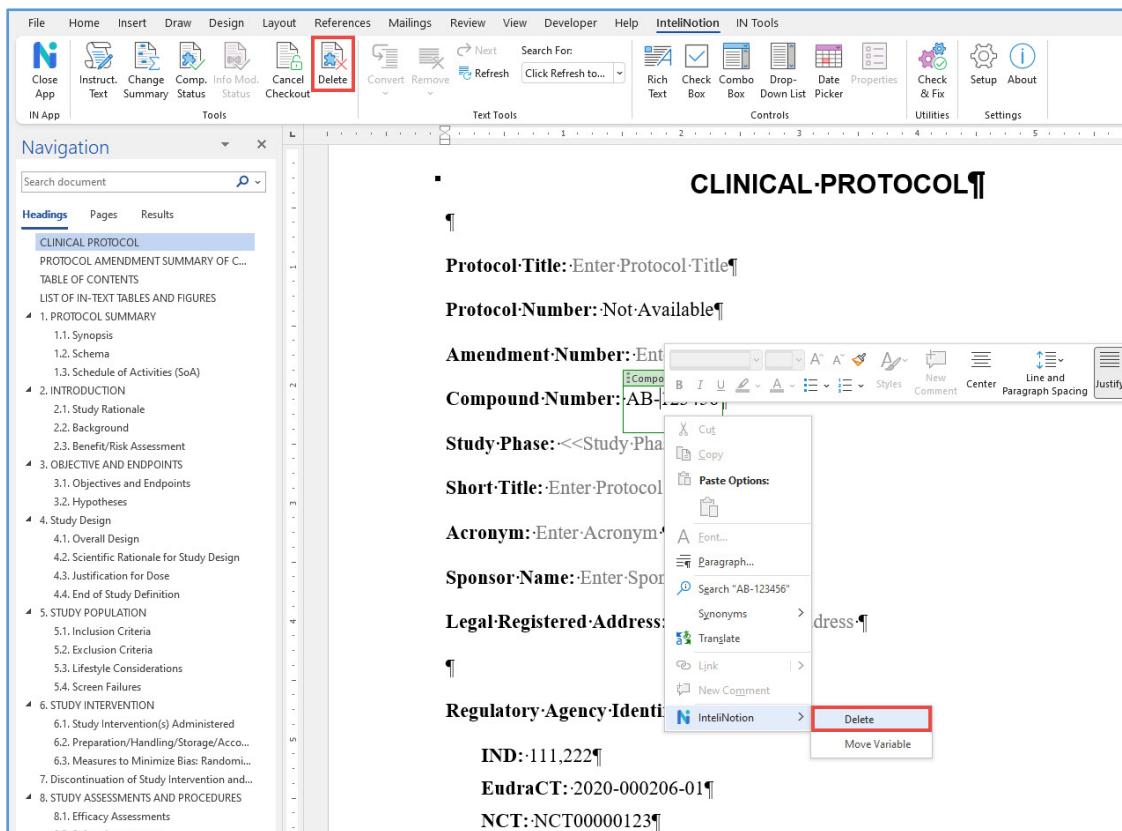
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## 1.14 DELETING A COMPONENT OR VARIABLE FROM THE DOCUMENT

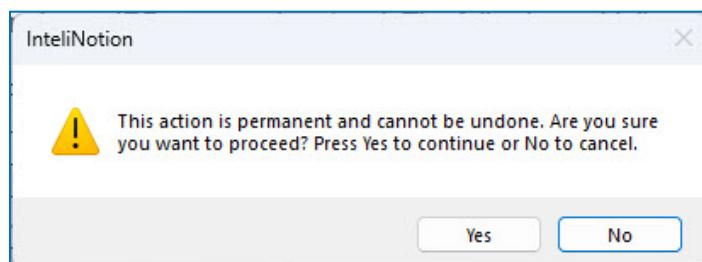
To delete a component or variable from the document, follow the steps listed below.

1. Right-click on it in the document, hover over the **InteliNotion** option and click **Delete**. Alternatively, the user can click on the component or variable and then click **Delete** in the Tools group of the **InteliNotion ribbon**.



**Note:** If a component or component set is not configured for delete, the option to delete will not appear on the *the InteliNotion* sub-menu

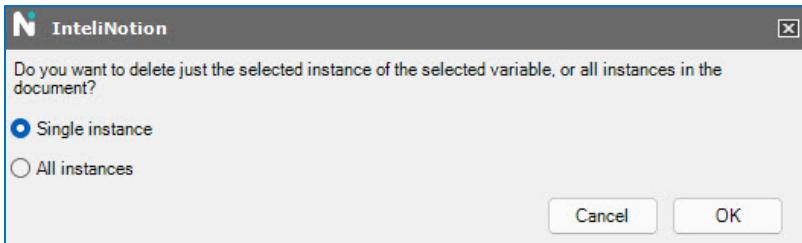
2. A pop-up window will appear warning the user that this action is permanent. Select **Yes** to delete, **No** to cancel.



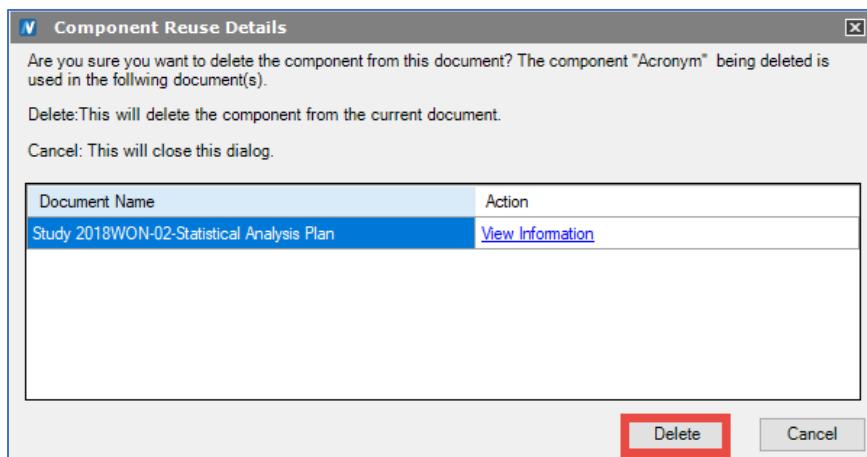
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- If the element is a variable, the following box will display. Select **Single instance** to delete only the single instance of the variable, or **All instances** to delete all instances of the variable within the document, as applicable.



3. If the component is reused in another document, the user is notified before deleting it from the current document. Click **Delete** to confirm deletion.



## Notes

- Components that are present in the generated document can only be deleted from the document if allowed per the info model or template policy. However, any new components that are added by the user while authoring (eg, a branched instance of an existing component in the document) can be deleted.
  - If a user does not have permission to delete a component from the system in its entirety, they will be notified of this fact when subsequently saving the document.
- If any components are configured in a parent-child type manner (eg, the parent component of study objective has a child component of endpoint), the parent component cannot be deleted until all child component(s) are deleted first. The document must also be saved after deleting the child component(s) before the parent component can be deleted.
- When deleting a variable, the user will be asked if just the single instance or all instances of the variable should be deleted.

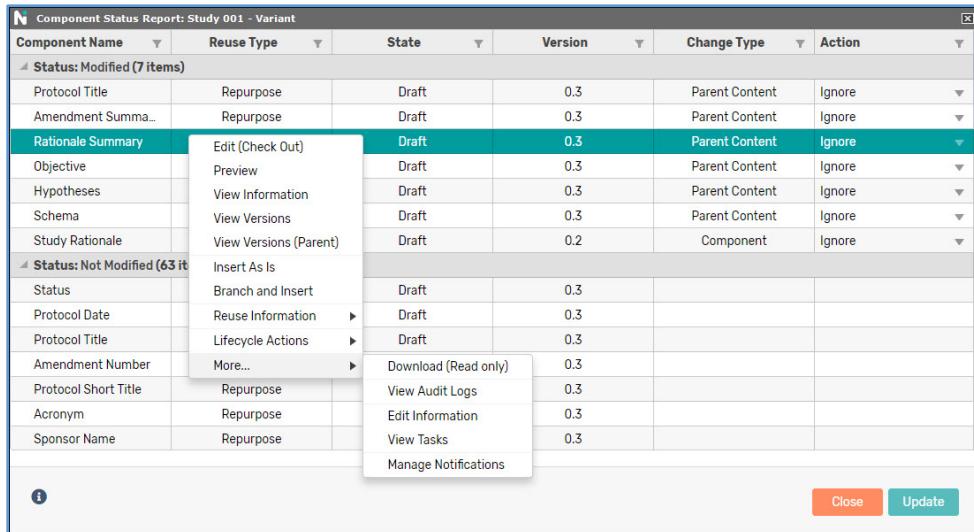
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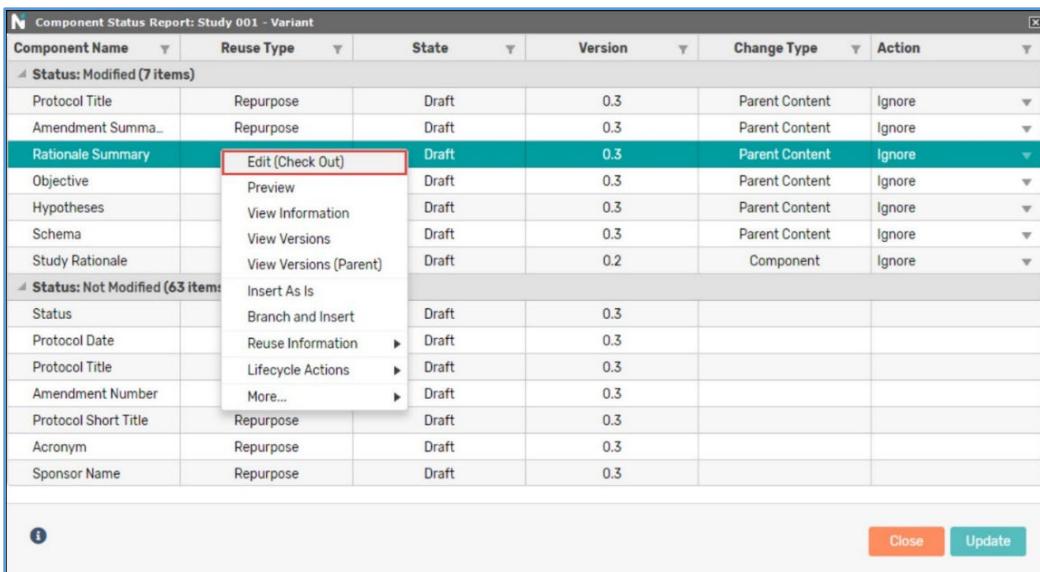
## 1.15 EDITING A DOCUMENT'S INDIVIDUAL COMPONENT

An individual component may be edited or updated independent of its source document, as needed, using the right-click menu in the document's Component Status Report.



The source document is the document **only** where the component is editable (ie, it was de novo or repurposed from another source). To edit the component individually, open the source document's Component Status Report via the *InteliNotion Word App* or *Web Console* following the steps mentioned in [Module 8, Section 2.3](#) and then right-click on the component to select **Edit (Check Out)**.

*InteliNotion Word App:*



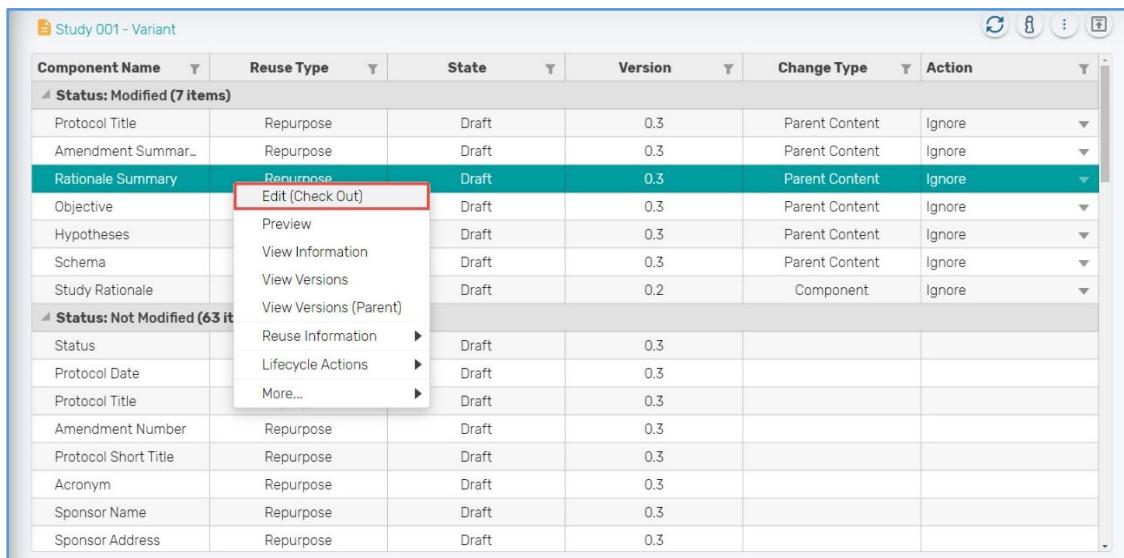
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**Note:** Component should be edited through the component status report; editing through the properties button on the ribbon is not possible.

*Web Console:*



Component Name	Reuse Type	State	Version	Change Type	Action
Protocol Title	Repurpose	Draft	0.3	Parent Content	Ignore
Amendment Summary	Repurpose	Draft	0.3	Parent Content	Ignore
Rationale Summary	Repurpose	Draft	0.3	Parent Content	Ignore
Objective	Preview	Draft	0.3	Parent Content	Ignore
Hypotheses	View Information	Draft	0.3	Parent Content	Ignore
Schema	View Versions	Draft	0.3	Parent Content	Ignore
Study Rationale	View Versions (Parent)	Draft	0.2	Component	Ignore
Status	Reuse Information	Draft	0.3		
Protocol Date	Lifecycle Actions	Draft	0.3		
Protocol Title	More...	Draft	0.3		
Amendment Number	Repurpose	Draft	0.3		
Protocol Short Title	Repurpose	Draft	0.3		
Acronym	Repurpose	Draft	0.3		
Sponsor Name	Repurpose	Draft	0.3		
Sponsor Address	Repurpose	Draft	0.3		

When finished editing the component, save and check it in following the same steps as described for saving a document in [Section 2](#).

If a component is reused as is from an upstream document or library, it cannot be edited via the Component Status Report for the document where it has been reused.

If the source document is checked out, the following operations are not allowed for an individual, editable component viewed in its **Component Status Report**:

- Edit (Check Out)
- Cancel Check Out
- Check In
- Edit Information
- Task/lifecycle actions such as completing or canceling a task

**Note:** If the source document is checked out, the component can **only** be edited via the document if it is opened for editing.

If any component is viewed via **Search**, **Dashboards**, or **Widgets** within the *InteliNotion Word App* or *Web Console*, the following operations are not allowed:

- Edit (Check out)
- Cancel Check out

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- Check in
- Edit Information
- Task/Lifecycle actions:
  - Complete Task
  - Cancel Task

## 1.16 SINGLE AUTHORIZING BEST PRACTICES

The following best practices should be considered during single authoring of a document or component:

- It is recommended to have no more than 5 documents open at one time. This includes both *InteliNotion* and non-*InteliNotion* documents.
- As mentioned in [Module 4 Section 1](#), the **Name** of the document must not exceed 100 characters.
- Tagging: reused components do not retain their tag. Reused components always 'inherit' the tag that was already applied to the downstream/target component - regardless if the source component had a tag applied to it or not.
- *MS Word's Track Changes* functionality can be used to track updates made to any editable areas of a component or document. However, the use of track changes is not supported within non-editable areas (eg, as-is reused component). If a locked component contains a comment that a user attempts to reply to or resolve during single authoring, when the document is saved, the system will warn the user that an 'invalid update' was made to the component, and it must be discarded before the save can be completed.
  - If an entire component is deleted when **Track Changes** are on, the content and the content control box are deleted, but the content reinserts in the document after it is saved. Users are required to remove the content manually. In addition, the deleted component will still display in the **Components List** until the deletion is accepted.
  - If an error message displays when the user attempts to **Accept All Changes**, a message will also display informing the user which **Track Changes** are in restricted components.

**Note:** When working in track changes if there is a change that will not be marked as a change the user will be alerted.

- When using **Track Changes**, do not configure **Restrict Editing** on the document to enforce the use of track changes, as this may result in a tracked change appearing where no content was modified (eg, placeholder text displayed within an empty component will appear as newly inserted after saving the document).

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- The *MS Word* undo/redo function is not supported when authoring a document and performing certain *InteliNotion* actions. These include the actions listed in the table below:

InteliNotion Action	MS Word Undo/Redo Supported	Alternate InteliNotion Action
<b>Reuse component from the InteliNotion Word App (Search, Library, Navigator)</b>	✗	Use right-click <b>Clear Reuse</b> option from sub-menu
<b>Add repeating element/component</b>	✓	NA
<b>Insert variable</b>	✓	NA
<b>Accept updated version of reused component via Component Status Report</b>	✓	NA
<b>Move component here</b>	✓	NA
<b>Override edit restriction</b>	✗	None
<b>Delete component</b>	✗	Admin-type user can reinsert the component (it will not contain any content)
<b>Delete variable</b>	✗	Reinsert the variable
<b>Save or Save &amp; Check In</b>	✗	Revert prior version if needed

**Notes:**

- Undo/redo of *InteliNotion* actions is no longer permitted after the document or component is saved. If a partial undo action is completed, this may lead to the component and/or document becoming corrupted.
- Undo/redo of typical *MS Word* functions (eg, copy/paste, type text) will work as expected.

