



Authoring Configurations

Guide

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1. ABOUT THIS GUIDE

This guide provides information on how to manage various authoring configurations in *InteliNotion*, such as configuring the information models, creating a document template, and adding library components. These actions are typically restricted to users with a superuser or admin-type level of access in the system.

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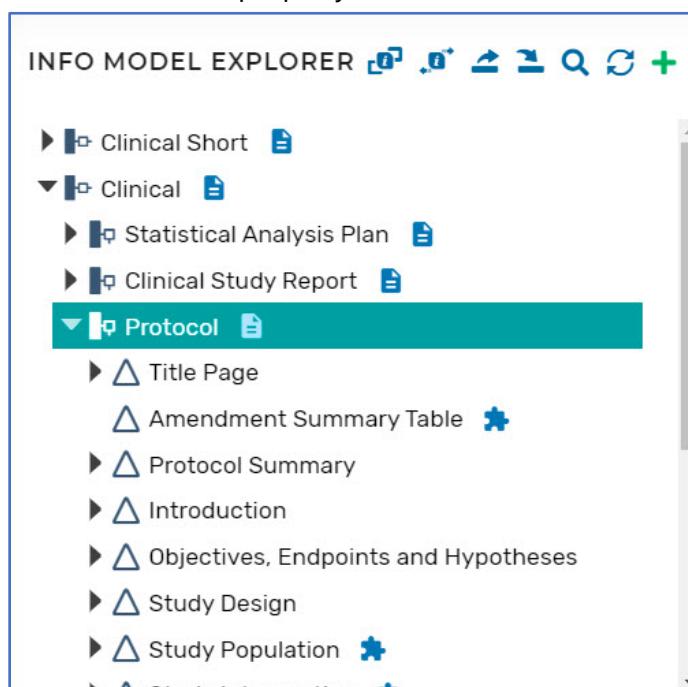
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2. CONFIGURING INFO MODEL

The info model describes the content structure for a hierarchy (e.g., for a document) and defines its parts or elements with associated reuse policy, if/when applicable. There are 2 types of elements - content components that are intended to contain de novo (new) or reused text, tables, images, etc. and variables that will be sourced directly from a related metadata/property's value. A hierarchical set defined for a document must contain all the elements needed to represent the different types of content to be included in that document.

The structure of the info model is client-specific, but an example of the structure for clinical content is as follows:

- **Hierarchical Set** for a business area
 - **Hierarchical Set** for elements used for a single document type
 - **Placeholder Element** – can be used to group other elements (not required)
 - **Element** for a content component
 - **Hierarchical Set** for property-bound elements (eg, variables) used commonly for multiple documents
 - **Element** for a bound property value



Note: Variable elements will be marked with a  icon.

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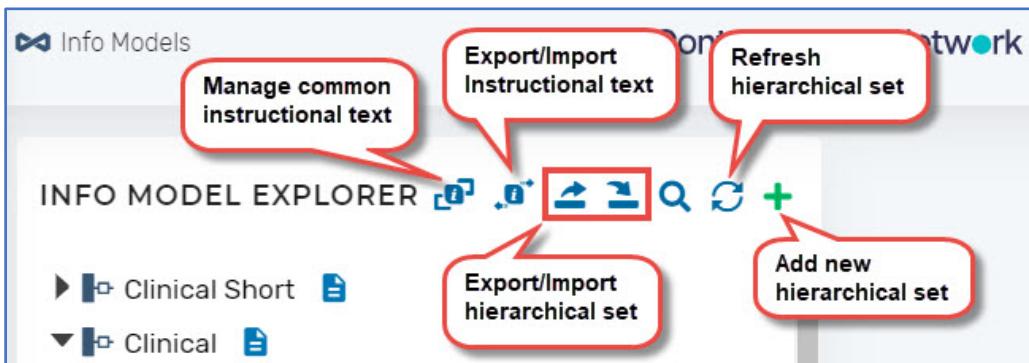
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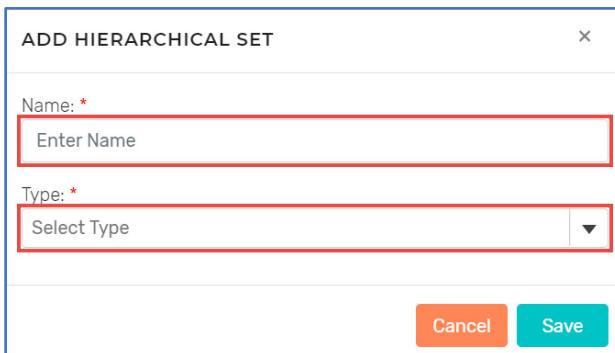
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2.1 ADDING HIERARCHICAL SETS

1. Click the Info Models option in the left-hand navigation pane of the Web Console.
2. Multiple icons will be displayed in the top-right corner.



3. Click the **add icon**  to create a new (parent) hierarchical set (eg, for a business area).
4. Complete the form to add a hierarchical set.
 - a. Enter a **Name** and click the **Type** dropdown.



The 'ADD HIERARCHICAL SET' dialog box contains two main input fields: 'Name:' with a required asterisk and a text input field 'Enter Name'; and 'Type:' with a required asterisk and a dropdown menu labeled 'Select Type'. At the bottom right are 'Cancel' and 'Save' buttons.

- b. Select **Document**.



The 'ADD HIERARCHICAL SET' dialog box shows the 'Type:' dropdown menu open, with 'Document' selected. Other options visible in the dropdown are 'Dossier' and 'Form'.

Note: The **Form** and **Dossier** types are to support other functions within the platform.

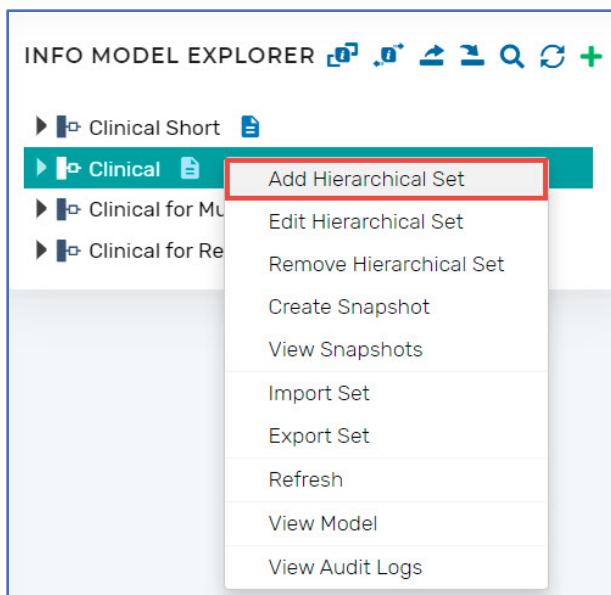
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c. Click **Save**.

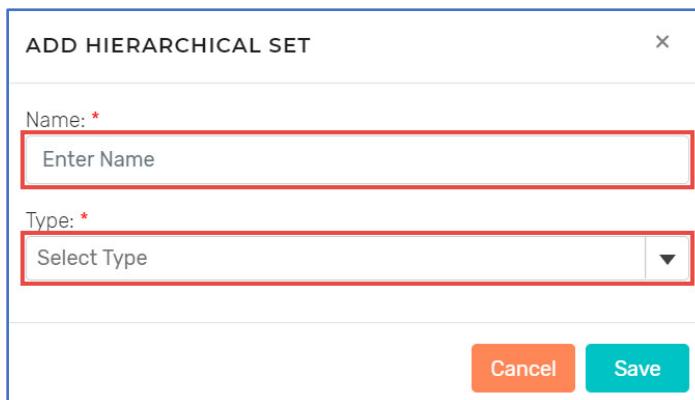


5. Right-click the newly added (or existing) parent hierarchical set (eg, for a business area) and click **Add Hierarchical Set** to add a child hierarchical set (eg, for a document).



6. Complete the form to add a child hierarchical set.

a. Enter a **Name** and click the **Type** dropdown.

A screenshot of the "ADD HIERARCHICAL SET" dialog box. It contains two fields: "Name:" with a red border around the input field "Enter Name", and "Type:" with a red border around the dropdown menu "Select Type". At the bottom are "Cancel" and "Save" buttons.

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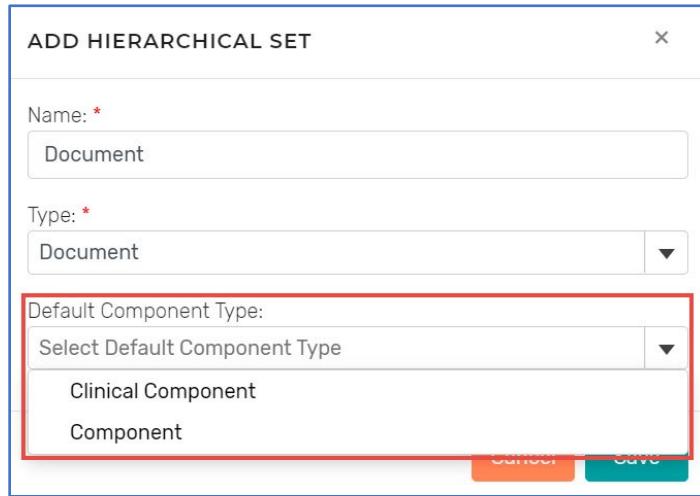
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b. Select **Document**.



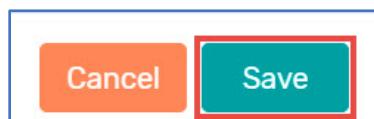
The screenshot shows the 'ADD HIERARCHICAL SET' dialog box. The 'Name:' field contains 'Enter Name'. The 'Type:' dropdown menu is open, showing three options: 'Document' (which is highlighted with a red box), 'Dossier', and 'Form'.

c. Select a **Default Component Type** (eg, **Component**, **Clinical Component**) that will be used as the default **Business Object** value for each element added to the set (see [Section 2.2](#) below for details).



The screenshot shows the 'ADD HIERARCHICAL SET' dialog box. The 'Name:' field contains 'Document'. The 'Type:' dropdown menu is open, showing 'Document'. Below it, the 'Default Component Type:' dropdown menu is open, showing 'Select Default Component Type' (highlighted with a red box), 'Clinical Component', and 'Component'.

d. Click **Save**.



7. Repeat Steps 3 to 6 to finish creating the new child hierarchical sets, as needed.

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2.2 ADDING ELEMENTS

There are various ways in which an element can be configured for a hierarchical set, depending on its anticipated type of content.

- **Placeholder element** - not intended for use within a template (eg, as a content component), but added to collect/group certain elements to assist with navigation of the hierarchical set.

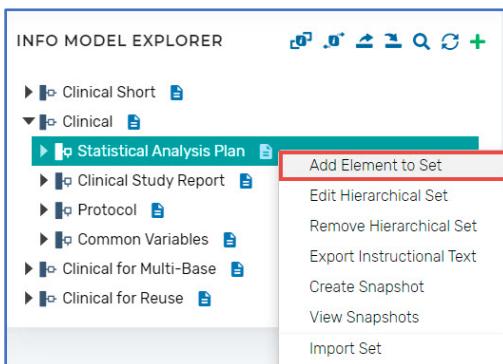
Note: Placeholder elements are not required but can be helpful to group elements, eg, elements that are typically included in the same section within a document.

- **Single de novo (new) content component** - new content added to a single component instance.
- **Repeating de novo content component** - new content added to multiple different instances (eg, objectives, endpoints).
- **Sequentially reused content component** - content reused from 1 document to another (eg, from protocol to statistical analysis plan [SAP]) will be auto inserted into the document during its generation.
- **Library reused content component** - content reused from a preconfigured library will be auto inserted into the document during its generation, based on prespecified metadata/property match.
- **Table component** - expected to contain a table which will contain multiple, individual content components. There are 2 different types of table elements that can be inserted into a template:
 - 'Hierarchical' set type table
 - 'Set In Relation' type table
- **Component Set** – a preconfigured grouping of components that can be reordered and inserted into a document under a single content control as part of a set.
- **Metadata/property-sourced component** - (also referred to as a variable in the generated document): a prespecified business object's property [value] is used to populate the content within the component (eg, protocol number, sponsor name, date-time).

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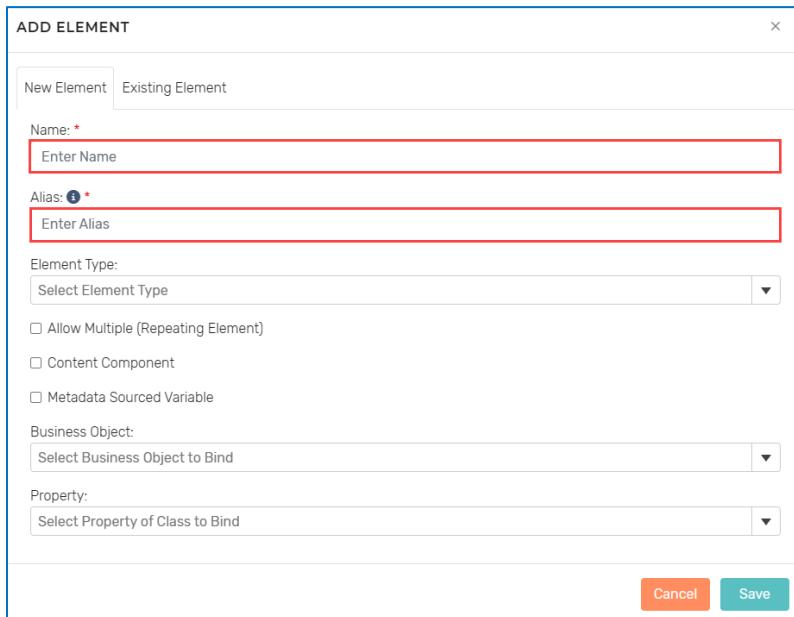
To add any type of element right-click a child hierarchical set (eg, for a document) and select **Add Element to Set**.



This will bring up the **Add Element** window. For detailed steps on how to fill out the various fields, see the subsections below, with instructions specific to each type of element to be configured and added to the system.

2.2.1 Placeholder Element

On the **Add Element** page, enter the **Name** and **Alias**. The following special characters are not allowed in the **Name**: ?, <, >, " and click **Save**.



Note: 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.

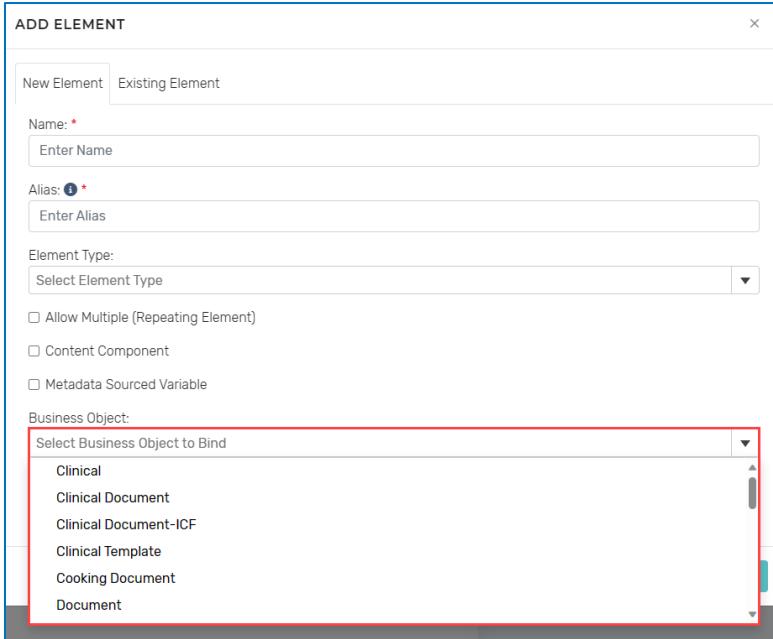
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2.2.1.1 Placeholder Element with Binding

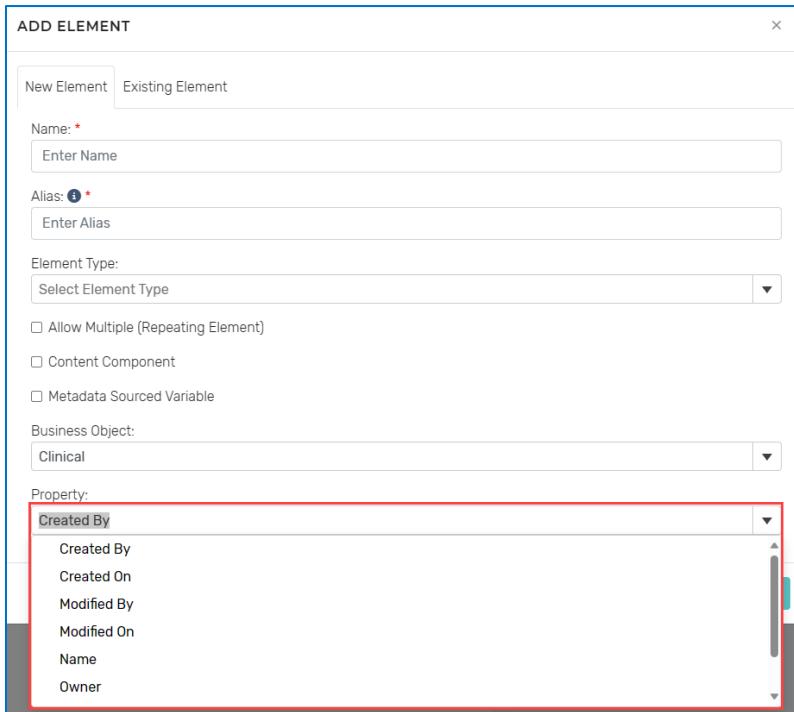
To bind a placeholder element to a specific type of business object, follow the steps listed below.

1. Select the applicable BO from the drop-down menu.



The screenshot shows the 'ADD ELEMENT' dialog box. In the 'Business Object:' section, a dropdown menu is open, listing several options: Clinical, Clinical Document, Clinical Document-ICF, Clinical Template, Cooking Document, and Document. The 'Clinical' option is the first item in the list and is highlighted with a red box.