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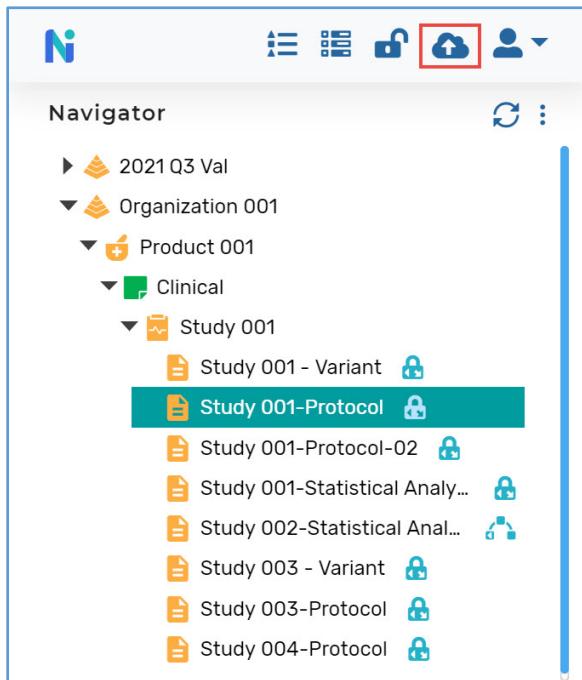
## 2. SAVING AND CHECKING IN A DOCUMENT

### 2.1 SAVING AND CHECKING IN

A document should be saved to the system periodically during authoring to ensure that any edits made to the document and/or components are uploaded and versioned accordingly. The user can either save all changes and leave the document open for additional editing or save all changes and check in the document along with any edited components, which closes the document and ends editing.

**Note:** Do not use *MS Word's* **Save** option but instead save to the system (ie, cloud) as described below. If an attempt is made to save to another location, a warning message will appear to notify the user that the document may no longer be available to be saved to the cloud.

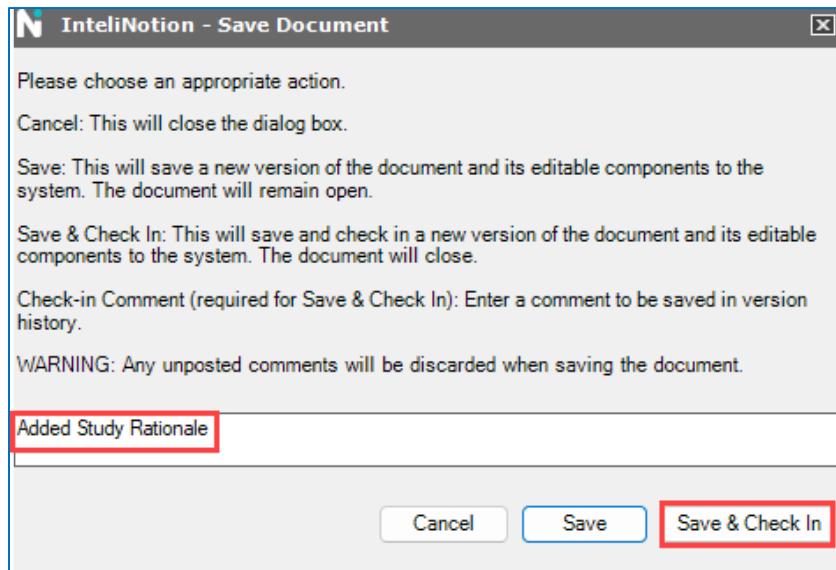
1. Click on the **save icon**  in the *InteliNotion Word App*.



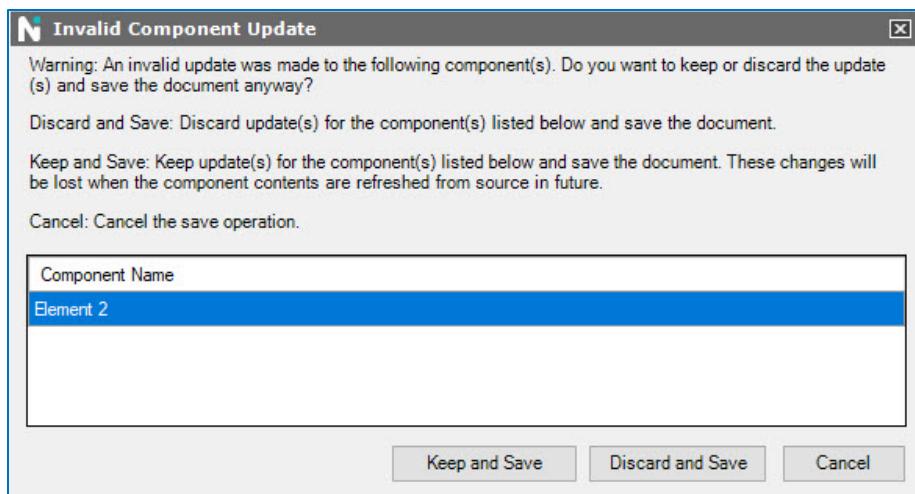
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2. In the pop-up window, click **Save & Check In** to save the document and check it in immediately. The user must enter a reason/comment in the area provided to be saved with the version history.



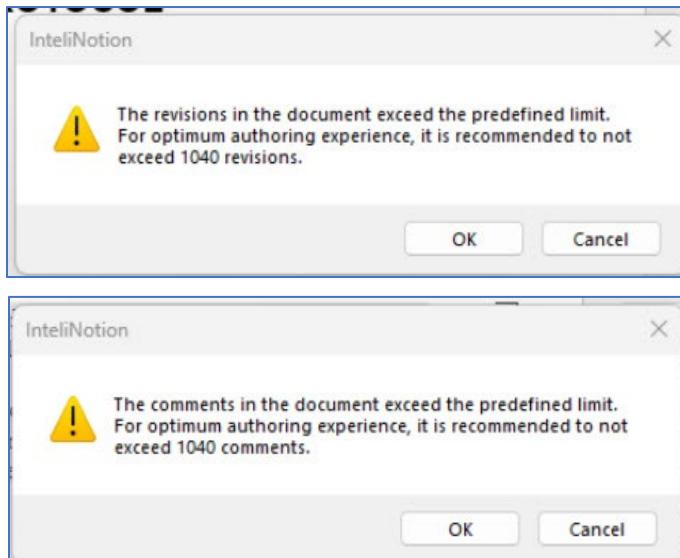
- If the document contains a component that is locked for editing, but the system detects some type of change was made inside its content (eg, a table caption number was refreshed), the following error message will display. Click **Keep and Save**, **Discard and Save** or **Cancel**, as applicable.



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- If the configured number of revisions or comments allowed is exceeded, one of the following messages will display.



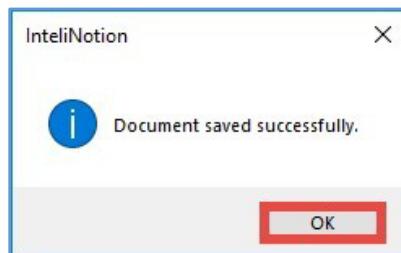
**Notes:**

- The user can use the **Save** option to just save the edits made to the document and then check it in later or use the **Cancel** option to discard saving and return to the document.
- When saving and checking in a document, only the components that have been modified in that authoring session will be up versioned.
- See [Module 11](#) of this User Guide for instructions on how to configure the option to save to an external repository.

3. While the document is being saved, a progress bar will appear on the screen.



4. After the document is saved, the following message will appear on the screen. Click **OK** to continue.



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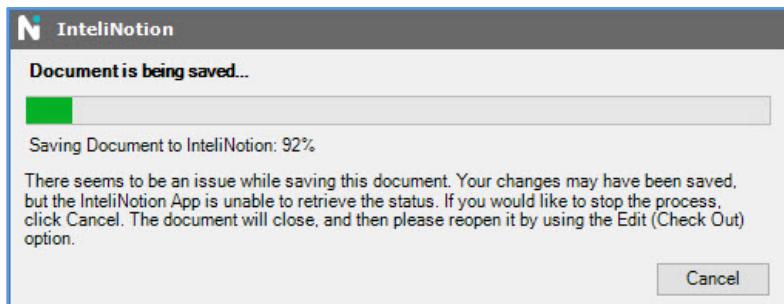
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**Notes:**

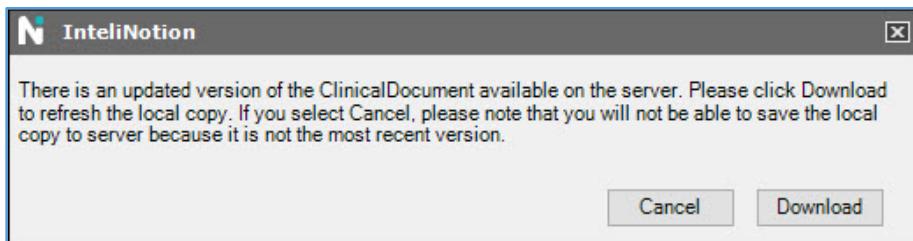
- If the user selected the **Save** option, the document will remain open in *MS Word*. If the user selected the **Save & Check In** option, the document will close.
- If the user attempts to close *MS Word* without first saving the document to the system, he/she will be prompted to save changes locally. If possible, click **Cancel** and save the document to the system following the steps above. If saving to the system is not possible (eg no internet), click **Save** to save the changes locally in the user's local data folder. The next time the user opens the document (ie, **Edit (Checkout)**), the locally saved copy will be opened from the user's data folder.
- If the user inadvertently saves the document to another online location, the document can no longer be saved to the cloud, and a warning message will display accordingly.

### 2.1.1 Troubleshooting if Save was Not Successful

1. If there is an error during the document save process, a **Cancel** button will appear after ~2 minutes in the save progress bar, allowing the user to cancel the operation.



2. Click **Cancel**, then **Edit (Check Out)** the document again via the *Web Console* or *InteliNotion Word App*. The user will be prompted to complete one of the following two actions:
  - **Download:** Click this option to update the local copy with the latest version available on the server.
  - **Cancel:** Click this option to cancel the operation and close the document.



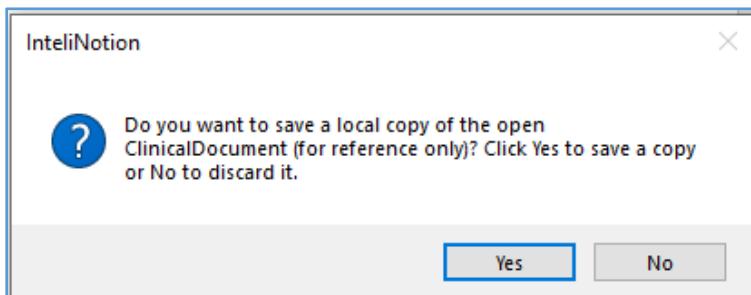
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**Note:** If the user selects **Cancel**, the document will remain open; however, it cannot be saved back to the system.

3. After the user clicks **Download**, either:

- The document will be refreshed, and the user can immediately start editing it, and then save it to the system, as needed.
- The user will be prompted to complete one of the following two actions:
  - **Yes:** If selected, the user will be prompted to select a location to save a local copy of the document so that it can be used as a reference to check additional content changes that may not have been saved to the server. After the local copy is saved, the latest version from the server will open and then the user can start editing it.
  - **No:** If selected, the latest version from the server will open and the user can start editing it. No local copy of the document is saved for reference.



## 2.2 CHECKING IN VIA THE WORD APP

If a document is checked out to someone, it will display a **lock icon**  beside its name. If the user hovers over the document name, the user's name who has the file checked out will display.

 = Document (or other business object) is checked out to the current user

 = Document (or other business object) is checked out to someone else

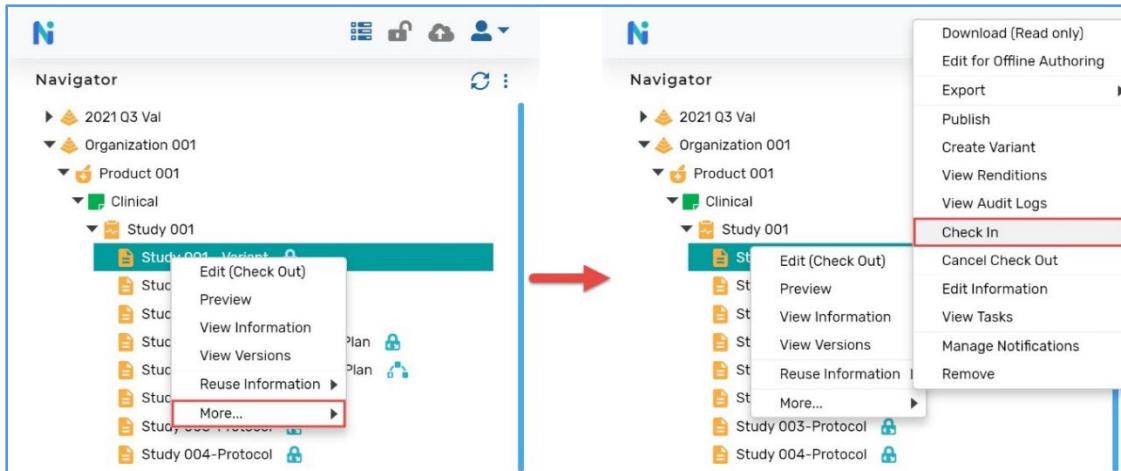
If the user does not have the document open, but still has it checked out, the user can check it in without having to open the document first.

**Note:** This **Check In** option is only available via the *InteliNotion Word App*.

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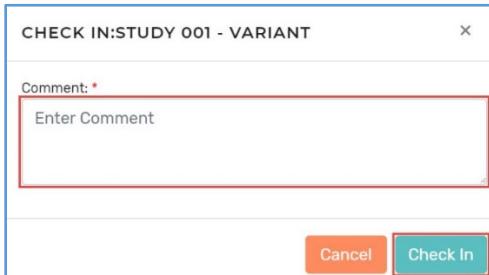
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- To check in a document, right-click on its name, and under **More**, click **Check In**.



**Note:** Checking in a document creates a new version of the document and any edited components.

- Enter a comment in the **Comment Box** that appears on the screen, and click **Check In**.

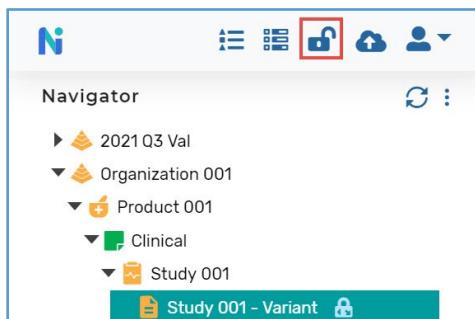


- The document will successfully check in.

## 2.3 CANCELING A DOCUMENT CHECKOUT

Canceling checkout on a document can be done in the *InteliNotion Word App* in a few ways:

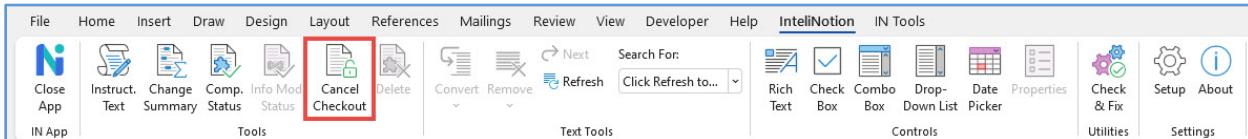
- Option 1: Click on the **Cancel Checkout icon**  in the *InteliNotion Word App* pane.



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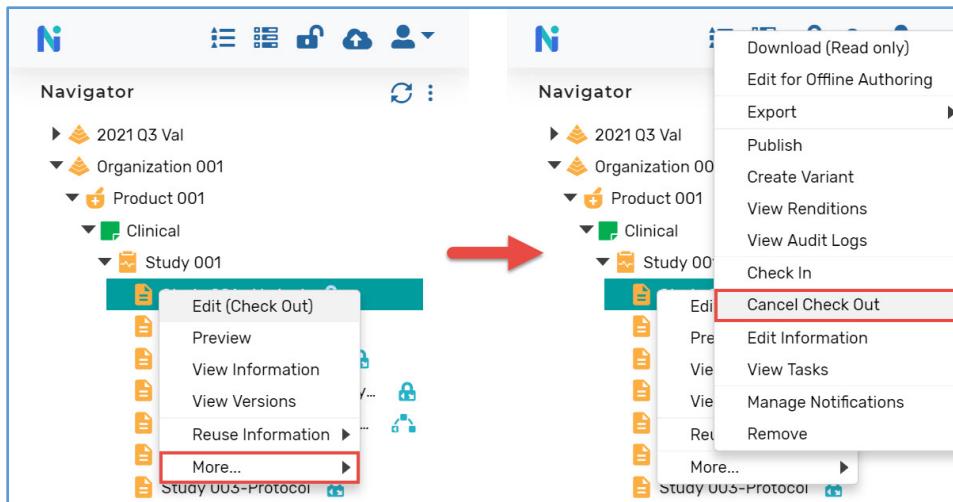
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- Option 2: Click on the **Cancel Checkout icon** (🔒) in the InteliNotion ribbon.



**Note:** It is recommended for an individual user to cancel checkout on his/her document or a component via the *InteliNotion Word App*. If checkout is canceled via the *Web Console*, any changes saved locally to the user's Data folder will be lost if/when the document/component is subsequently edited/checked out again and then saved (this is regardless of who cancels checkout, eg, the individual user or an admin). The **only** way to view/recover these local changes after canceling checkout via the *Web Console* would be to access the user's local copy and then take appropriate steps as needed.

- Option 3: Right-click on the document's name and under **More**, click **Cancel Check Out**.

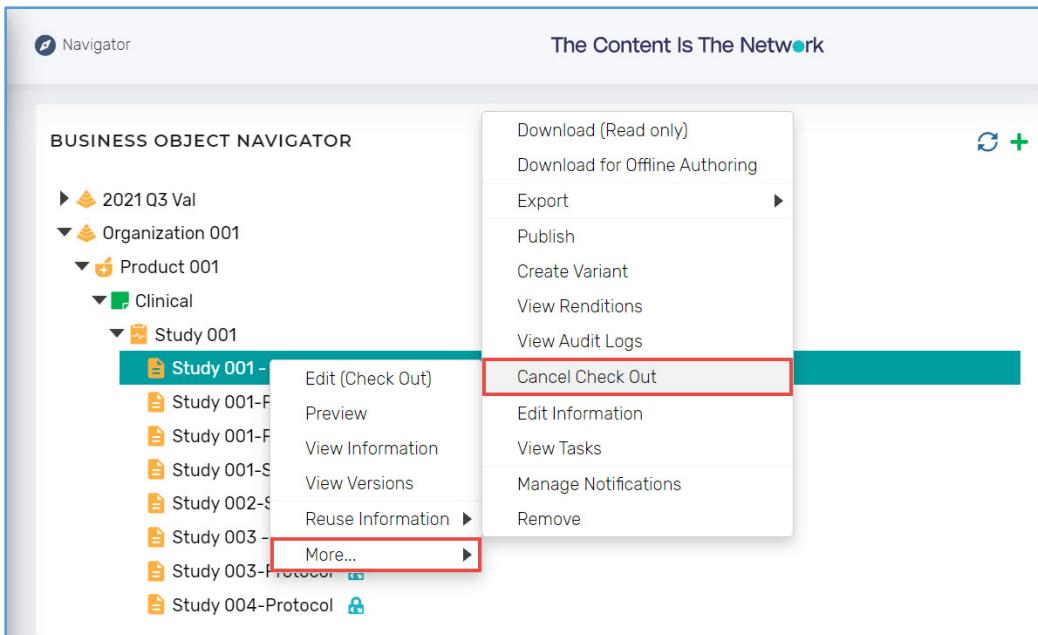


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Cancelling checkout on a document can be done in the *Web Console* as follows:

- Right-click on the document name and under **More**, click **Cancel checkout**.



**Notes:** Cancelling checkout does not create a new version of the document but instead restores it to its previous version. However, if the document was saved while checked out, it will restore to the saved version and not the original version before the document was checked out.

### 2.3.1 Bulk Cancel Document Checkout

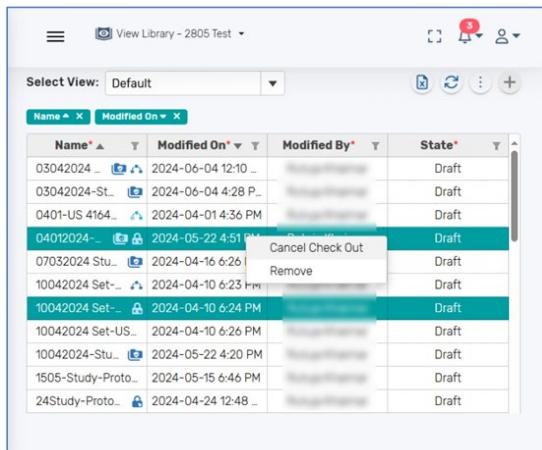
Once a non-managed library is configured by an administrator or user with non-managed library functional permission settings, then multiple documents can be bulk canceled in single authoring, co-authoring, or collaborative review.

1. Multiple documents are selected from the non-managed library datasheet view, then the user will right-click to bulk cancel.

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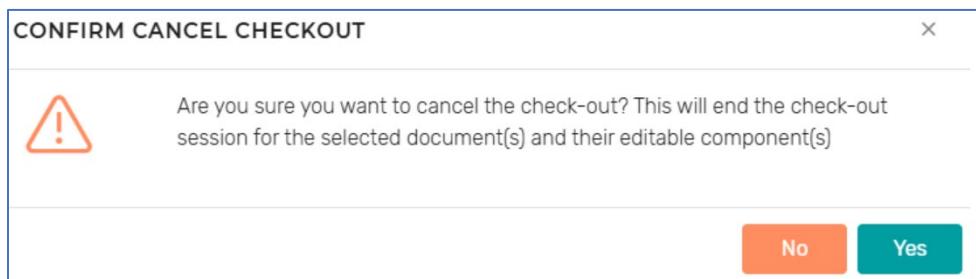
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- a. In single authoring, the **Cancel Check Out** option can be selected.

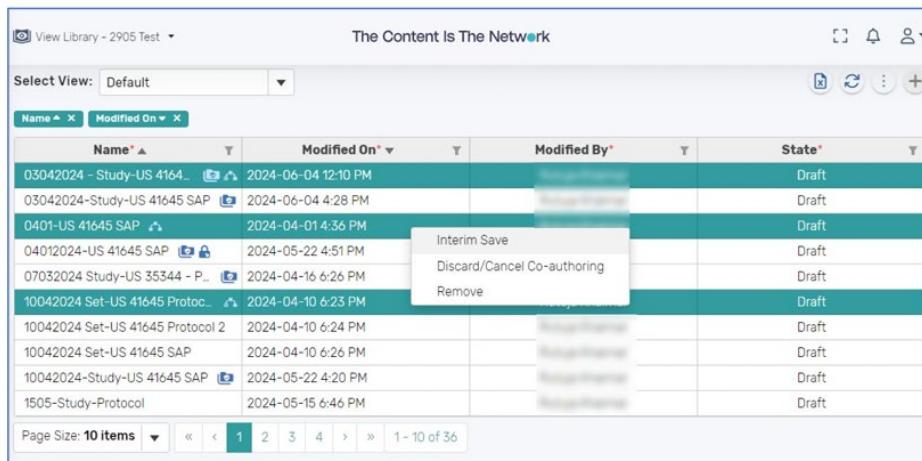


Name*	Modified On*	Modified By*	State*
03042024 ...	2024-06-04 12:10 ...		Draft
03042024-St... 0401-US 4164...	2024-06-04 4:28 P...		Draft
0401-US 4164...	2024-04-01 4:36 PM		Draft
04012024-... 07032024 Stu...	2024-05-22 4:51 PM		Draft
10042024 Set-...	2024-04-16 6:26 PM		Remove
10042024 Set-...	2024-04-10 6:24 PM		Draft
10042024 Set-US...	2024-04-10 6:26 PM		Draft
10042024-Stu...	2024-05-22 4:20 PM		Draft
1505-Study-Proto...	2024-05-15 6:46 PM		Draft
24Study-Proto...	2024-04-24 12:48 ...		Draft

- b. A popup will display asking the user to confirm cancel checkout of the documents in co-authoring. Click **Yes** to proceed.



- c. In co-authoring, the **Discard/Cancel Co-authoring** option can be selected.

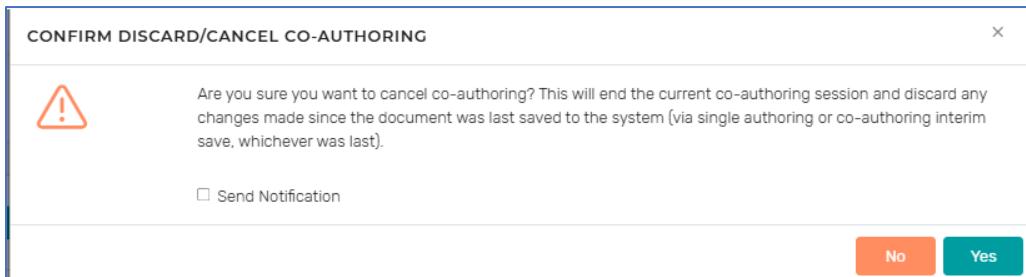


Name*	Modified On*	Modified By*	State*
03042024 - Study-US 41645 SAP	2024-06-04 12:10 PM		Draft
03042024-Study-US 41645 SAP	2024-06-04 4:28 PM		Draft
0401-US 41645 SAP	2024-04-01 4:36 PM		Draft
04012024-US 41645 SAP	2024-05-22 4:51 PM		Draft
07032024 Study-US 35344 - P...	2024-04-16 6:26 PM		Draft
10042024 Set-US 41645 Protoc...	2024-04-10 6:23 PM		Remove
10042024 Set-US 41645 Protocol	2024-04-10 6:24 PM		Draft
10042024 Set-US 41645 SAP	2024-04-10 6:26 PM		Draft
10042024-Study-US 41645 SAP	2024-05-22 4:20 PM		Draft
1505-Study-Protocol	2024-05-15 6:46 PM		Draft

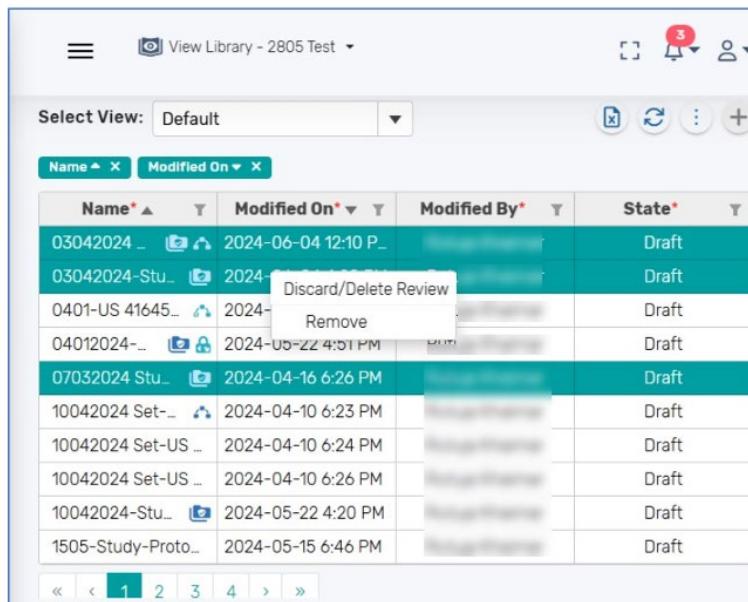
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- d. A popup will display asking the user to confirm discard/cancel checkout of the documents in co-authoring. Click **Yes** to proceed.



- e. In collaborative review, the **Discard/Delete Review** option can be selected.



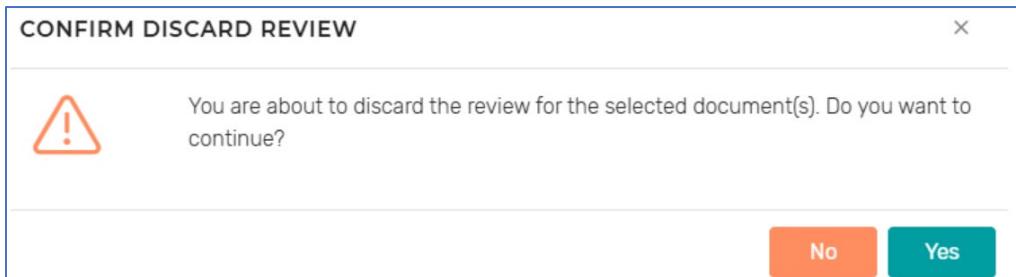
The screenshot shows a 'View Library - 2805 Test' interface. A table lists documents with columns: Name\*, Modified On\*, Modified By\*, and State\*. One row, '07032024 Stu...', has a context menu open over it. The menu options are: Discard/Delete Review (highlighted), Remove, and Print. The table data is as follows:

Name*	Modified On*	Modified By*	State*
03042024 ...	2024-06-04 12:10 PM	[REDACTED]	Draft
03042024-Stu...	2024-06-04 12:10 PM	[REDACTED]	Draft
0401-US 41645...	2024-05-22 4:51 PM	[REDACTED]	Draft
04012024-...	2024-05-22 4:51 PM	[REDACTED]	Draft
07032024 Stu...	2024-04-16 6:26 PM	[REDACTED]	Draft
10042024 Set-...	2024-04-10 6:23 PM	[REDACTED]	Draft
10042024 Set-US ...	2024-04-10 6:24 PM	[REDACTED]	Draft
10042024 Set-US ...	2024-04-10 6:26 PM	[REDACTED]	Draft
10042024-Stu...	2024-05-22 4:20 PM	[REDACTED]	Draft
1505-Study-Proto...	2024-05-15 6:46 PM	[REDACTED]	Draft

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- f. A popup will display asking the user to confirm discard checkout of the documents in co-authoring. Click **Yes** to proceed.



- g. After performing the action, the user will get an email notification informing documents with their status (eg, successfully canceled or discarded). If there was an issue, the email will inform with the document name, status, and reason the document failed to cancel or discard (eg, document no longer checked out, user doesn't have permission rights)

**Note:**

- Mixed document types (eg, some documents checked out in single authoring, and others checked out in co-authoring) will not have the ability to cancel, discard, or delete. Only the 'Remove' option will be displayed.
- Only users with C-R-U-D-O or relevant override configured permissions are allowed to cancel checkout of other user's documents.

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### 3. CO-AUTHORING A DOCUMENT

The co-authoring functionality allows multiple users to work on the same document simultaneously.

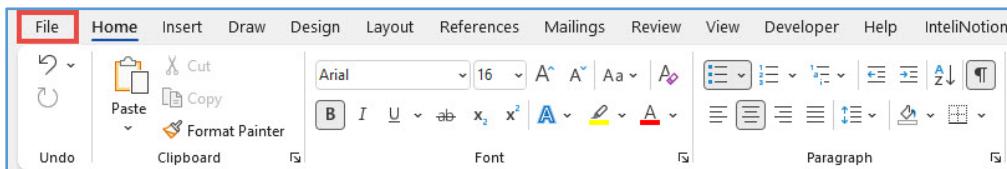
#### 3.1 CO-AUTHORING PREREQUISITES

Ensure that the **AutoSave** option is enabled in *MS Word* and follow the steps listed below.

**Notes:**

- This option may not be available due to one of the following reasons: 1) an older version of *MS Word* is being used; 2) AutoSave is not allowed per corporate policy; or 3) AutoSave is not turned on.
- If using an unsupported version of *MS Word*, the user will receive an error message, and the InteliNotion document will not open.

1. Click on **File** in the toolbar.

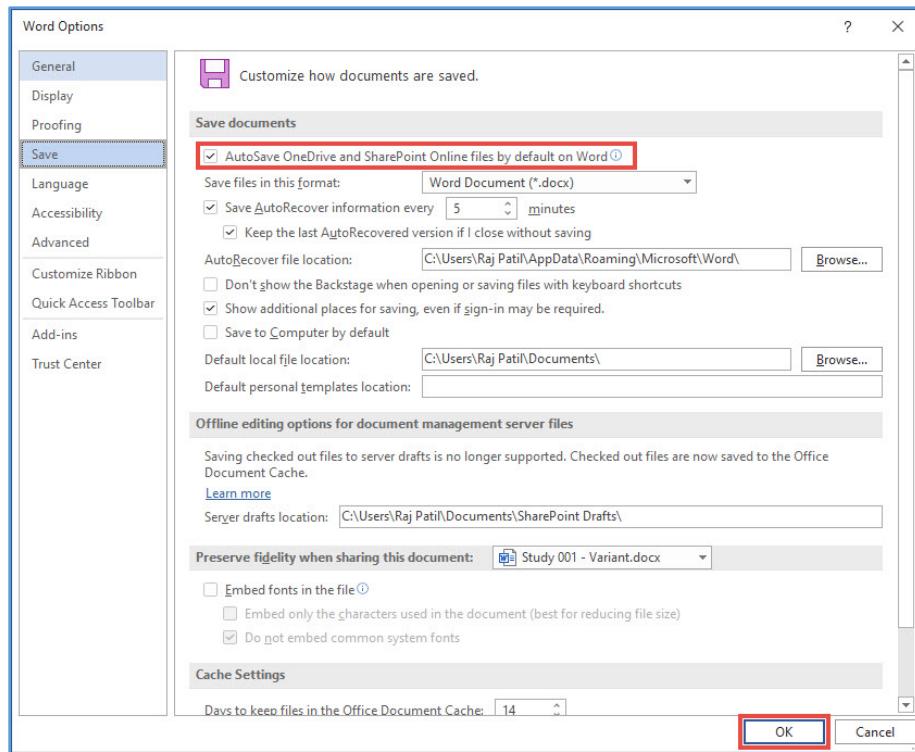


2. Click on **Options** from the left-hand navigation pane.

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3. The **Word Options** window will appear on the screen. Click on the **Save** option and check the **AutoSave OneDrive and SharePoint Online files by default on Word** option, if not checked, and click **Ok**.