2. Select the applicable property from the drop-down menu.

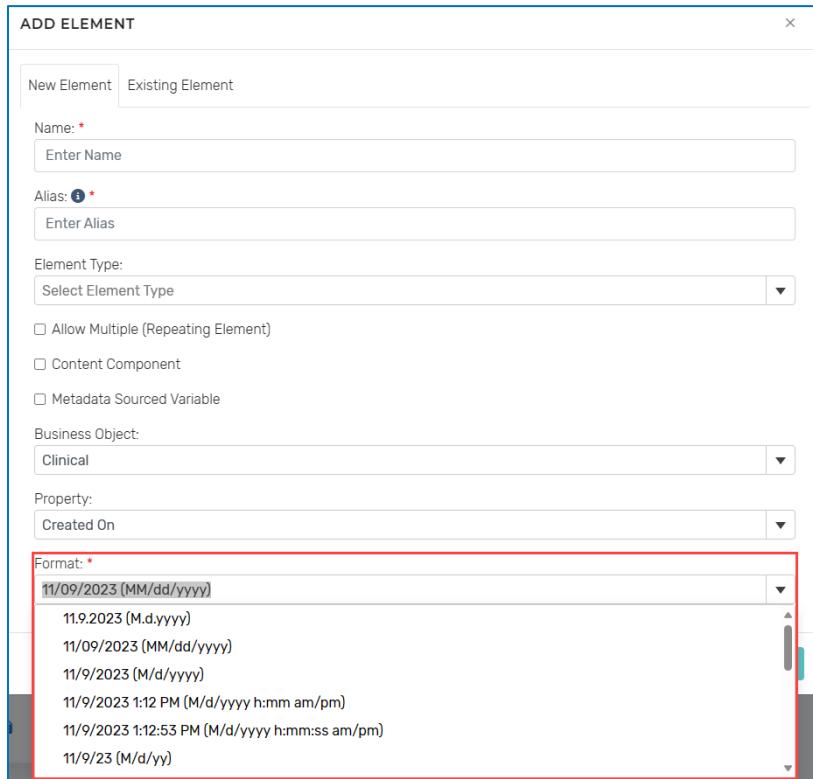


The screenshot shows the 'ADD ELEMENT' dialog box. In the 'Property:' section, a dropdown menu is open, listing several options: Created By, Created On, Modified By, Modified On, Name, and Owner. The 'Created By' option is the first item in the list and is highlighted with a red box.

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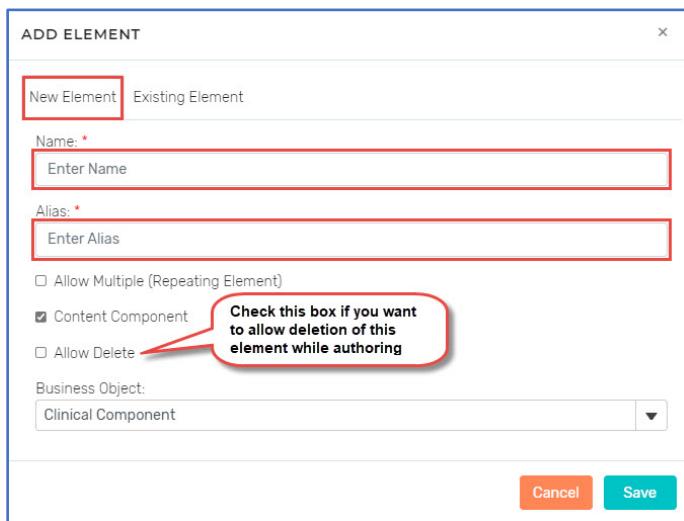
3. If the property selected contains a date, i.e. **Created On** or **Modified On**, select the date format from the drop-down menu and click **Save**.



The screenshot shows the 'ADD ELEMENT' dialog box. In the 'Property' section, 'Created On' is selected. Below it, the 'Format' dropdown is open, displaying various date and time formats. A red box highlights the dropdown menu.

2.2.2 Single de novo Content Component

1. On the **New Element** page, enter the **Name** and **Alias**.
2. Click the **Content Component** checkbox. If applicable, click the **Allow Delete** checkbox (this policy applies to the related component within the generated document). Click **Save**.

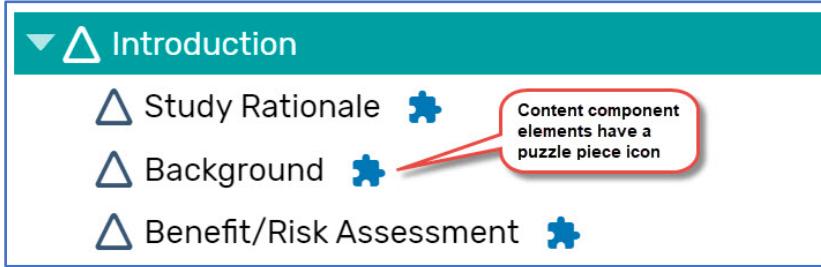


The screenshot shows the 'ADD ELEMENT' dialog box with the 'New Element' tab selected. The 'Name' and 'Alias' fields are highlighted with a red box. The 'Content Component' checkbox is checked and highlighted with a red box. A callout bubble points to the checkbox with the text: 'Check this box if you want to allow deletion of this element while authoring'. The 'Save' button is at the bottom right.

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3. After the element is saved, a  icon that indicates it is a content component will appear.

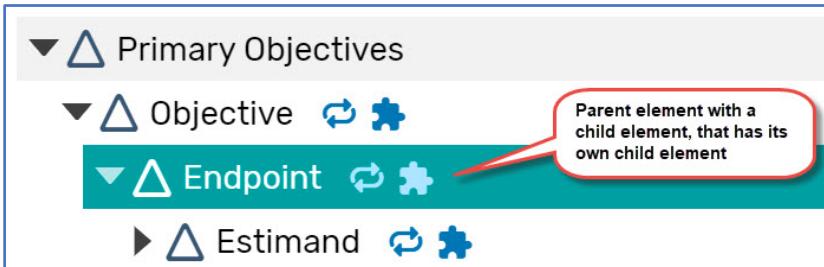


2.2.3 Repeating de novo Content Component

1. On the **New Element** page, enter the **Name** and **Alias** and click the **Allow Multiple** checkbox. If applicable, click the **Allow Delete** checkbox, and click **Save**.
2. After the element is saved, an additional icon that indicates it is a *repeating* content component appears.



Note: An element must be repeating if reuse of its instantiated component from multiple base documents of the same type (eg, CSR) into a single downstream document (eg, M2.7.4) is desired. If 2 or more repeating components are related and are intended to be included within a tabular format, they can be configured in a parent-child manner such that if/when a repeating parent element is added by a user, the child elements will be automatically added as well.

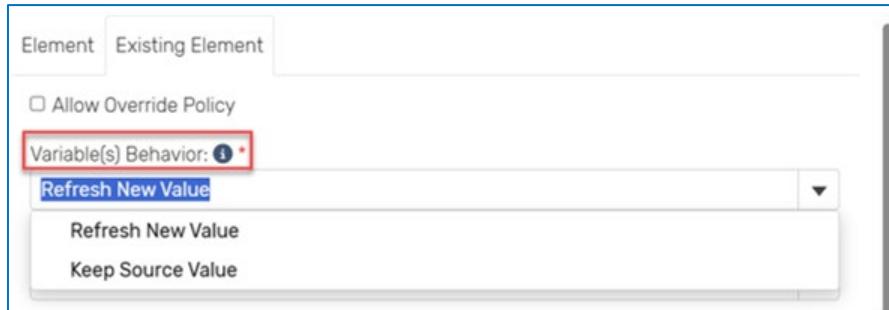


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2.2.4 Sequentially Reused Content Component

1. Click the **Existing Element** tab. Then, click on the **Variable(s) Behavior** and select the appropriate Variable behavior.

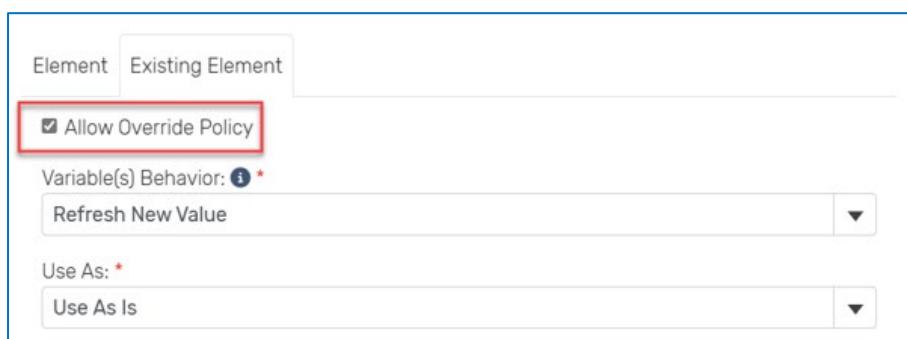


Note: Select either **Refresh New Value** (modification allowed) or **Keep Source Value** (modification not allowed) for Variable Behavior. **Refresh New Value** is selected as default.

2. Click the **Use As Is** dropdown and select the appropriate reuse policy.



Note: Select either **Repurpose** (modification allowed) or **Use As Is** (modification not allowed); the clone reuse policy is not used for sequential reuse. If the **Use As Is** reuse policy is selected, click the **Allow Override Policy** checkbox to allow the user to override the intended reuse policy for the component in the generated document.