#### **Notes:**

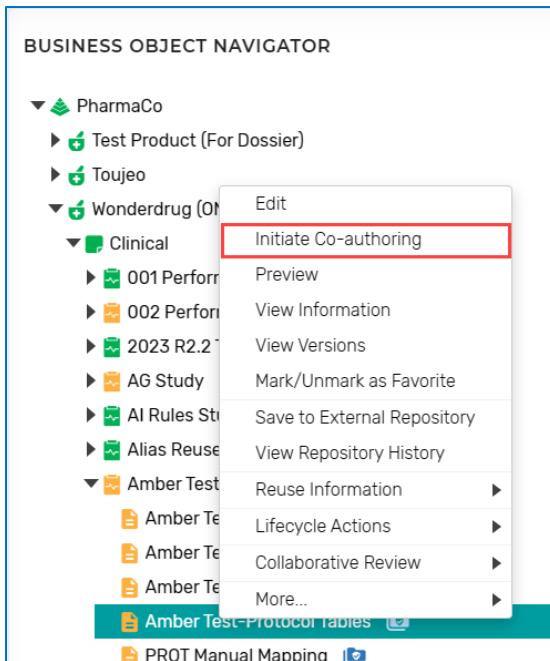
- If the auto-save option cannot be found or turned on, follow the steps in [Section 3.7](#).
- See [Module 4 Section 1](#) for details on how to generate a document before initiating coauthoring.
- See [Section 1](#) for details on how to edit the document before initiating co-authoring (**not mandatory**).
- See [Section 2](#) for details on how to save and check in the document if it is opened for editing before initiating co-authoring.
- Exporting a document is not currently supported while in co-authoring.
- If the document is over 4MB, it must have content controls to be eligible for co-authoring.

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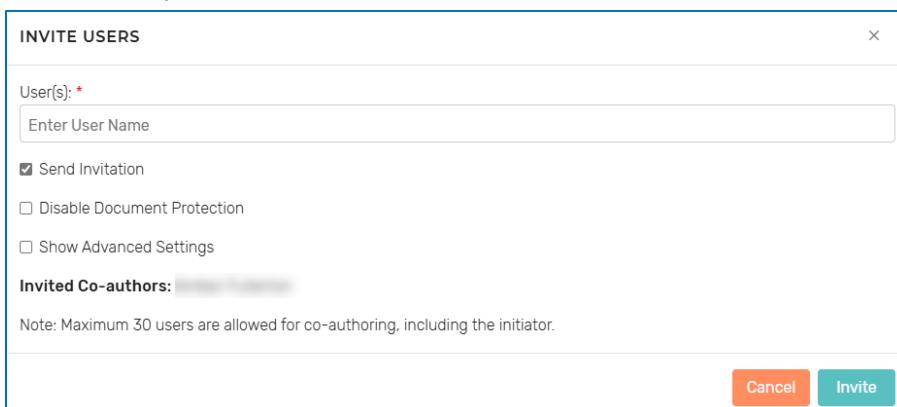
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## 3.2 INITIATING CO-AUTHORING

1. In the **Navigator**, right-click on the document name, and click **Initiate Co-authoring**.



2. The **Invite Users** window will appear on the screen with the co-authoring initiator's name added by default to the **Invited Co-Authors**.



### **Notes:**

- Co-authoring initiators can only invite users with permitted access permission to view a document or task in tandem. All invited users must have at least Read permission so that the co-author can confirm co-authoring was initiated. If any do not have access, a warning message displays listing the user(s) without document access. Here,

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the document or task will still be initiated for co-authoring for the remaining users, but the user without permission will not have access to the document. However, if none of the invited users have Read permissions, the co-authoring session is aborted and an error message displays.

- Document Protection functions are available through *InteliNotion*. For detailed instructions on the Document Protection configuration options, please refer to [Module 9 Section 3](#).
- If the document has previously been in co-authoring, the names of the previous co-authors will be automatically pre-populated. Additional co-authors can be added, or the pre-populated co-authors can be removed as applicable.

**INVITE USERS**

User(s): \*

Send Invitation  
 Disable Document Protection  
 Show Advanced Settings

**Invited Co-authors:**

Notes:

1. The user(s) who were invited to the previous co-authoring session for this document will be pre-populated.  
2. Maximum 30 users are allowed for co-authoring, including the initiator.

**Cancel** **Invite**

**Note:** The note informing user that previous co-authors will be pre-populated will only display if the document has previously been in co-authoring.

3. Enter the other users' names that will be part of the co-authoring session.

**INVITE USERS**

User(s): \*

Send Invitation  
 Disable Document Protection  
 Show Advanced Settings

**Invited Co-authors:**

Note: Maximum 30 users are allowed for co-authoring, including the initiator.

**Cancel** **Invite**

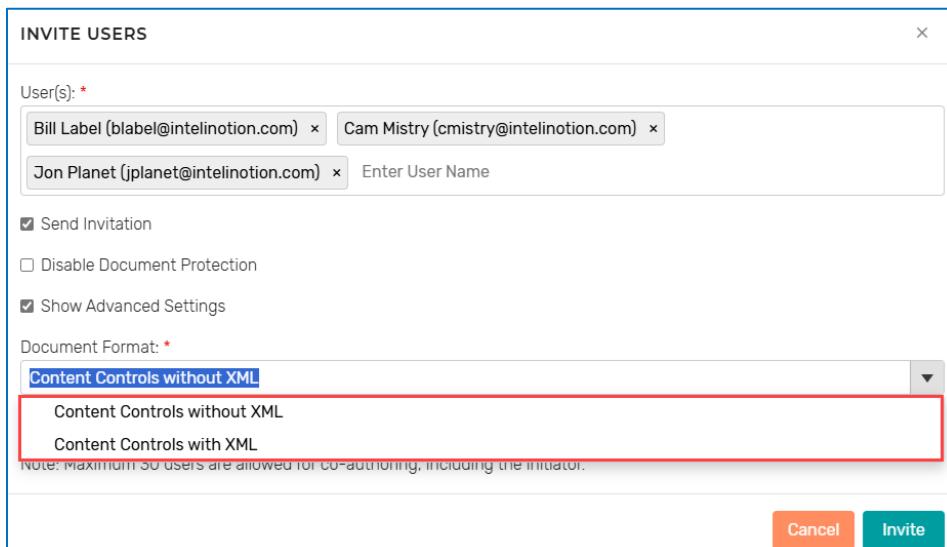
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## Notes

- The maximum number of users allowed for co-authoring is configurable and can be set by the system administrator.
- When a user creates a new task for a document, he/she shall be able to specify if a co-authoring session will be automatically initiated for the same users who were included in the task assignment. If he/she elects to initiate co-authoring along with the new task assignment, assigned users will not receive an additional co-authoring invitation email. If he/she does not elect to initiate co-authoring along with new task assignment, co-authoring cannot be initiated until the open tasks are completed.

4. *If* desired and available per the configuration, to switch the **Document Format** settings, check the checkbox next to **Show Advanced Settings**, and choose **Content Controls without XML** or **Content controls with XML**, and click **Invite**.



INVITE USERS

User(s): \*

Bill Label (blabel@intelinotion.com) x Cam Mistry (cmistry@intelinotion.com) x  
Jon Planet (jplanet@intelinotion.com) x Enter User Name

Send Invitation  
 Disable Document Protection  
 Show Advanced Settings

Document Format: \*

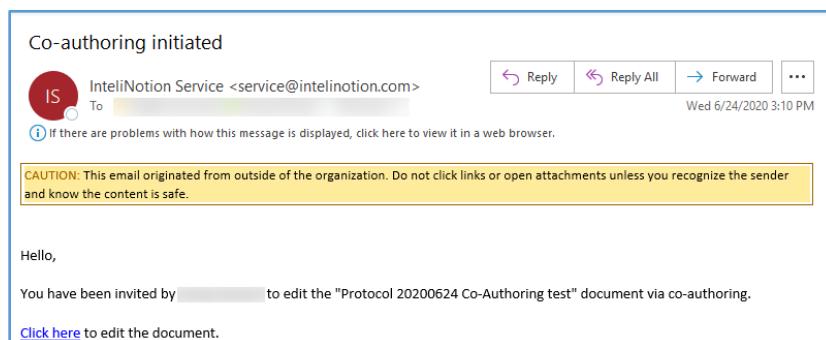
Content Controls without XML

Content Controls without XML  
Content Controls with XML

NOTE: Maximum 50 users are allowed for co-authoring, including the initiator.

Cancel Invite

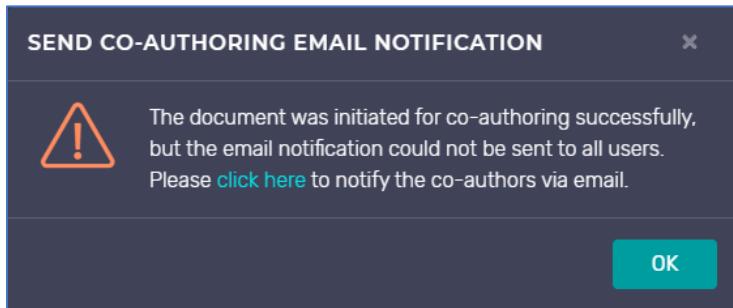
5. All the co-authors, including the initiator, receive an email invitation with a direct access link to the document:



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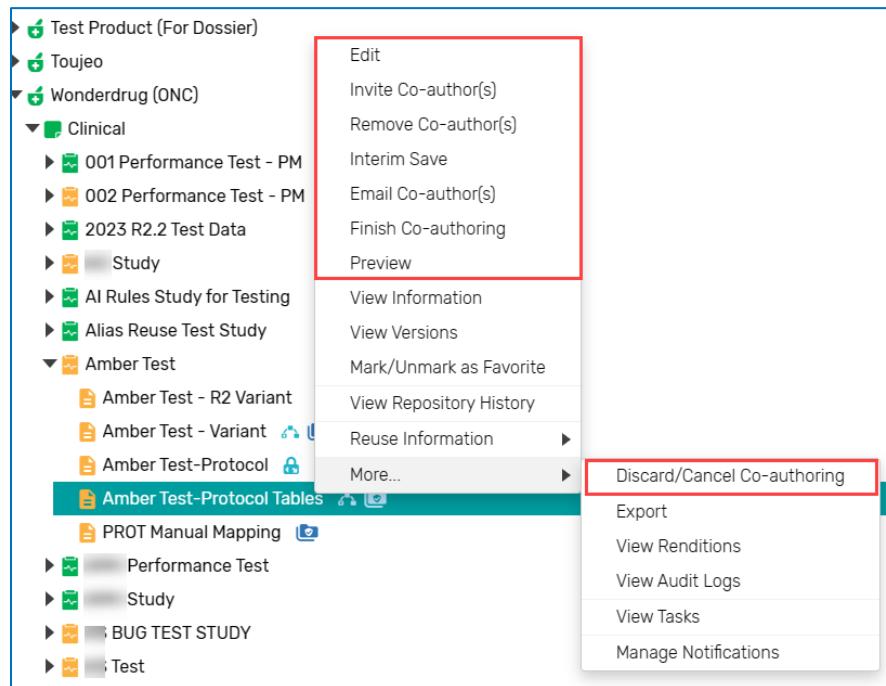
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**Note:** If sending the coauthoring invitation email(s) fail, the user will get the following message asking him/her to send the invitation(s) manually to the co-authors.



6. The document will now go into co-authoring mode. While the document is in this mode the following changes will occur.

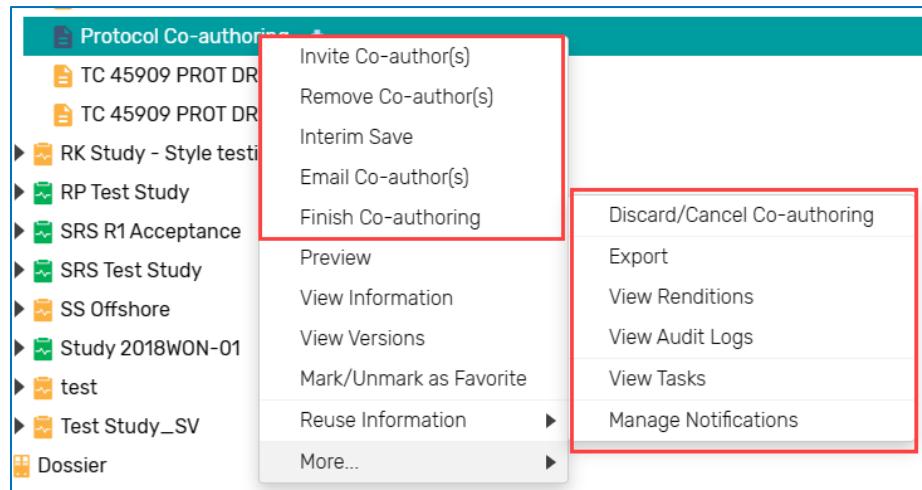
- The co-authoring initiator will see an  icon beside the document name and all other users see an  icon beside the document name.
- The right-click menu options change to be specific for co-authoring as follows:
  - Invited co-authoring users can edit the document and are able to see an **Edit (Co-authoring)** option; the co-authoring initiator and authorized users also see the additional options shown below.



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- Non-invited co-authoring users are not able to access the document and therefore do not see an **Edit (Co-authoring)** option.



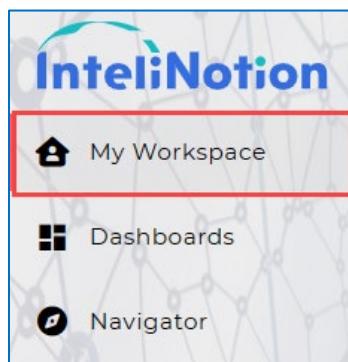
#### **Notes:**

- Authorized users (eg, admins, those with override permission for document) can cancel a co-authoring session by clicking the **Cancel Co-authoring** option available to them. After co-authoring is canceled, all invited users receive a system-generated email notification advising them that this has occurred.
- A user may initiate co-authoring in tandem with initiating a task. See [Module 9 Section 1.1.2](#) for more details.

### **3.2.1 My Co-authoring Documents**

Once a document is in co-authoring, assigned users can navigate to the My Co-authoring Documents page to see a list of documents currently in active co-authoring. Follow the steps listed below to navigate to and view the co-authoring documents page.

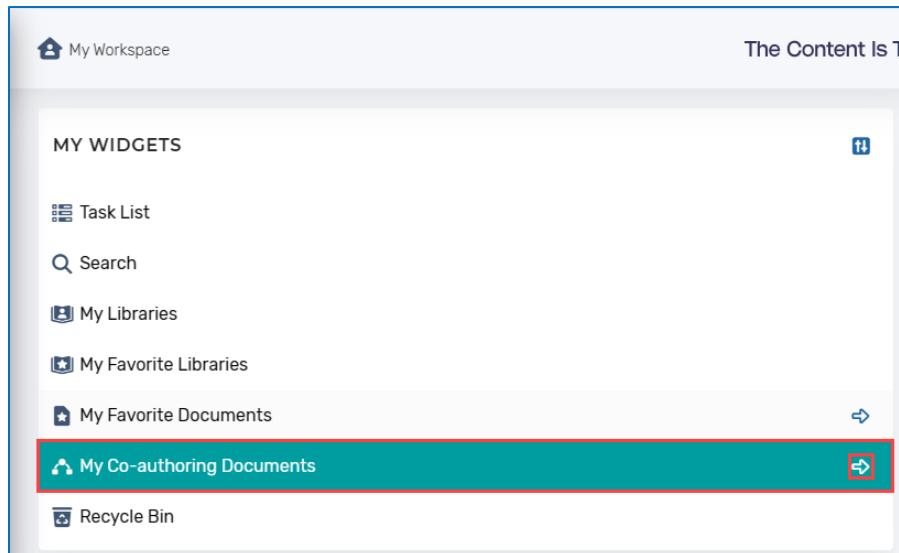
1. In the *InteliNotion Web Console* left hand navigation pane, click on **My Workspace**.



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2. The **My Workspace** page will display. Either double click on **My Co-authoring Documents** or highlight the workspace and click the arrow.