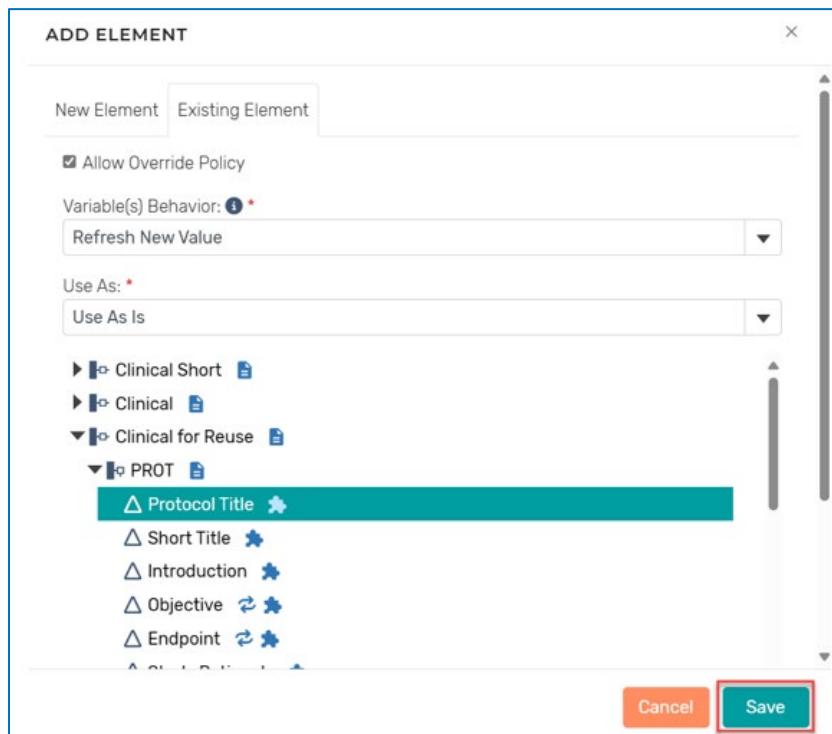
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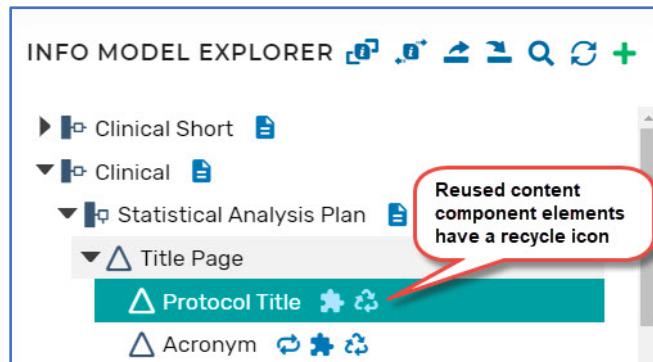
3. Expand another hierarchical set to locate the element to reuse, click on it to select/highlight it, and click **Save**.



Notes:

- A user can only reuse elements from a hierarchical set that is different from the one for which he/she is adding the new element.
- If an element has already been reused into the document, reuse from one hierarchical set into another will not be allowed.
- If a reused element with deleted instructional text is removed from the downstream document and is subsequently reused in a different location, the instructional text will re-associate and be present in the latest instance.

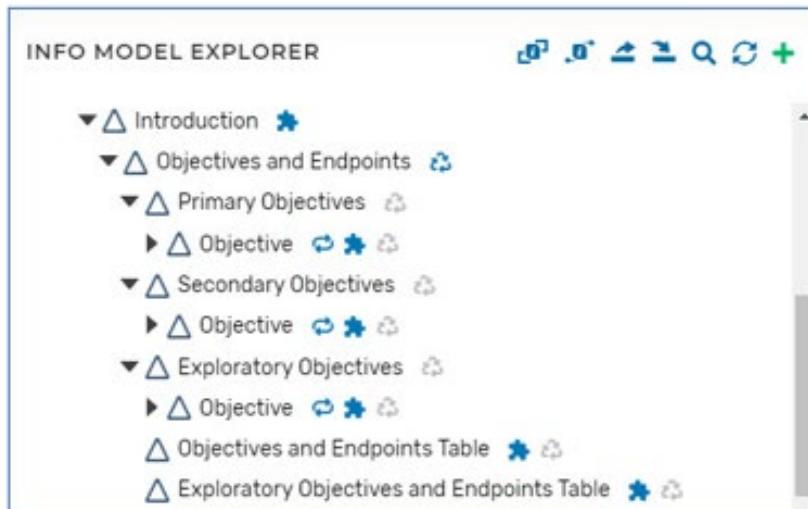
4. After the element is saved, an additional icon that indicates it is sequentially reused content will appear.



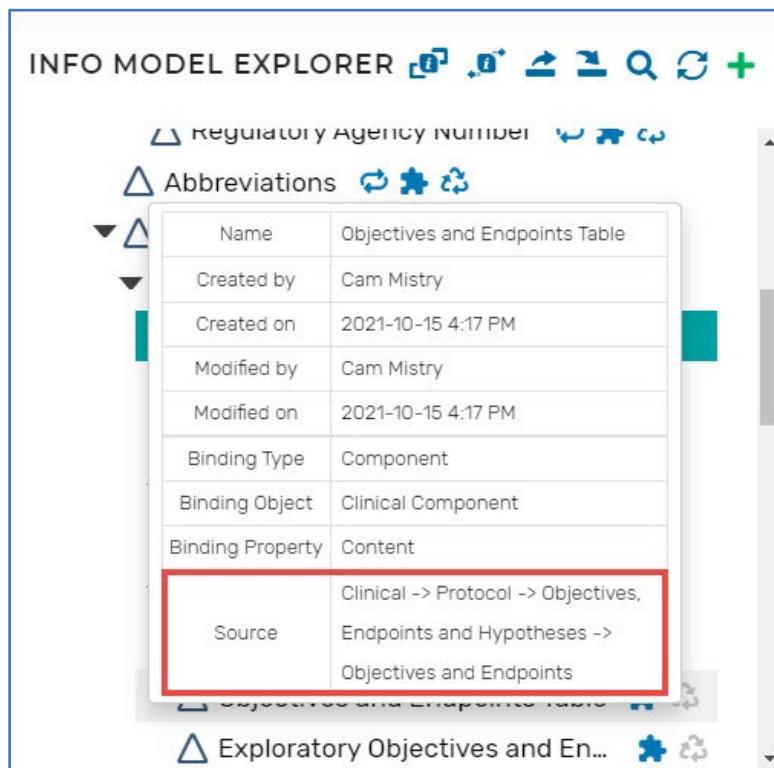
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Note: When an element for reuse includes 1 or more child elements, all child elements will be reused along with their parent and will display the **recycle icon** in gray.



Note: The source (e.g., Clinical Protocol) for a reused element will be displayed in a tooltip when hovering over the element with the cursor.



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2.2.4.1 Limitations and Known Behavior

See the following list for limitation and behavior of reused components.

- Whenever a component is ad hoc reused during authoring (via search, navigator or libraries), the behavior of any variable inside that reused component will always be **Refresh New Value**.
- When configuring the variables behavior for an element/component included in a table set, the SAME behavior (refresh vs keep source) will be applied for all components within the table set (just like their reuse policy).
- When configuring the variables behavior for an element/component included in a component set, *IF* the set is reused in its entirety, then the SAME behavior (refresh vs keep source) will be applied for all components within the component's set. IF the set's components are reused individually, however, then DIFFERENT behavior (refresh vs keep source) can be selected for the components within the component set (just like their reuse policy).
- When adding/updating an existing element to a document the user has the option to configure **Component Behavior** to decide whether the component should **Keep Source Value** or **Refresh New Value**. The default value is set to **Refresh New Value**. Please refer to the **Application Admin Guide Section 2.2.4** for further information on this option.
- After upgrade, the configuration for existing reused elements by default will set the **Variable(s) Behavior** value as **Refresh New Value**.
 - If an existing template is edited, reused elements will not show as **Modified** in the Info Model Status Report as a result of the upgrade.
- When configuring the variables behavior for an element/component that gets reused twice (eg, PROT-SAP-CSR), with **Keep Source Value** behavior then the source will always be considered as an immediate upstream/parent document.
- If reused components contain the same variable, but with different behavior assigned (ie, 1 has "Keep Source Value" and other has "Refresh Value"), the variable value in the reused components in the child document will have different values (they will not sync with one another).
- If a component containing the same variable is also reused manually while authoring, its value will always refresh to current document's context and have no effect on existing variables within existing components in the document.

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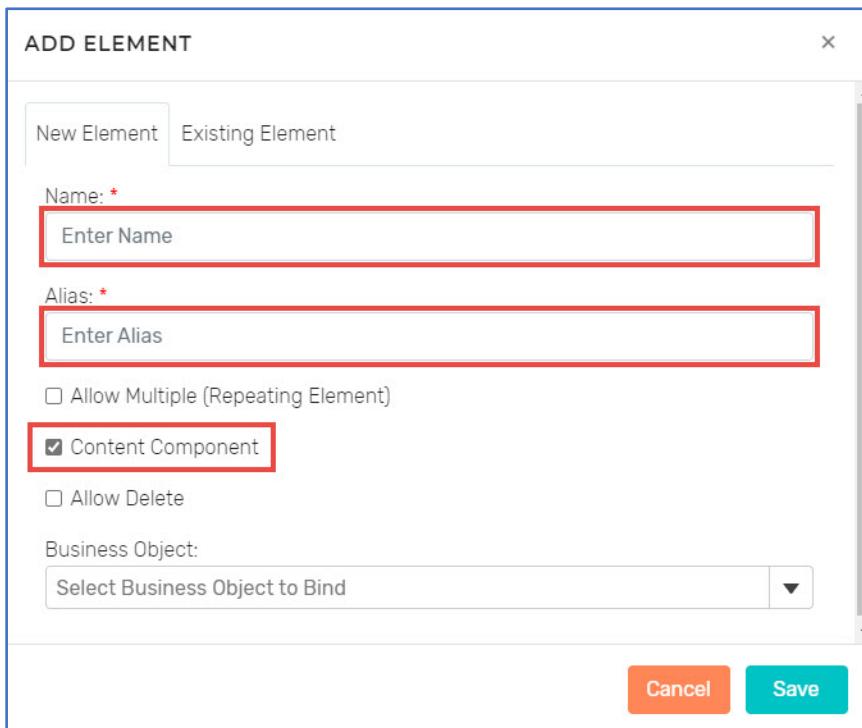
2.2.5 Library Reused Content Component

Before this type of element can be configured, a few prerequisites must be met:

- To be used for library component auto-insertion, an appropriate **managed library** must be available (see [Section 5.1](#) for details).
Note: The individual library components can be added later (see [Section 6](#) for details).
- The intended property (eg, condition) to be used for auto-inserting the relevant library component into the document must be bound to the related component's business object class.
- Once the individual library components are added to a library, an appropriate property value must be assigned to match against the document during its generation. The library component may be assigned multiple property values (eg, Phase 1, Phase 1b, Phase 1/2) if it is intended to be used for multiple matches.

After all prerequisites are met, an element for a library reused content component may be added as follows:

1. On the Add Element page, enter the **Name** and **Alias**. Then click the **Content Component** checkbox. If applicable, click the **Allow Delete** checkbox.



The screenshot shows the 'ADD ELEMENT' dialog box. It has two tabs at the top: 'New Element' (selected) and 'Existing Element'. Below are input fields:

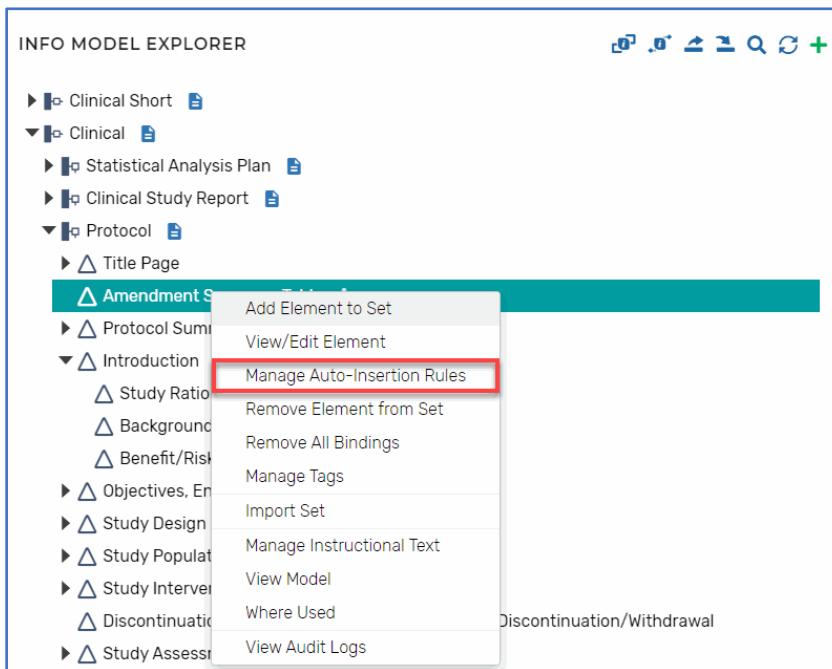
- Name:** * Enter Name
- Alias:** * Enter Alias
- Allow Multiple (Repeating Element)
- Content Component
- Allow Delete
- Business Object:** Select Business Object to Bind

At the bottom are 'Cancel' and 'Save' buttons.

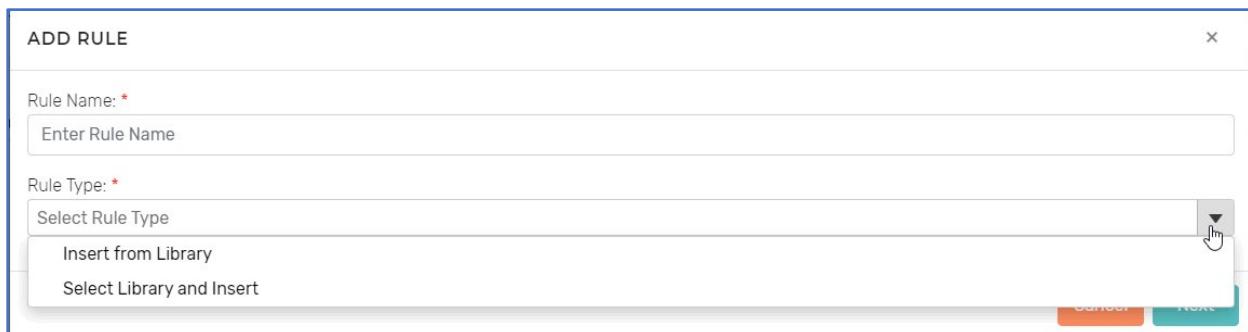
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2. After the component is created an auto-insertion rule can be applied. On the right-click option on the info model component select **Manage Auto-Insertion Rules**.



3. To create a rule, click on the  sign and the **ADD RULE** window will open.



4. Enter a name for the rule and select the **Rule Type**:

- Insert From Library
 - In the **Next** screen select the **Initiation Library**, the **Reuse Policy** (as-is or Repurposed) and the **Initiation Criteria**.
 - Select the initiation criteria to match.

Note: Typically, a 'metadata' property is used. A 'Yes/No' property should not be used because explicit 'yes' and 'no' values cannot be matched between a library component and a document. Refer to the **InteliNotion Application Admin Guide** for details on business object properties.

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ADD RULE

Initiation Library: *	Reuse Policy: *
2023 R1 TC 459500	Use As Is

Select one or more library component property(ies) to match against document property(ies). You can drag and drop the selected property(ies) to specify the order in which the match will be performed.

Initiation Criteria: *	Match Empty Value(s)
Compound Number	<input type="checkbox"/> X
OR	
Country 2021 Q4	<input type="checkbox"/> X
+ Add Another	

Cancel **Previous** **Save**

- iii. Check **Match Empty Value(s)** if the intention is to insert a library component that doesn't have that property populated (eg in the below example the component will be inserted if the **Compound Number** matches, or the **Country** matches).

ADD RULE

Initiation Library: *	Reuse Policy: *
2023 R1 TC 459500	Use As Is

Select one or more library component property(ies) to match against document property(ies). You can drag and drop the selected property(ies) to specify the order in which the match will be performed.

Initiation Criteria: *	Match Empty Value(s)
Compound Number	<input checked="" type="checkbox"/> X
OR	
Country 2021 Q4	<input type="checkbox"/> X
+ Add Another	

Cancel **Previous** **Save**

- iv. Another rule can be defined by clicking the **+Add Another** button (see above example), up to a limit of five. The following conditions apply, depending on the configuration of the rules, as listed below:

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- The system will execute the rules in OR condition in the order they are listed, ie *InteliNotion* will first look for the initiation criteria using the first row and if the component is not found, will look for the second rule, etc.
- Note:** To change the order of execution, drag and drop the rules into the desired order of execution.
- If the **Match Empty Value(s)** option is not checked, the selected properties will be executed with the AND condition such that only the component with all matching properties will be inserted. If there is more than one component that matches the conditions, the latest modified component will be inserted.
 - If the **Match Empty Values(s)** option is selected, the rule execution will use the properties in the specified order as shown below.

ADD RULE

Initiation Library: *	Reuse Policy: *
001 Test Managed Library	Use As Is
Select one or more library component property(ies) to match against document property(ies). You can drag and drop the selected property(ies) to specify the order in which the match will be performed.	
Initiation Criteria: *	Match Empty Value(s)
3 values selected	<input checked="" type="checkbox"/>
Therapeutic Area Study Phase Protocol Number	
+ Add Another	
<input type="checkbox"/> Allow Reuse Policy Override	
i Cancel Previous Save	

- Find the components with all the selected set of properties (shown above) in the initiation criteria with exact match.
- If the component is not found, the rule execution will search for the component with exact match of all properties except the last property listed and will consider the value for the last property as empty (ie, partial match). This process repeats, as shown in the below example, following the order of properties listed.

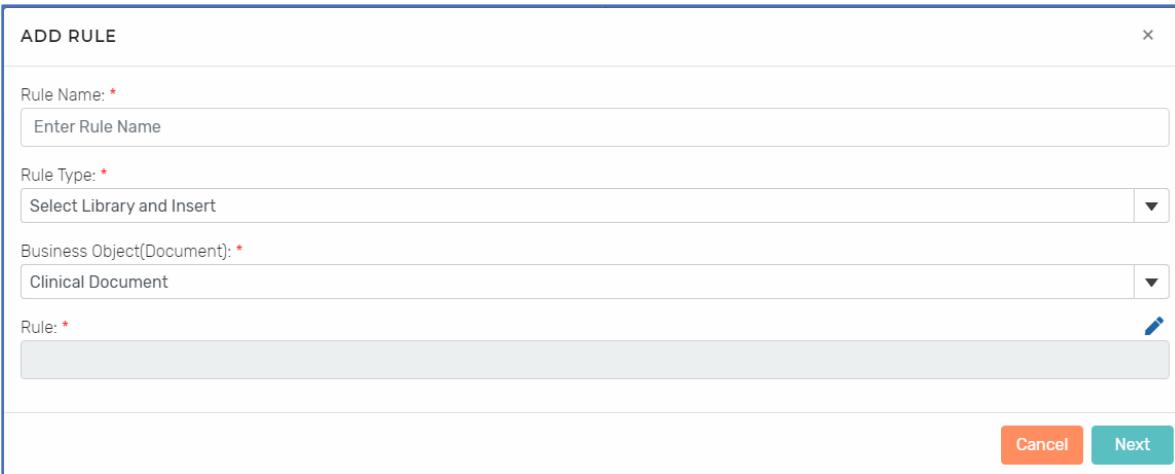
Properties	Search							
	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th
Therapeutic Area	✓	✓	✓	✓	✗	✗	✗	✗
Study Phase	✓	✓	✗	✗	✓	✓	✗	✗
Protocol Number	✓	✗	✓	✗	✓	✗	✓	✗

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b. Select **Library** and **Insert**

- This option allows the user to select a library based on a rule to insert a component.
- A **Business Object** needs to be selected for which the rule should be applied (eg, **Clinical Document**).