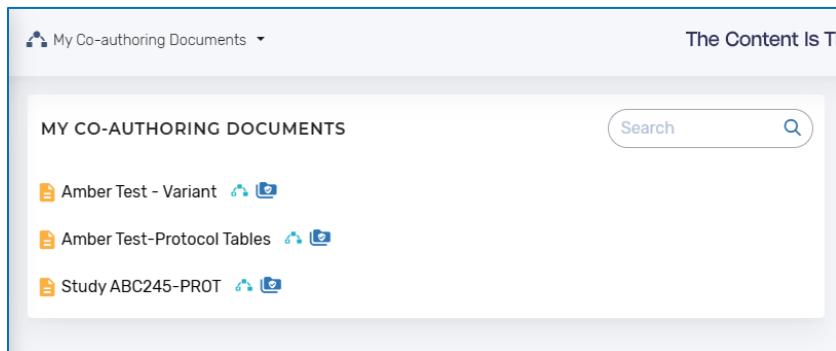


The Content Is T

**MY WIDGETS**

- Task List
- Search
- My Libraries
- My Favorite Libraries
- My Favorite Documents
- My Co-authoring Documents
- Recycle Bin

3. The **My-Co-authoring Document** workspace will display a list of assigned documents in active co-authoring.



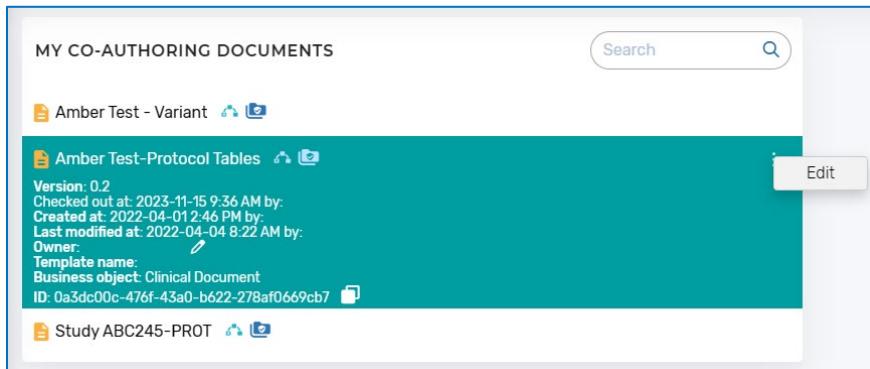
The Content Is T

**MY CO-AUTHORING DOCUMENTS**

Search

- Amber Test - Variant
- Amber Test-Protocol Tables
- Study ABC245-PROT

4. Highlight the applicable document and proceed with co-authoring actions as desired.



**MY CO-AUTHORING DOCUMENTS**

Search

Amber Test - Variant
Amber Test-Protocol Tables
Study ABC245-PROT

Version: 0.2  
Checked out at: 2023-11-15 9:36 AM by:  
Created at: 2022-04-01 2:46 PM by:  
Last modified at: 2022-04-04 8:22 AM by:  
Owner:  
Template name:  
Business object: Clinical Document  
ID: 0a3dc00c-476f-43a0-b622-278af0669cb7

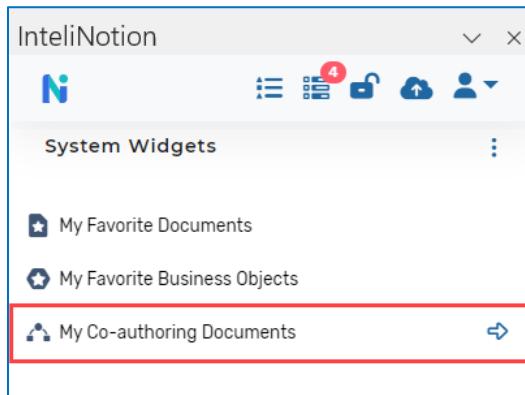
Edit

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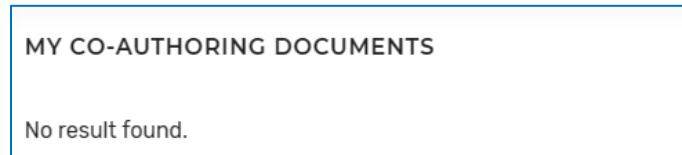
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### **Notes:**

- This page is also available via the *Word App System Widgets* workspace, as shown below.



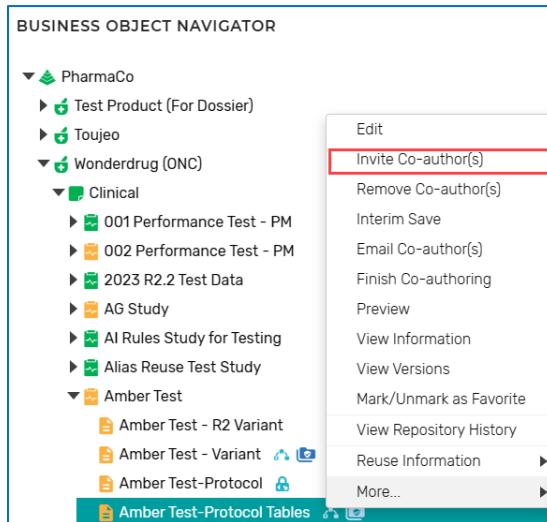
- If the user does not have any documents in co-authoring, the **My Co-authoring Documents** page will appear as shown below.



### **3.3 ADDING MORE CO-AUTHORING USERS**

Once co-authoring is initiated for a document, additional co-authors can be added by the initiator, any user with C-R-U-D-O permissions, or an admin.

1. In the **Navigator**, right-click on the document name and click **Invite Co-author(s)**.

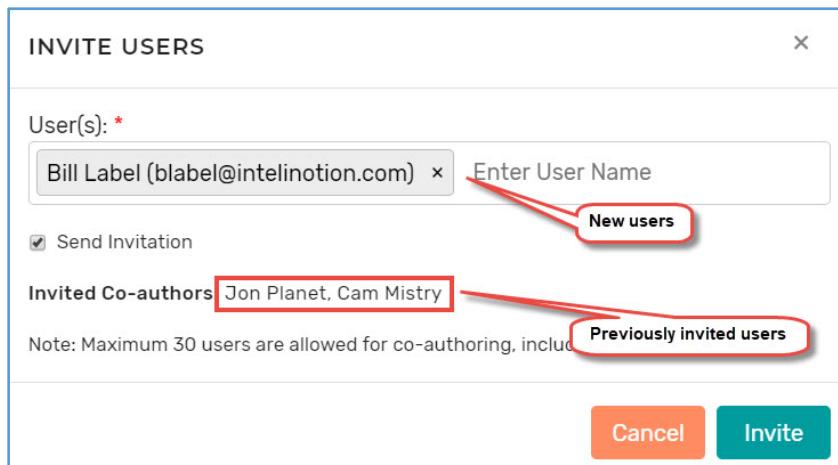


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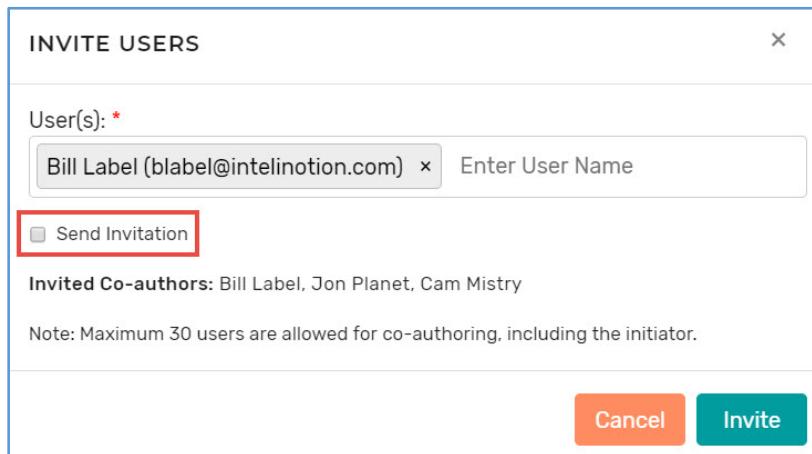
2. Enter the new usernames, uncheck the **Send Invitation** checkbox, if appropriate, and then click **Invite**.



The screenshot shows the 'INVITE USERS' dialog box. It has fields for 'User(s): \*' (containing 'Bill Label (blabel@intelinotion.com)') and 'Enter User Name'. A red box highlights the 'New users' link next to the user input field. Below this is a checked checkbox for 'Send Invitation'. Another red box highlights the 'Previously invited users' link next to a list of names ('Jon Planet, Cam Mistry'). A note at the bottom states: 'Note: Maximum 30 users are allowed for co-authoring, including the initiator.' At the bottom right are 'Cancel' and 'Invite' buttons.

**Note:** If co-authoring was initiated in tandem with task creation for a document, the original **Task** form will launch instead of the **Invite Users** form shown above. Refer to [Module 9 Section 1](#) for details on how to complete the task form.

3. Uncheck the **Send Invitation** checkbox to suppress the system-generated email invitation from being sent to all the co-authors.



The screenshot shows the same 'INVITE USERS' dialog box as above, but with the 'Send Invitation' checkbox unchecked. A red box highlights the unchecked state of the checkbox. The rest of the interface is identical to the first screenshot.

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4. If **Send Invitation** is checked, all the co-authors, including the initiator, receive an email invitation with a direct access link to the document:

Co-authoring initiated

 IntelNotion Service <service@intelinotion.com>  
To [REDACTED] Wed 6/24/2020 3:10 PM

[Reply](#) [Reply All](#) [Forward](#) [...](#)

[View in web browser](#)

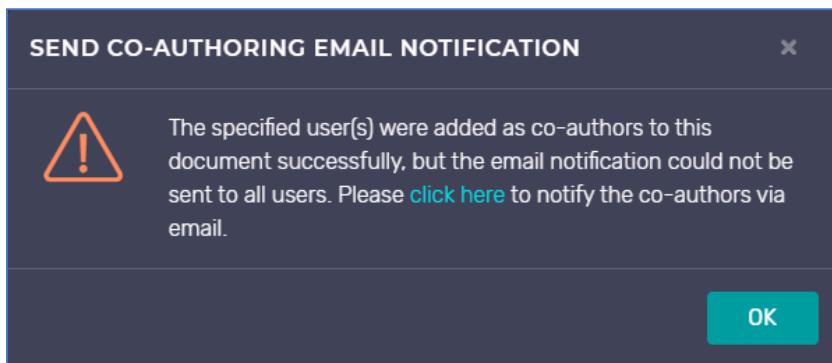
**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

You have been invited by [REDACTED] to edit the "Protocol 20200624 Co-Authoring test" document via co-authoring.

[Click here](#) to edit the document.

**Note:** If sending the co-authoring invitation email(s) fail, the user will get the following message asking him/her to send the invitation(s) manually to the co-authors.

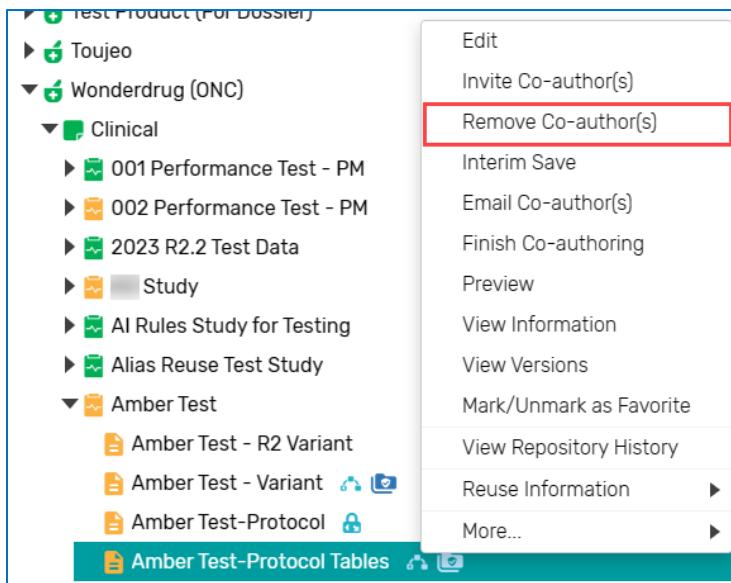


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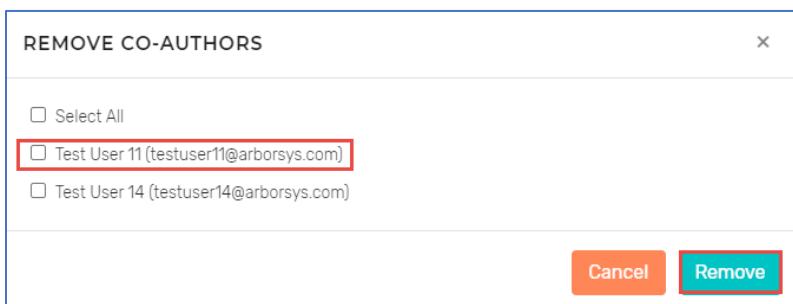
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### 3.4 REMOVING CO-AUTHORS

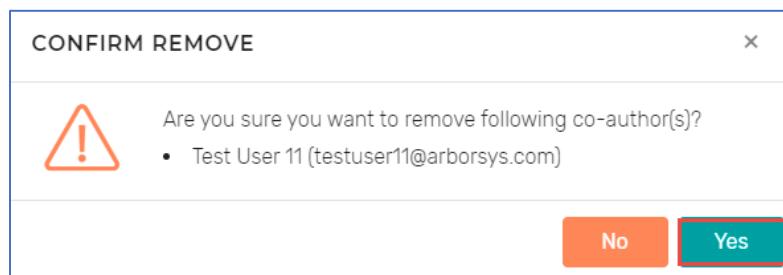
1. In the **Navigator**, right-click on the document name and click **Remove Co-author(s)**.



2. Choose the user to be removed from co-authoring by clicking the checkbox next to his/her name. Click **Remove**.



3. A confirmation message will display. Click **Yes** to remove the user from co-authoring.



**Note:** Removing co-authors from a document in active co-authoring can be done by the initiator, any user with C-R-U-D-O permissions, or an admin.

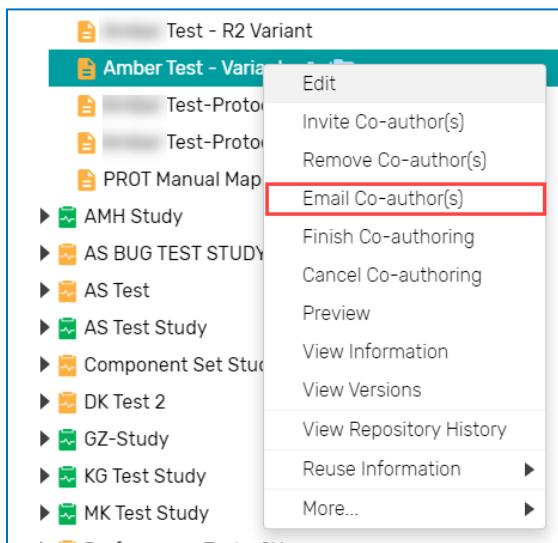
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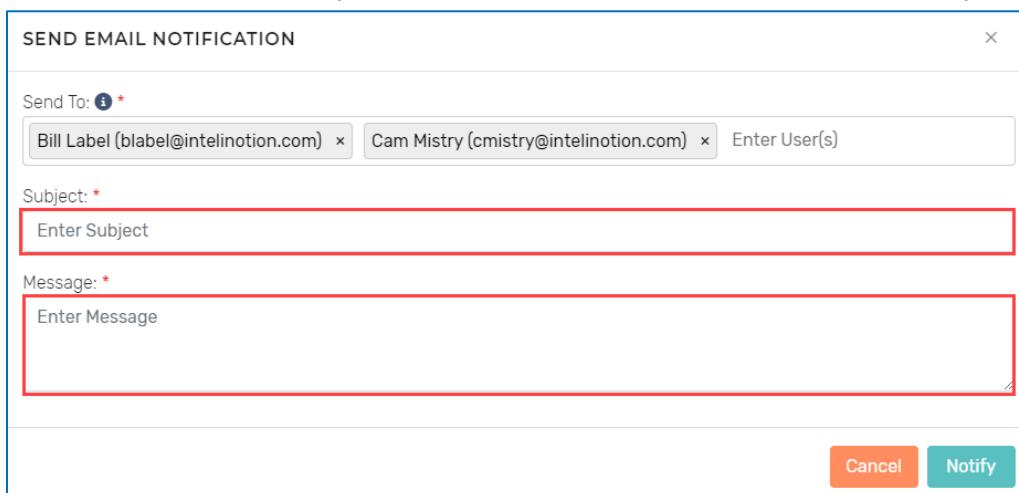
### 3.5 NOTIFYING CO-AUTHORS

While a document is in co-authoring, *InteliNotion* gives the option to send an email on demand to all invited coauthors or system users. This enables co-authors to communicate any updates or progress made. This action can be completed by the co-authoring initiator, an admin, or a user with C-R-U-D-O permissions. Follow the steps listed below to send an email during a co-authoring session.

1. Navigate to the document under co-authoring, right click, and choose **Email Co-authors**.



2. The email notification screen will display. The invited co-author names will be populated automatically, but users can be added or deleted as necessary.

A screenshot of the "SEND EMAIL NOTIFICATION" dialog box. It has fields for "Send To:" (with entries for Bill Label and Cam Mistry), "Subject:" (placeholder "Enter Subject"), and "Message:" (placeholder "Enter Message"). At the bottom are "Cancel" and "Notify" buttons.

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3. Fill out the **Subject** line, enter the message in the **Message** box, and click **Notify**.

SEND EMAIL NOTIFICATION

Send To: Bill Label (blabel@intelinotion.com)  Cam Mistry (cmistry@intelinotion.com)  Enter User(s)

Subject: \*  
Notification of First Pass Completion

Message: \*  
Sending this notification to inform everyone that the first pass changes are complete, and track changes reconciliation can begin at this time. Thanks, and let me know if you have any questions.

Cancel Notify

4. *InteliNotion* will send an email to the listed users.

Notification of First Pass Completion

 InteliNotion Service <service@intelinotiondev.onmicrosoft.com>  
To  blabel@intelinotion.com;  cmistry@intelinotion.com;

If there are problems with how this message is displayed, click here to view it in a web browser.

CAUTION: This email is from the external sender. Exercise caution with links and attachments.

Sending this notification to inform everyone that the first pass changes are complete, and track changes reconciliation can begin at this time. Thanks, and let me know if you have any questions.