ADD RULE

Rule Name: *

Enter Rule Name

Rule Type: *

Select Library and Insert

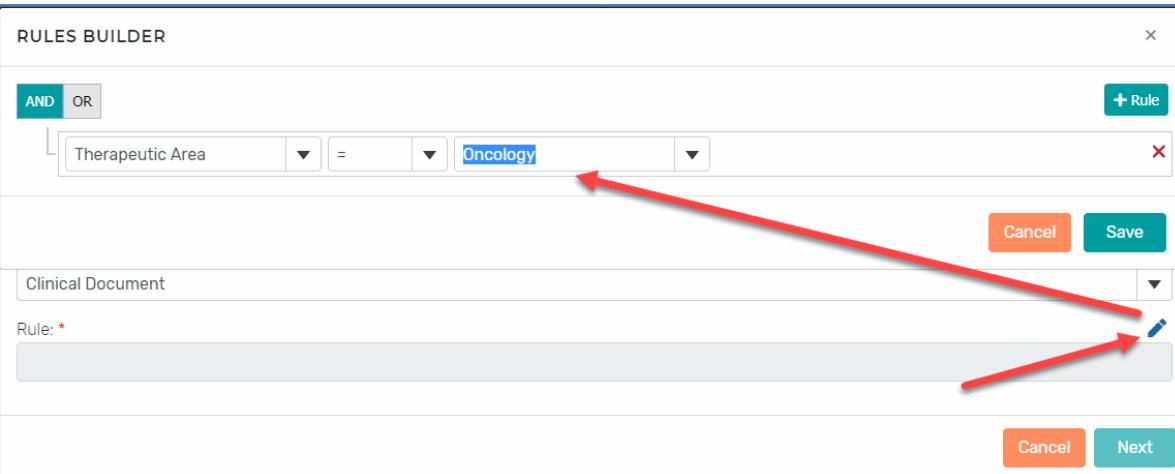
Business Object(Document): *

Clinical Document

Rule: *

Cancel Next

- The library selection rule(s) needs to be specified (eg, **Therapeutic Area = Oncology**).



RULES BUILDER

AND OR

Therapeutic Area = Oncology

Clinical Document

Rule: *

Cancel Save

Cancel Next

- In the **Next** screen, the component selection must be specified as in the **Insert from Library** above.

Notes:

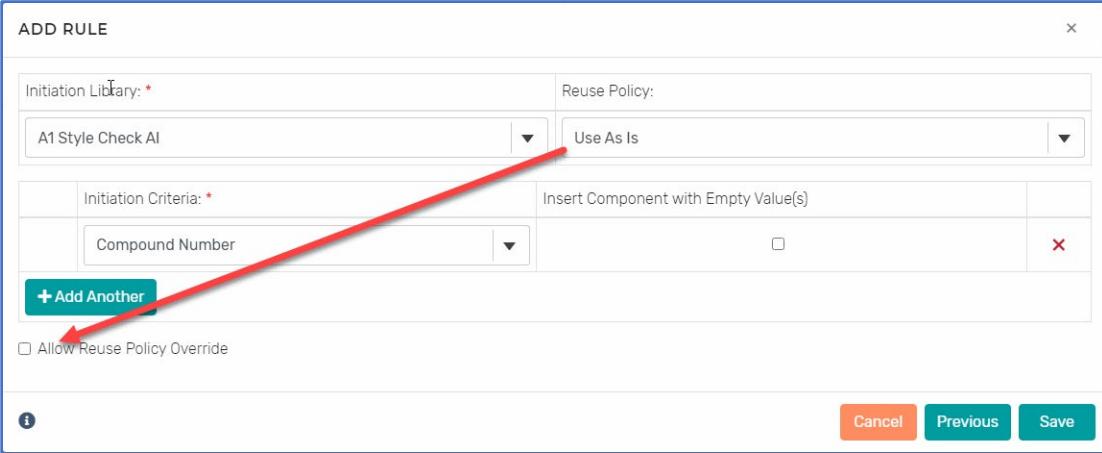
- Up to 5 rules can be defined and are processed in display order. Rules can also be rearranged to change the processing order.
- If the selected **Library Policy** is **Use As Is**, an **Allow Library Policy Override** checkbox is displayed. If this box is checked, the user will be able to override

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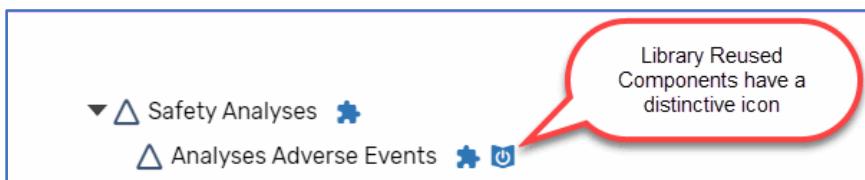
this reuse policy restriction for the component within the generated document, after entering a rationale for doing so.

- Multiple values can be selected for **Property Binding**. If multiple values are selected, the library component will insert only if all selected properties have a matching value.



The screenshot shows the 'ADD RULE' dialog box. It has two main sections: 'Initiation Library:' and 'Reuse Policy'. Under 'Initiation Library:', 'A1 Style Check AI' is selected. Under 'Reuse Policy', 'Use As Is' is selected. Below these, there's a section for 'Initiation Criteria:' with 'Compound Number' listed. A red arrow points from the text above to the 'Add Another' button in this section. At the bottom, there's a checkbox for 'Allow Reuse Policy Override' and three buttons: 'Cancel', 'Previous', and 'Save'.

- After the element is saved, an additional icon that indicates it is a library reused content component will appear.



2.2.6 Metadata/Property-Sourced Component

Before this type of element can be configured, the intended metadata/property to be used as the content source must be bound to the relevant business object class (see Step 2 below).

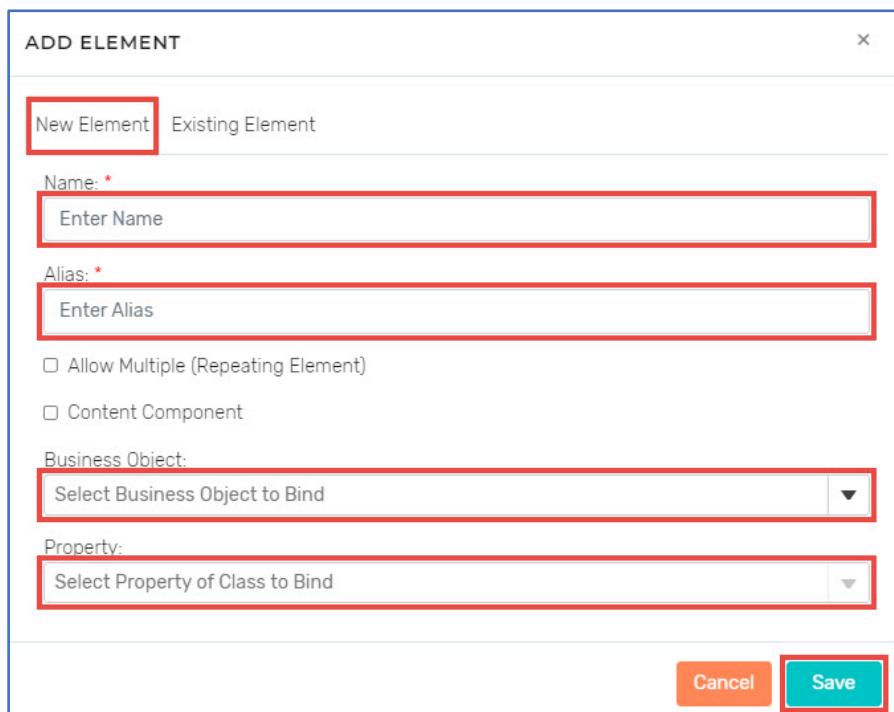
After the prerequisite is met, an element for a metadata/property-sourced component may be added as listed below.

- On the **New Element** page, enter the **Name** and **Alias**.
- Click the Business Object dropdown to select the relevant business object from which the related property value will be used for content (eg, **Clinical Document, Study**).

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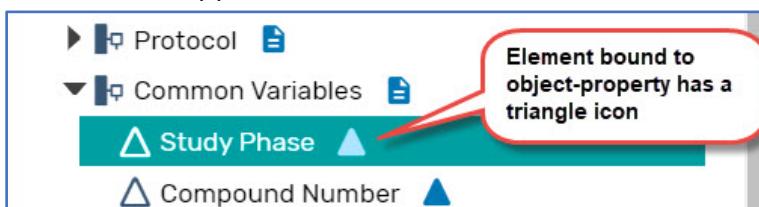
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3. Click the **Property** dropdown to select the related property itself (eg, protocol number, sponsor name), and click **Save**.