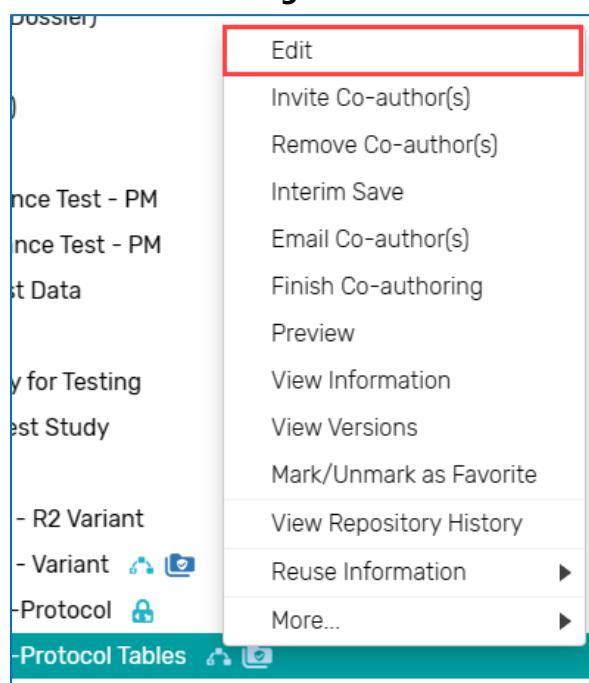
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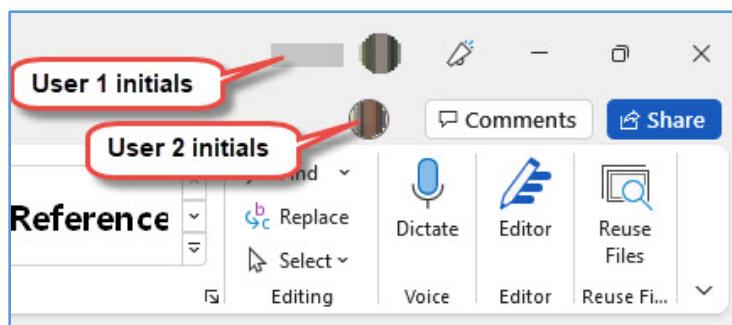
### 3.6 EDITING THE DOCUMENT WITH AUTOSAVE ON

When a document is co-authored, **AutoSave** will automatically be enabled (this may take several seconds). This allows for other users' edits to appear in real-time for all users co-authoring the document. It should be noted, however, that certain types of edits may take longer to appear than others (eg, typed text may appear immediately, while the formatting applied to the text will appear several seconds later).

1. The invited users can either click the link in the invitation email (if sent) or right-click on the document name in the **Navigator** and click **Edit**.



2. Once the document is open, a user's initials are visible at the top-right corner of the MS Word window; this allows a user to see the other users co-authoring the document at the same time. Click on a user's initials to view more information about him/her.

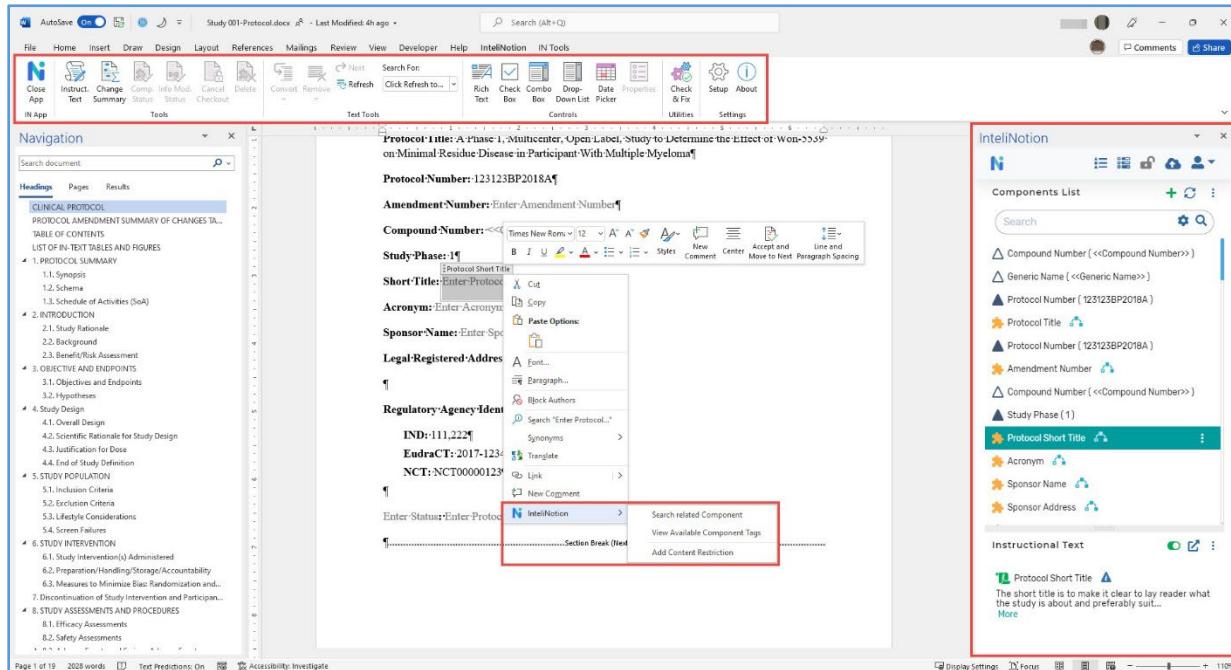


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3. Edit the document, as needed, using the various authoring functionalities described in [Section 1](#). Refer to [Section 3.12](#) for a list of features that are not supported during co-authoring.



## Notes

- If co-authoring is being completed with XML support, all functions covered in [Section 1](#) will be available for use.
- For the intra-document reused components (ie, those with more than 1 instance in the document), **only** the 1st instance within the document can be edited during co-authoring. The other existing and/or any newly inserted component instance(s) will be locked for editing, as indicated by a red highlight. To locate the editable instance, right-click in the non-editable component, hover over the **InteliNotion** option and click **Locate Source Component**. Any edits made to the 1st instance during co-authoring will sync to the other instance(s) during the finish co-authoring process.
- If a new component is inserted via **Insert Branched Instance**, the initial content may not be the same as the source component from which the new component was created.

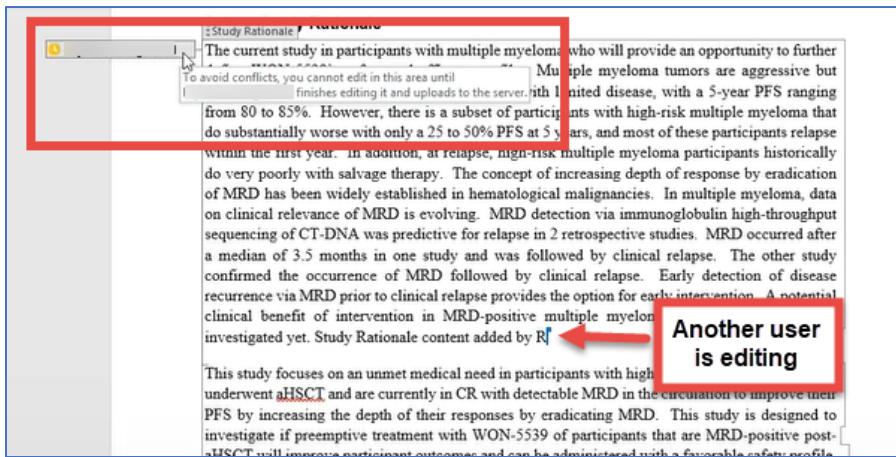
Multiple users can edit a component at once, but **only 1** user at a time can edit a single paragraph within the component. If a user is editing a paragraph, it will be locked for editing for other users; in this case, a message will be displayed indicating the user who is currently editing

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the paragraph. After the user's cursor leaves the paragraph and his/her changes are saved, it will become unlocked so that other users can edit it.



As the user makes edits in the document, they are autosaved and automatically synced to another user's open document. Sync times vary and depend on the type of edit that was made (eg, edits to existing text may display in real-time, whereas insertion of a new table may take 15+ seconds).

**Note:** When a user completes their co-authoring, it is strongly recommended to close the document.

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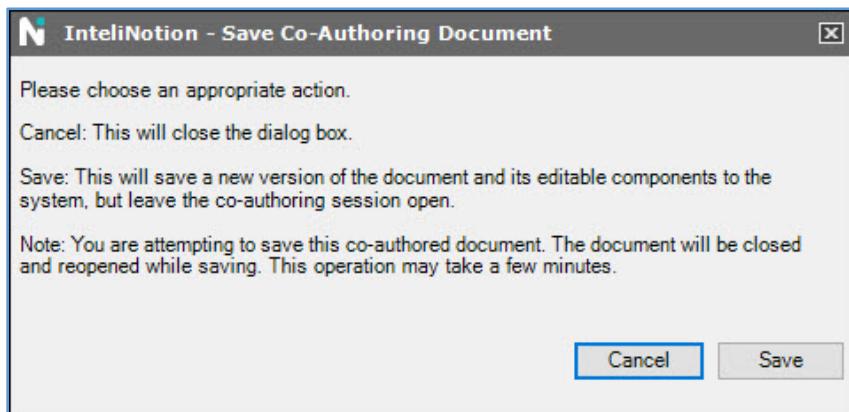
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### 3.7 INTERIM SAVE DURING CO-AUTHORING

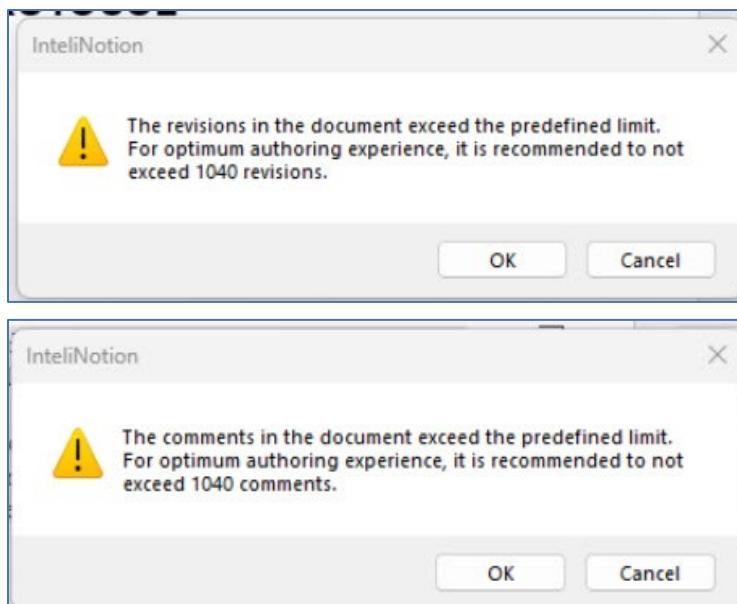
Before finishing co-authoring, which saves the last co-authored version of the document to the system, the co-authoring initiator, user with relevant 'override' permission (based on assigned role), or admin can save interim versions of the document to the system, as needed.

To perform an interim save of the document in the *Word app*:

1. With the document open in co-authoring mode, click the **save icon**  in the *InteliNotion Word App*.
2. A confirmation message will display. Click **Save**.



- *IF* the configured number of revisions or comments allowed is exceeded, one of the following messages will display.



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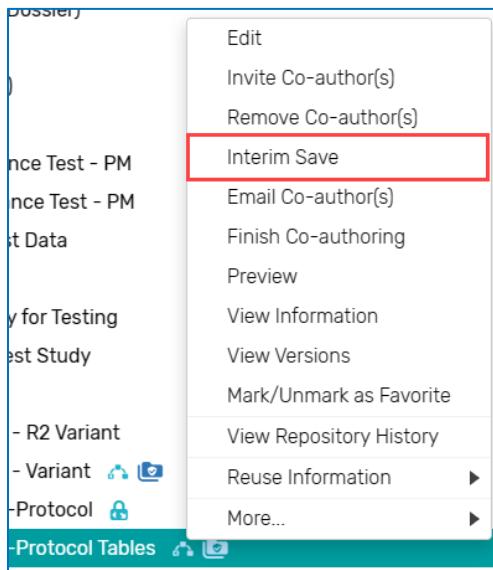
3. The latest version of the document (as well as any of its edited components) is saved to the system, and then the document will close and reopen.

**Note:**

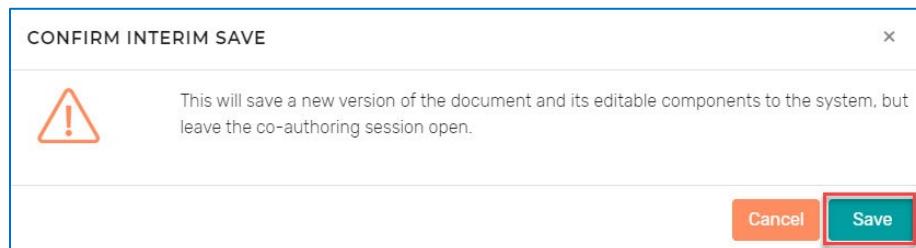
- If Autosave is not on and the user chooses to turn it on, it will take approximately 30 seconds for AutoSave to reenable automatically. However, if the user clicks in an editable component this should turn AutoSave back on.
- Admins can invite themselves to an existing co-authoring session and perform an interim save of the document while in co-authoring if the document being co-authored was initiated for co-authoring with the **Document Format** setting **Content Control without XML** (see [Section 3.2](#)).

To perform the interim save in the *InteliNotion Web console*:

1. In the **Business Object Navigator**, right click on the document that is being co-authored and click **Interim Save**.



2. This will bring up a warning that interim saving the document will save a new version of the documents without closing the current version of the document being co-authored. Click **Save**.



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**Note:** When a user performs an interim save, *InteliNotion* will update version the document and **only** the components that were modified during the authoring session.

3. A confirmation message will appear.

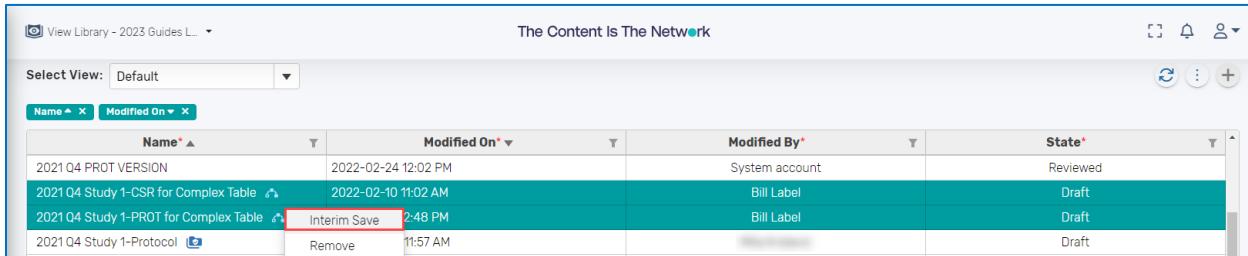
 Document saved successfully.

**Note:** The co-authoring initiator or admin performing the save will have an option to enter a comment before completing the interim save, which can be checked when viewing versions.

### 3.7.1 Bulk Interim Save During Co-Authoring

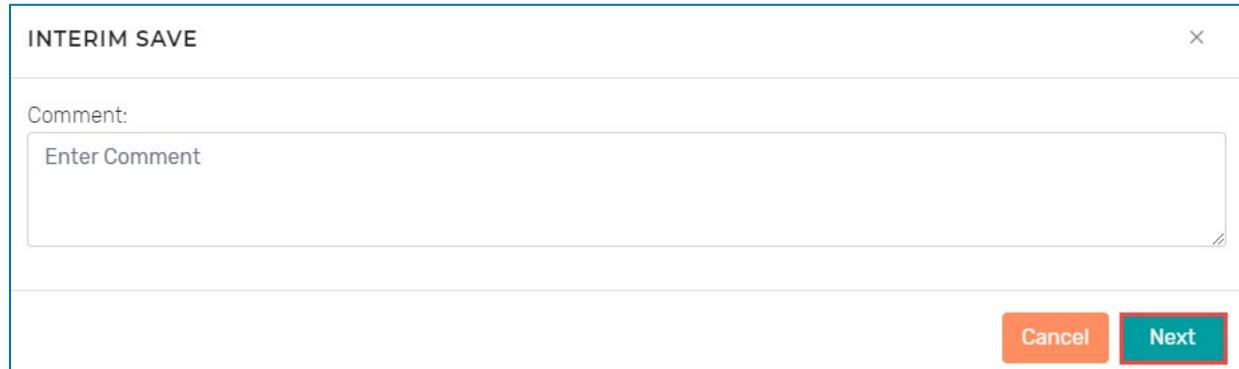
If multiple documents are in co-authoring, it is possible for the co-authoring initiator, a user with C-R-U-D-O permissions, or an admin to perform a bulk interim save from the non-managed library view. Follow the steps listed below to perform a bulk interim save.

1. Navigate to the applicable non-managed library.
2. Select the documents in co-authoring to be interim saved. Right click and choose **Interim Save**.



Name*	Modified On*	Modified By*	State*
2021 Q4 PROT VERSION	2022-02-24 12:02 PM	System account	Reviewed
2021 Q4 Study 1-CSR for Complex Table	2022-02-10 11:02 AM	Bill Label	Draft
2021 Q4 Study 1-PROT for Complex Table	Interim Save 2:48 PM	Bill Label	Draft
2021 Q4 Study 1-Protocol	Remove 11:57 AM		Draft

3. The interim save comment box will display. If desired, enter a comment into the comment box and click **Next**.



INTERIM SAVE

Comment:

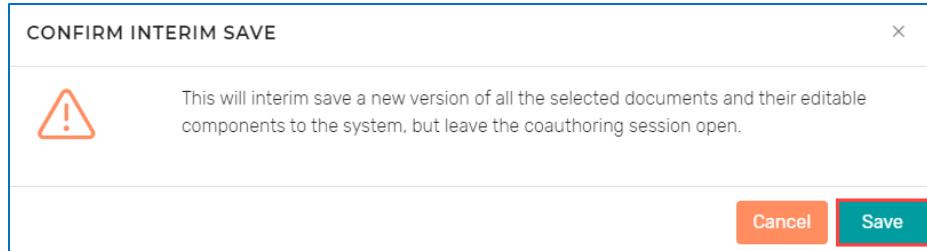
Enter Comment

Cancel Next

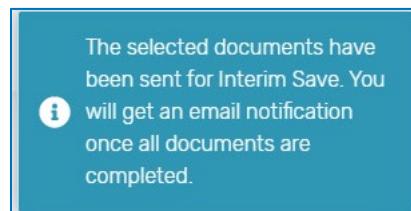
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4. This will bring up the **Confirm Interim Save** form. Click **Save**.



5. A pop-up will display informing the user that the interim save has been initiated successfully.



- a. If the save was able to complete with no errors, the user will receive a confirmation email with the information that both documents have saved.

Co-authoring Interim Save Status

InteliNotion Service <service@intelinotiondev.onmicrosoft.com>

[View in web browser](#)

**CAUTION:** This email is from the external sender. Exercise caution with links and attachments.

Hello,

A request was submitted to interim save the following document(s) in co-authoring - please see the status of each document below.

Document Name	Status	Comments
2021 Q4 Study 1-CSR for Complex Table	Saved	
2021 Q4 Study 1-PROT for Complex Table	Saved	

- b. If there were errors, the user will receive an email with any error information, explaining why the applicable documents did not save successfully.

**From:** InteliNotion Services <[service@intelinotion.com](mailto:service@intelinotion.com)>  
**Sent:** Tuesday, April 11, 2023 2:27 PM  
**Subject:** Interim Save Status

Hello,

The following documents were initiated for Interim Save. Please check the status of the documents below:

Document Name	Status	Comments
Document - 6	Failed to Save	Not acceptable: A request to save co-authoring document is not allowed because the document is no longer available for co-authoring.
TP Study-Protocol - 1	Failed to Save	Error: An error has occurred while downloading the document. The Co-Authoring backend service returned the error:
Document - 2	Saved	
Document - 3	Saved	
Document - 5	Saved	
Document - 7	Saved	
Document - 4	Saved	
Document - 1	Saved	

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## 3.8 CONFLICT RESOLUTION

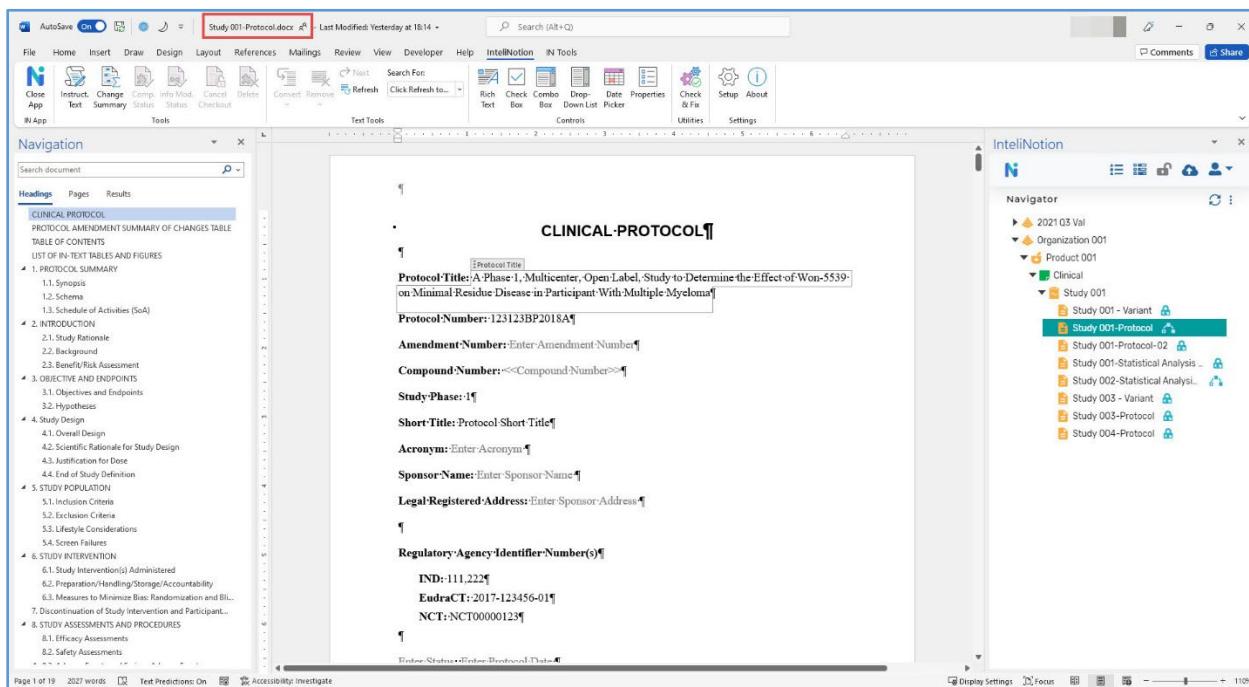
*InteliNotion* leverages *MS Word's* feature to lock content at the paragraph level (not component level) while it is being edited by one user. If another user tries to edit the content of the same paragraph, the user is notified that the paragraph is currently locked for editing.

There may be times, however, when multiple users are able to simultaneously edit the same component of the document (eg, when entering new content in an empty component). When the users' edits are saved, a conflict may occur. These conflicts must be resolved, typically by the user whose edits were saved last.

To resolve the conflict, follow the *Microsoft* resolution protocol steps, available at the following [link](#).

## 3.9 FINISHING CO-AUTHORING

Once all users have finished their edits, they must ensure any final changes are saved (this is confirmed if **Saved** appears in the *MS Word* window's bar) and close the document using the *MS Word's* **Close**  option.



**Note:** If locked components have comments against them or have been changed against the reuse policy, a pop-up will display to prevent the user from saving. The user will have to select **Clean Up and Save** and address the comments and reuse issues as applicable before the document can be saved.

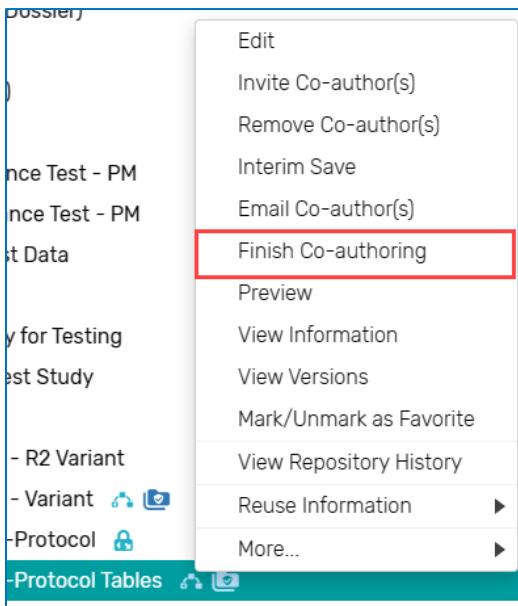
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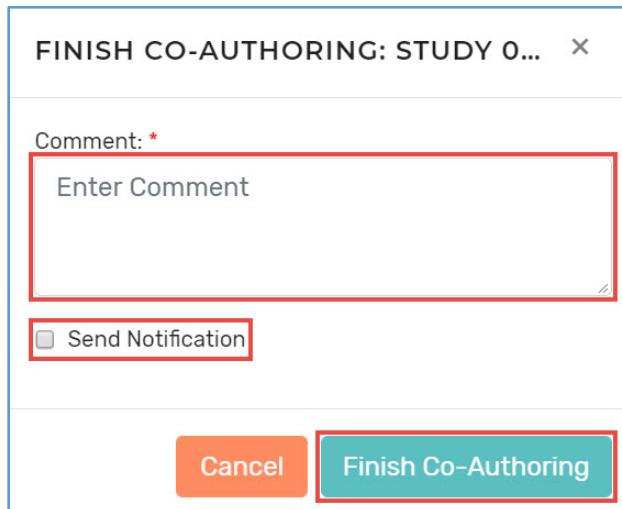
The co-authoring initiator or user with C-R-U-D-O permissions can finish co-authoring as follows:

1. Navigate to the document, either via the *InteliNotion Word App* or *Web Console*, rightclick on its name, and click **Finish Co-authoring**.



**Note:** Admins can also finish co-authoring for another user's document (ie, a document that was initiated for co-authoring by another user).

2. Enter a **Comment** in the required field and click the **Send Notification** checkbox if the co-authors (ie, invited users) should receive a finish co-authoring email. Then click **Finish Co-Authoring**.



FINISH CO-AUTHORING: STUDY 0... ×

Comment: \*

Enter Comment

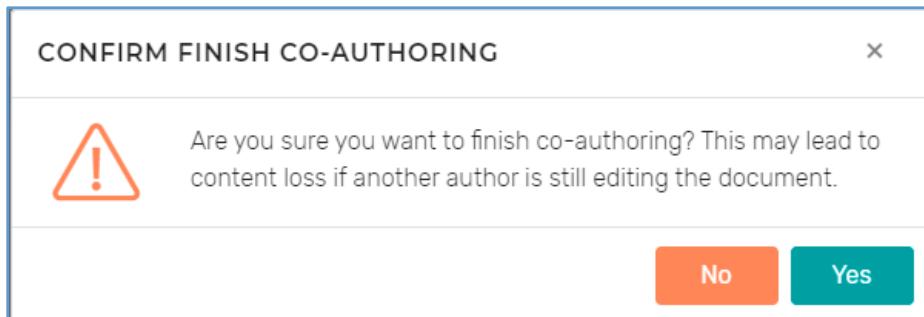
Send Notification

Cancel Finish Co-Authoring

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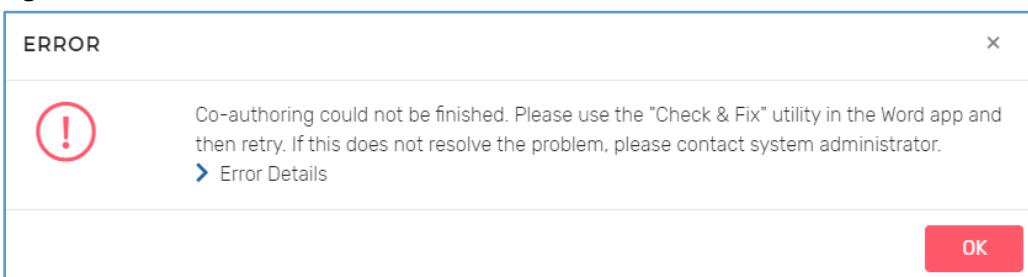
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3. Click **Yes** in the confirmation message to proceed with finishing co-authoring.



**Notes:**

- If any users still have the document open for co-authoring, the request to finish (or cancel) co-authoring is allowed. However, if a user is still making edits during the finish (or cancel) co-authoring process, those edits may be lost. In addition, it may take a few minutes for the system to alert the user that the document is no longer in co-authoring, and therefore his/her changes cannot be saved.
- After finishing co-authoring is complete, regardless if an email is received, the invited co-authors will no longer be able to edit the document in co-authoring mode.
- If co-authoring was initiated in tandem with task creation, the task initiator may be alerted that there are still open tasks when completing the finish co-authoring process. Refer to [Module 9 Sections 1.1.2 and 1.1.3](#) for details.
- If the datatype of any of the variables were changed during the co-authoring session, the following error message will display. Please refer to [Section 2.1.1](#) for information on how to resolve the issue and try again.



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- After the co-authoring session has finished successfully, a new version of the document and the editable components that were changed in the co-authoring session is created in the system. Also, a system-generated comment is added to that version in the version history of both the editable components and documents, which includes the name of the users invited to the co-authoring session. All edits made during coauthoring are retained in the new version and reflected when the document is next opened in single-user authoring mode.

**VIEW VERSIONS: PROT CREATED VARIANT2**

	Version	Modified On	Modified By	Comment
<input type="checkbox"/>	0.2	2023-03-29 4:09 PM	Cam Mistry	test
<input type="checkbox"/>	0.1	2023-03-29 3:51 PM	Cam Mistry	Clinical Document created variant of the "PROT D document on 2023-03-29 3:51 PM by Cam Mistry. The component and variable content/value may not reflect the last update if not yet refreshed into the document/component. (This means that in certain cases, the variable content/value may be empty.) If the document is exported via right-click menu option (under More), however, then the component and variable content/value will include the auto-refreshed content.

**Owner:** Cam Mistry  
**Name:** PROT CREATED VARIANT2  
**Compound Number:** AB-123456  
**Country:**  
**Established Name:**  
**EudraCT Number:**  
**Generic Name:**  
**Indication:**  
**IND Number:** 111,222  
**INN:**  
**NCT Number:**  
**Protocol Number:**  
**Study Phase:**  
**QC Checklist:**  
**Therapeutic Area:**  
**Trade Name:**  
**State:** Draft  
**Location Where Study Interventions are Administered:**  
**Study Evaluates Pharmacodynamics PD:**  
**Study Evaluates Pharmacokinetics PK:**  
**Study Interventions are Prepared at the Site:**  
**Study is a Device Study:**  
**Study is Blinded or Open Label or Sponsor Open:**  
**Study May Involve Breaking the Blind:**  
**Study Utilizes Interactive Response Technology IRT:**  
**Study is a Single Dose Study:**

**Close** **Compare Versions**

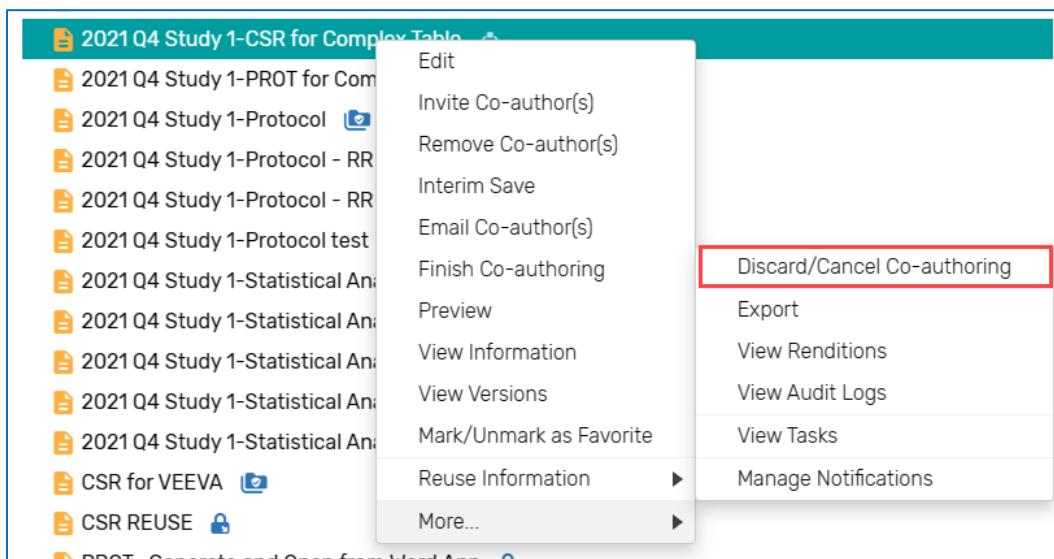
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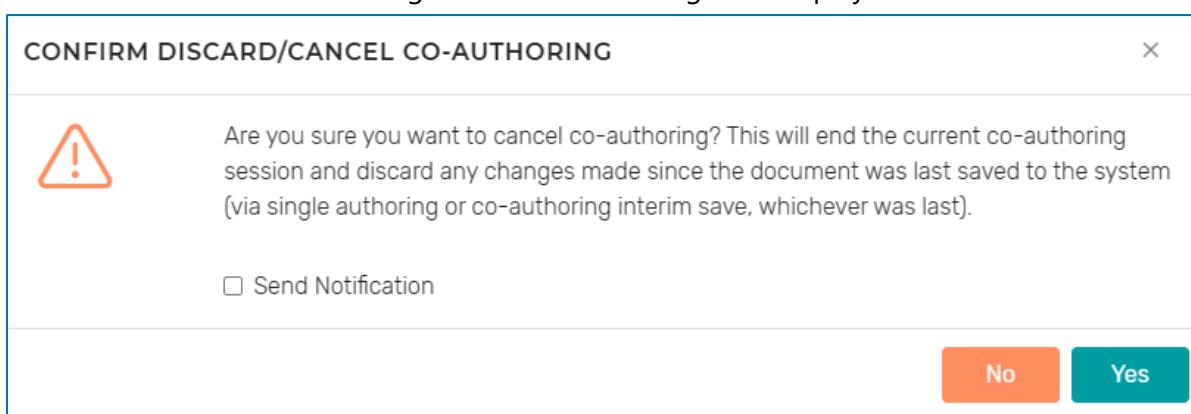
### 3.10 CANCELING CO-AUTHORING

If it is determined that co-authoring is not needed for a document, the co-authoring initiator or an admin can cancel the co-authoring session. When co-authoring is canceled, a new version of the document is not saved back to the system, so any edits that may have been made in co-authoring mode may be lost. Exception: If the co-authoring initiator performed an interim save (as per [Section 3.6](#)), those edits will not be lost since a version was manually saved to the system. Therefore, it is recommended to cancel co-authoring prior to any co-authors editing the document, ideally, and only if/when necessary.