The screenshot shows the 'ADD ELEMENT' dialog box. At the top, there are two tabs: 'New Element' (which is selected and highlighted with a red box) and 'Existing Element'. Below the tabs, there are input fields for 'Name:' (with a red box around it) and 'Alias:' (also with a red box). There are also several checkboxes: 'Allow Multiple (Repeating Element)' and 'Content Component'. Under 'Business Object:', there is a dropdown menu labeled 'Select Business Object to Bind' with a red box around it. Similarly, under 'Property:', there is another dropdown menu labeled 'Select Property of Class to Bind' with a red box around it. At the bottom right of the dialog box are two buttons: 'Cancel' (orange) and 'Save' (green).

4. After the element is saved, an icon that indicates it is an object-property bound component or variable appears.



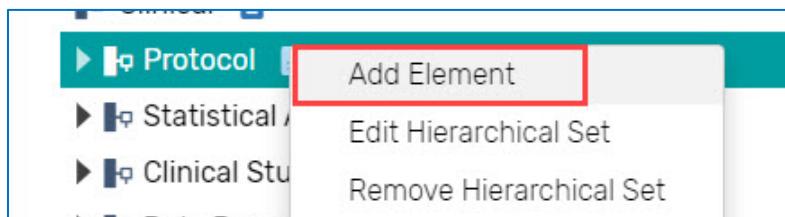
2.2.7 Adding a Table Type Element

Follow the steps listed below to add a table type element.

2.2.7.1 Adding a Hierarchical Type Table Set to the Info Model

Hierarchical type tables support parent-child elements. The user can add up to two levels of elements under the hierarchical type element.

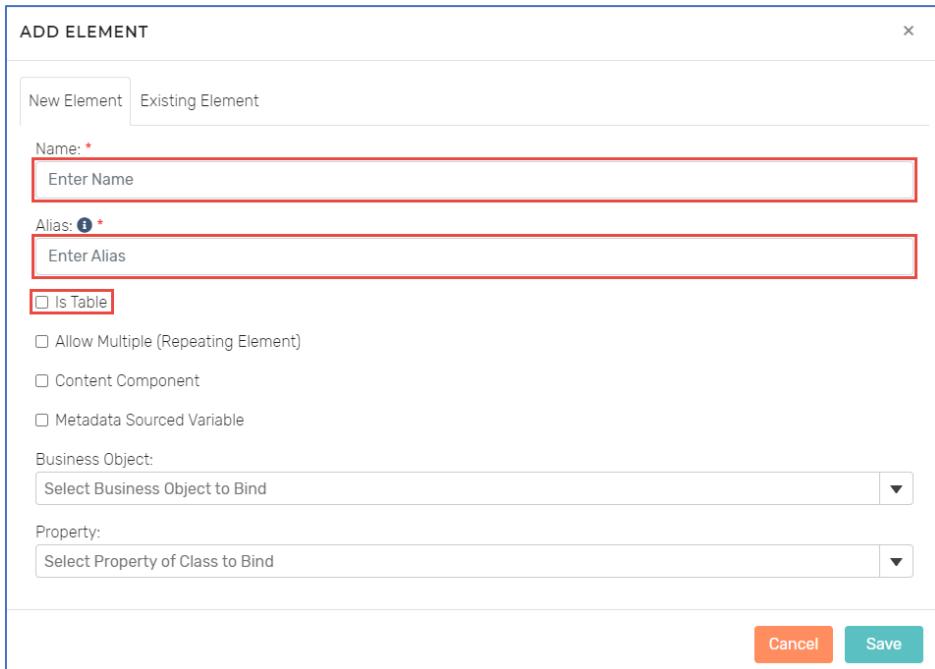
1. Right-click on the parent hierarchical set to add an element.



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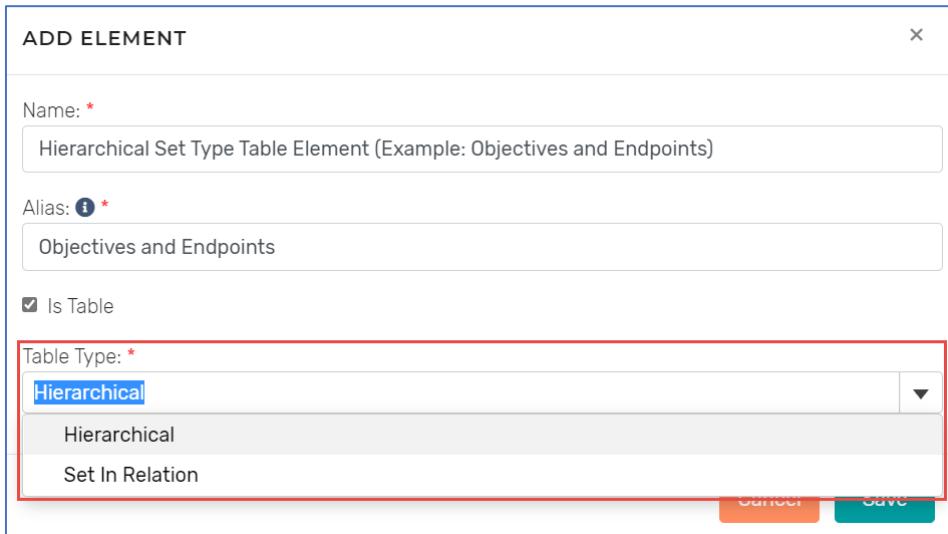
2. On the **Add Element** page, enter the **Name** and **Alias** and check the **Is Table** checkbox.



The screenshot shows the 'ADD ELEMENT' dialog box. At the top, there are two tabs: 'New Element' (selected) and 'Existing Element'. Below these are fields for 'Name:' (containing 'Enter Name') and 'Alias:' (containing 'Enter Alias'), both with red borders around them. A checkbox labeled 'Is Table' is checked and highlighted with a red border. Below these are three unchecked checkboxes: 'Allow Multiple (Repeating Element)', 'Content Component', and 'Metadata Sourced Variable'. Under 'Business Object:', there is a dropdown menu set to 'Select Business Object to Bind'. Under 'Property:', there is another dropdown menu set to 'Select Property of Class to Bind'. At the bottom right are 'Cancel' and 'Save' buttons.

3. The display will change to display drop-down options for **Table Type** selection:

- Hierarchical
- Set in Relation



The screenshot shows the 'ADD ELEMENT' dialog box with the 'Is Table' checkbox checked. Below it is a dropdown menu labeled 'Table Type:' with the value 'Hierarchical' selected. The dropdown menu also contains the options 'Hierarchical' and 'Set In Relation', which are highlighted with a red border. At the bottom right are 'Cancel' and 'Save' buttons.

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4. Select **Hierarchical** from the drop-down and click **Save** to add the element. This will be the table element for the hierarchical type table set.

ADD ELEMENT

Name: *
Hierarchical Set Type Table Element (Example: Objectives and Endpoints)

Alias:  *
Objectives and Endpoints

Is Table

Table Type: *
Hierarchical

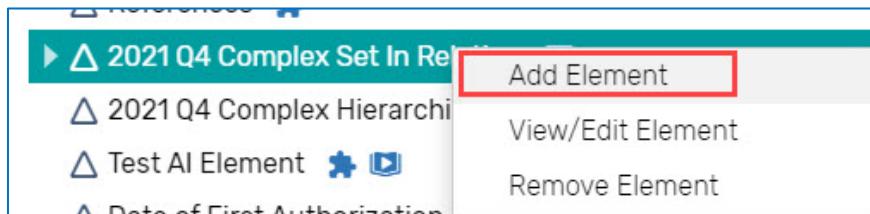
Cancel **Save**

Note: Table elements should be added under this set. Table type elements are indicated by the following icon .

▼  Protocol 

 Hierarchical Set Type Table Element (Example: Objectives and Endpoints) 

5. Right-click on the newly added table set and select the **Add Element** option to add a first level element to this set.



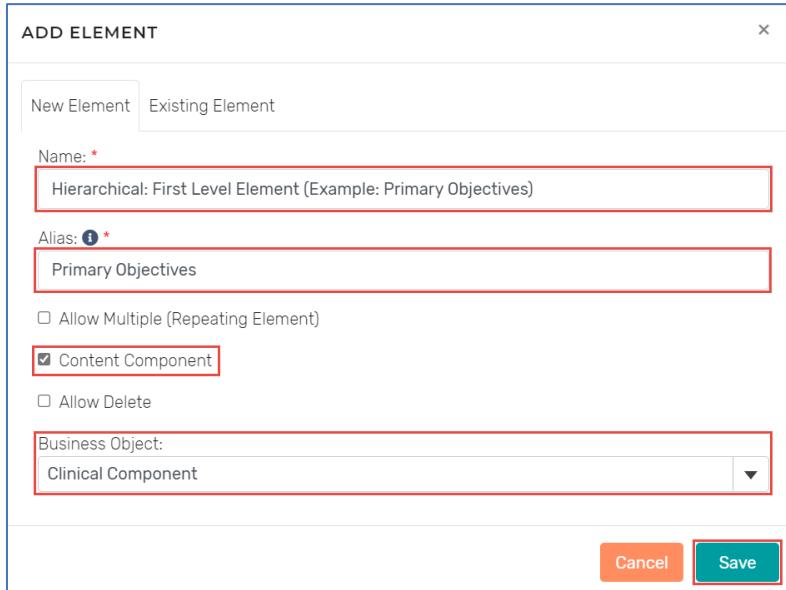
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6. On the **Add Element** page, enter the **Name** and **Alias**. Then click the **Content Component** checkbox. If applicable, Confirm **Business Object** selection and click **Save**.