1. Locate the document in Navigator and right-click to select **Discard/Cancel Co-Authoring**.



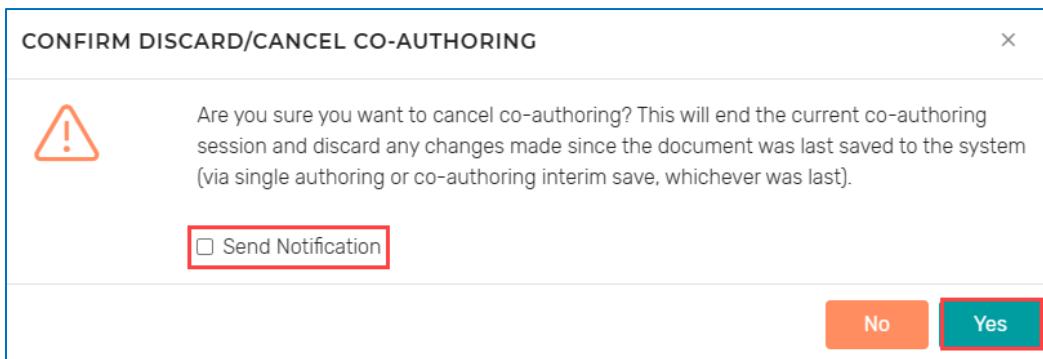
2. A Cancel Co-Authoring confirmation message will display.



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3. Click the **Send Notification** checkbox to have an email notification sent to users, if desired, and select **Yes** to cancel Co-Authoring for the document.



4. A canceled co-authoring successfully message will display.

 Canceled "Study 001-Protocol" co-author successfully.

**Note:** If co-authoring was initiated in tandem with task creation, the task initiator may be alerted that there are already completed tasks when completing the cancel co-authoring process. Refer to [Module 9, Sections 1.1.2 and 1.1.3](#) for details.

### 3.10.1 Bulk Cancel Co-Authoring

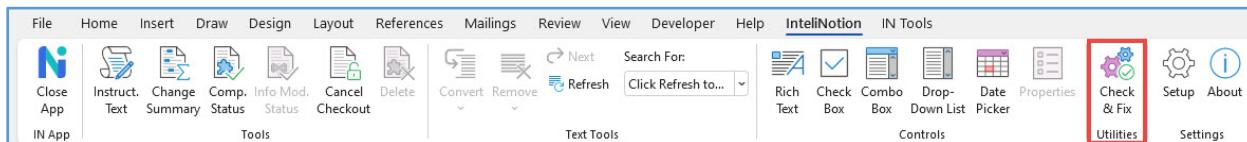
For detailed instructions on the bulk cancel function for documents in co-authoring (this functionality can be used to bulk cancel checkout, co-authoring, or documents in collaborative review), see [Section 2.3.1](#).

## 3.11 CHECK & FIX UTILITY

The **Check & Fix** utility helps to determine which variable(s) within a document have had the datatype changed (hence, corrupted) and repairs them back to the correct data type.

Perform the following steps to use this function.

1. Click on **Check & Fix** option under the **Settings & Utilities** section of the InteliNotion Ribbon.

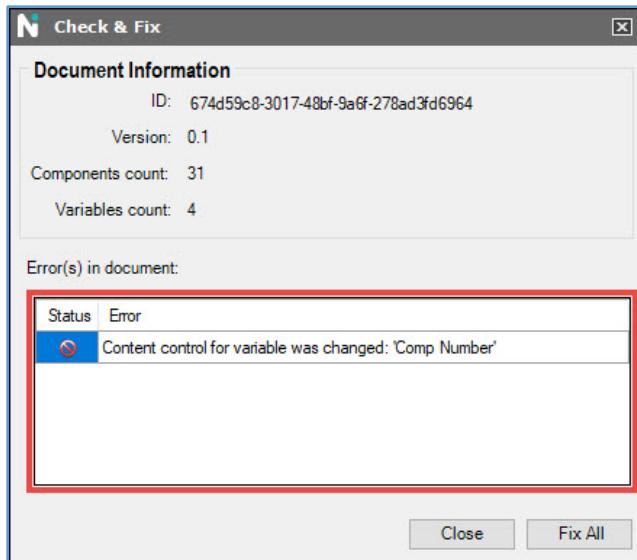


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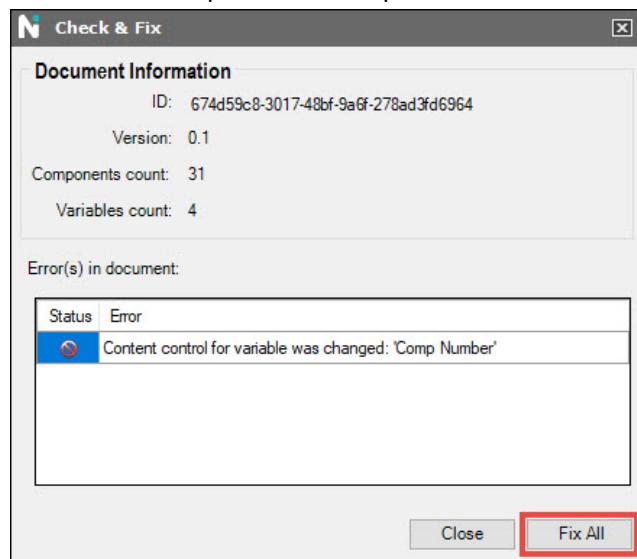
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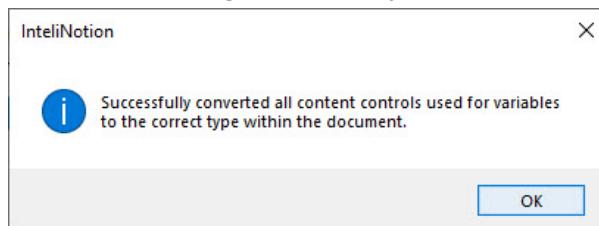
2. A dialog box displaying information about the variables within the document and the list of the corrupted variable(s) will appear on the screen.



3. Click on **Fix All** button to repair the corrupted variable(s).



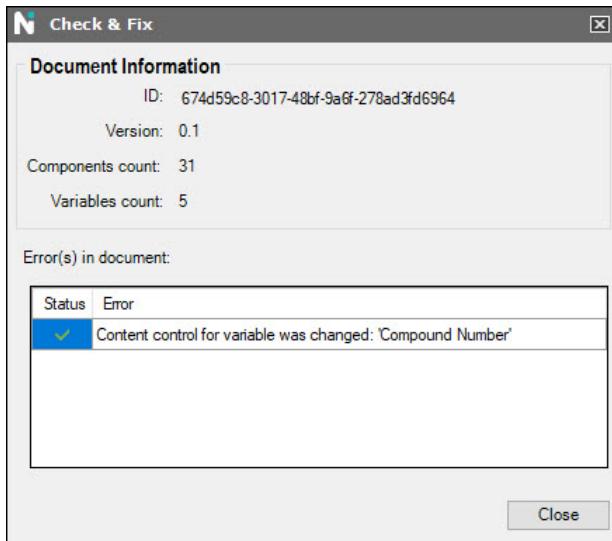
4. A conversion successful message will display on the screen.



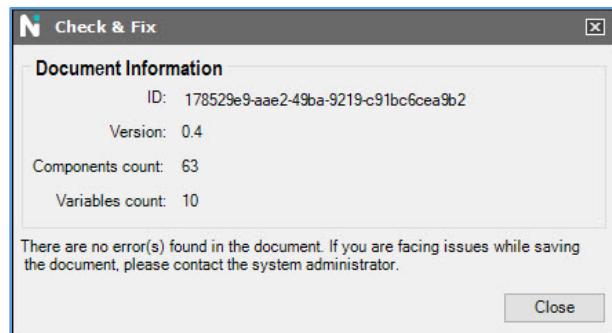
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5. Additionally, the datatype of the corrupted variable(s) will change to the appropriate type.



6. Re-run steps 1-3 to verify no variable(s) is/are corrupted within the document.



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### 3.12 CO-AUTHORING BEST PRACTICES

The following best practices should be considered during co-authoring to ensure optimum performance:

- Co-authoring requires AutoSave to be enabled. If it is not enabled, contact the admin.
- It is possible to delete components while in co-authoring mode.
- If sensitivity labels and encryption are being used in *Microsoft Office*, the user will need extra configuration steps to enable co-authoring for these documents. See [Enable coauthoring for documents encrypted by sensitivity labels in Microsoft 365](#).
- *Word* may not support @ mention functionality for guest users invited to the user's company organizational directory. Please contact the company IT department for further details.
- Always close the document if not actively editing it. This will prevent potential sync issues should the user become logged out due to inactivity.
  - If a document was accidentally left open in co-authoring mode for an extended period, *MS Word* may stop syncing changes. Therefore, before making additional changes, close the document, re-open it in co-authoring mode, and ensure auto-save is turned on before editing again.
- Avoid editing content in the same paragraph or component as much as possible. Look for icons indicating the presence of other authors.
  - This helps to avoid conflicts and a subsequent conflict resolution process that would otherwise be needed to reconcile changes made by multiple users.
- *Word* will prioritize textual changes for synchronization to other co-authors before it syncs more complex changes such as track changes, comments, formatting changes, etc. This is a normal behavior by design and not a flaw in co-authoring functionality.
- For the intra-document reused components (ie, those with more than 1 instance in the document), co-authors can **only** edit the 1st instance within the document (which will be highlighted in red).
- If the user intends to spend a long time on a section and would like other users to not be able to edit that section, a user can block other users by selecting one or more paragraphs and clicking **Block Authors** in the **Protect group** of *MS Word*'s review ribbon.
  - The user can unblock the locked sections later individually or in the entire document.

**Note:** This functionality works only if there are no other co-authors in the document.
- Certain *MS Word* undo/redo functions are not supported when co-authoring a document in InteliNotion. Refer to [Section 1.16](#) for details.

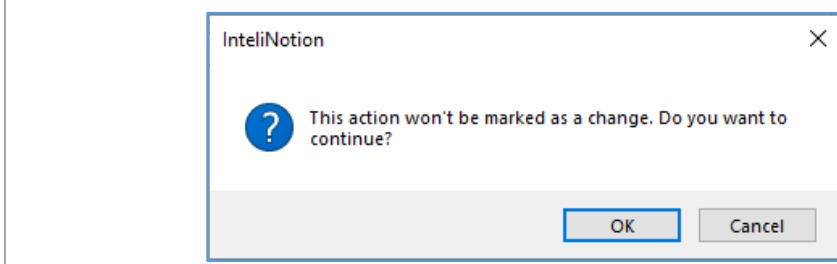
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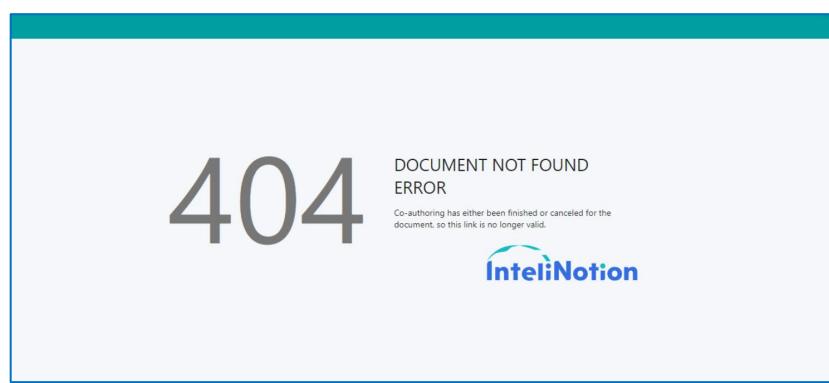
- If using **Track Changes** during co-authoring, do not configure **Restrict Editing** on the document to enforce the use of track changes, as this may result in a tracked change appearing where no content was modified (eg, placeholder text displayed within an empty component will appear as newly inserted after saving the document).
- If a user must use **Track Changes**, please be aware of the following known behaviors:
  - If one user turns on the Track Changes setting, it turns on for all users, as the change propagates to other users. The change in the setting as well as the edits made soon after may take a couple of minutes to propagate and appear as track changes.
  - If there are conflicts, the conflicting changes will be displayed as tracked. *MS Word* expects a user to accept or reject any changes that conflict with those of others in the same fashion as working with track changes.
  - When Track Changes are on, edits made by other authors may appear at a slower rate.

**Note:** When working in Track Changes if there is a change that will not be marked as a change the user will be alerted.



- The user can view the icon of other users who have the document open in *MS Word* at the top right of the window.
- If co-authoring has already been completed, the link furnished by *InteliNotion* will no longer work.

**Note:** If a link is used after co-authoring is completed, the following error message will display:



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Also, please note these additional **known behaviors**:

- After overriding an edit restriction or branching and inserting a component via Search, Libraries or Navigator, a user will not be able to perform any actions for that component (ie, using the ellipsis in the Components List) while the document is still in co-authoring.
- Undo/redo of *InteliNotion* actions is no longer permitted after the document or component is saved. If a partial undo action is completed, this may lead to the component and/or document becoming corrupted.

### 3.13 FEATURES AVAILABLE AND UNAVAILABLE DURING CO-AUTHORING

No.	Feature/Function	Supported?	Notes
1.	Component right-click menu in document: Search Related Component	✓	
2.	Component right-click menu in document: Search <specific text>	✓	
3.	Component right-click menu in document: Move and Move Here (a component)	✗	
4.	Component right-click menu in document: Insert repeated component	✓	Available based on configuration and user's permission
5.	Component right-click menu in document: Override edit restriction	✓	Available based on configuration and user's permission
6.	Component right-click menu in document: Add Content Restriction	✓	Available based on configuration and user's permission
7.	Component action in Word App Navigator: Insert As Is (from another document)	✓	Includes inserting a <u>new</u> component that does not have a corresponding one in the document already
8.	Component action in Word App Components List:Insert Identical Instance (from same document)	✓	
9.	Component action in Word App Navigator: Branch and Insert (from another document)	✓	Includes inserting a <u>new</u> component that does not have a corresponding one in the document already

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No.	Feature/Function	Supported?	Notes
10.	Component action in Word App Components List: Branch and Insert (from same document)	✓	This function is not available for a repeated component during a co-authoring session
11.	Component action in Word App Component Tags: Apply Component Tag	✓	Can also remove tag, if needed
12.	Component action in Word App Content Tags: Add Tag	✓	Can also remove tag, if needed
13.	Component action in Word App Components List: Edit (Check Out) component	✗	All editable components are checked out by default when co-authoring is initiated, so they cannot be checked out individually via Navigator
14.	Document action in Word App Navigator: Edit (Check Out) document	✗	Document is checked out by default when co-authoring is initiated
15.	Component/Document action in Word App Components List/Navigator: View Versions	✓	Includes ability to compare any versions prior to the initiation of co-authoring
16.	Component/Document action in Word App Components List/Navigator: Preview	✓	
17.	Component action from Word App Search (results): Insert As Is	✓	
18.	Component action from Word App Search (results): Branch and Insert	✓	
19.	Component action from Word App Library: Insert Component	✓	
20.	Insert new component from Word App Search, Libraries, or Navigator	✓	
21.	Word App Instructional Text Pane: Pop out Instructional Text [pane]	✓	
22.	InteliNotion Ribbon: [Pop out] Instructional Text	✓	
23.	InteliNotion Ribbon: Generate Summary of Changes	✗	Button is enabled, but behavior is unpredictable; therefore, do not recommend using
24.	InteliNotion Ribbon: Component Status Report	✗	

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No.	Feature/Function	Supported?	Notes
25.	InteliNotion Ribbon: Text Tools (for converting or removing styled text)	✗	Button is enabled, but behavior is unpredictable; therefore, do not recommend using
26.	InteliNotion Ribbon: Controls (for inserting date picker, etc.)	✓	Available based on user's permission
27.	InteliNotion Ribbon:Table Tools (for updating 'complex' tables)	✗	
28.	InteliNotion Ribbon or component right-click menu in document: Delete [component]	✗	
29.	InteliNotion Ribbon OR component right-click menu in document: Delete [variable]	✗	
30.	Variable action in Word App Components List: Add new variable (inside or outside a component)	✓	
31.	Content sync between 2 or more component instances in document (intra-document reuse)	✗	<b>Only</b> the 1st instance will be editable within the document during co-authoring.
32.	Document action in Word App Navigator: Export Document	✓	
33.	Document action in Word App Navigator: Interim Save [document]	✓	<b>Only</b> the user who initiated co-authoring or an admin can save interim versions back to the system
34.	Document action using save icon at top of Word App: [Interim] Save document	✓	<b>Only</b> the user who initiated co-authoring or an admin can save interim versions to the system
35.	Component right-click menu in document: Clear reuse	✓	
36.	Adding/editing component set	✓	

**Notes:**

- Undo/redo of InteliNotion actions is no longer permitted after the document or component is saved. If a partial undo action is completed, this may lead to the component and/or document becoming corrupted.
- Undo/redo of typical MS Word functions (eg, copy/paste, type text) will work as expected.

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