ADD ELEMENT

New Element Existing Element

Name: * Hierarchical: First Level Element (Example: Primary Objectives)

Alias: Primary Objectives

Allow Multiple (Repeating Element)

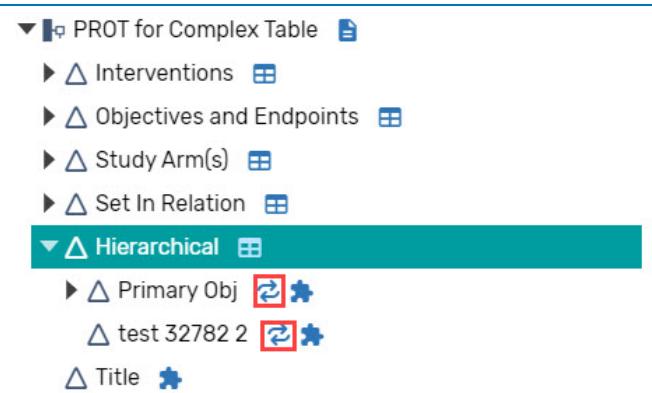
Content Component

Allow Delete

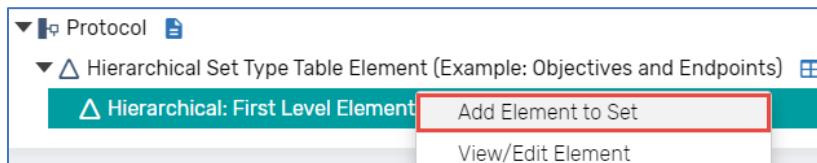
Business Object: Clinical Component

Cancel Save

Note: All table elements inserted under a table component will always be **Allow Multiple (Repeating Element)** regardless of the checkbox appearing unchecked during time of element creation. After the element is saved, the user will see the repeating icon beside the table element.



7. Right-click on the newly added table element and select **Add Element to Set** option to add a second level element to this set.



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8. On the **Add Element** page, enter the **Name** and **Alias**. Then click the **Content Component** checkbox.

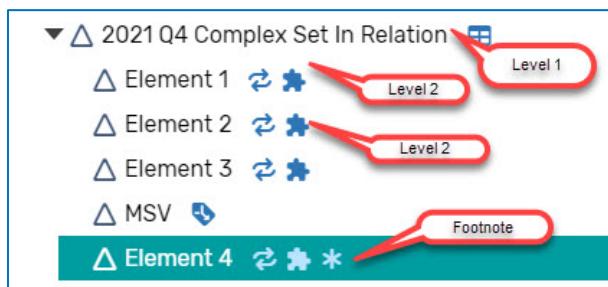
ADD ELEMENT

Name: *	<input type="text" value="Enter Name"/>
Alias: ⓘ *	<input type="text" value="Enter Alias"/>
<input type="checkbox"/> Allow Multiple (Repeating Element) <input checked="" type="checkbox"/> Content Component <input type="checkbox"/> Allow Delete <input type="checkbox"/> Is Footnote	
Business Object: <input type="text" value="Clinical Component"/>	
<input type="button" value="Cancel"/> <input type="button" value="Save"/>	

9. *IF* applicable, and the element to be added will become a footnote in the complex table, check the **Is Footnote** box. Confirm **Business Object** selection and click **Save**.

ADD ELEMENT

Name: *	<input type="text" value="Element 4"/>
Alias: ⓘ *	<input type="text" value="Endpoints Footnote"/>
<input type="checkbox"/> Allow Multiple (Repeating Element) <input checked="" type="checkbox"/> Content Component <input type="checkbox"/> Allow Delete <input checked="" type="checkbox"/> Is Footnote	
Business Object: <input type="text" value="Clinical Component"/>	
<input type="button" value="Cancel"/> <input type="button" value="Save"/>	



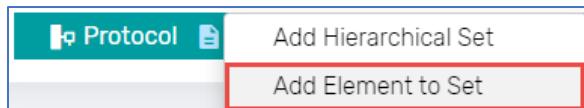
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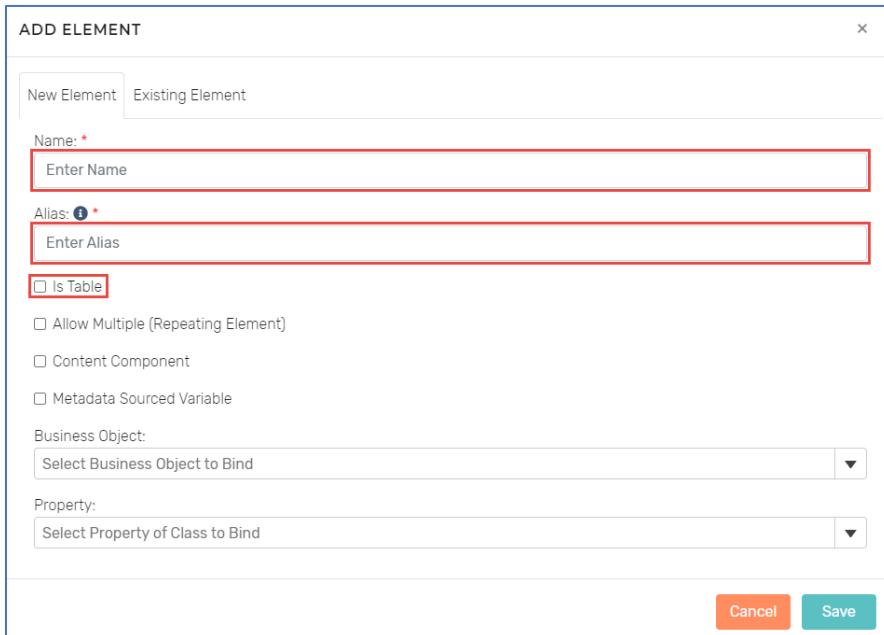
2.2.7.2 Adding a Set in Relation Type Table Set to the Info Model

A user can only add one level of elements under the **Set in Relation** type element. Parent-child elements are not supported in this table type element.

1. Right-click on the parent hierarchical set to add an element.



2. On the **Add Element** page, enter the **Name** and **Alias** and check the **Is Table** checkbox.



ADD ELEMENT

New Element Existing Element

Name: *
Enter Name

Alias: ⓘ *
Enter Alias

Is Table

Allow Multiple (Repeating Element)

Content Component

Metadata Sourced Variable

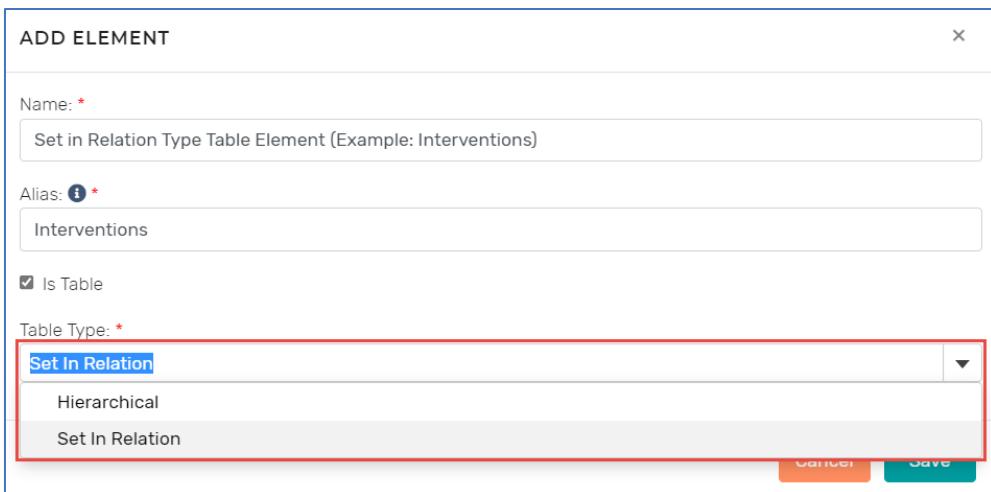
Business Object:
Select Business Object to Bind

Property:
Select Property of Class to Bind

Cancel Save

3. The display will change to display drop-down options for Table Type selection:

- Hierarchical
- Set in Relation



ADD ELEMENT

Name: *
Set in Relation Type Table Element (Example: Interventions)

Alias: ⓘ *
Interventions

Is Table

Table Type: *
 Set In Relation
 Hierarchical
 Set In Relation

Cancel Save

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4. Select **Set in Relation** from the drop-down and click **Save** to add the element. This will be the table element for the **Set in Relation** type table set.



ADD ELEMENT

Name: *
Set in Relation Type Table Element (Example: Interventions)

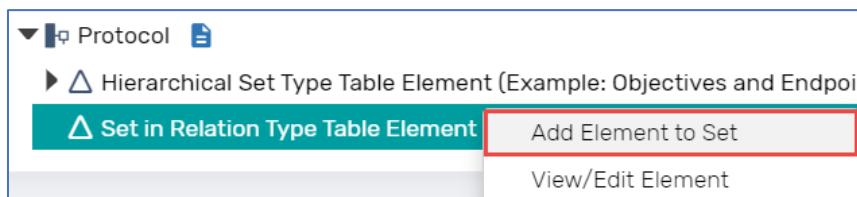
Alias: ⓘ *
Interventions

Is Table

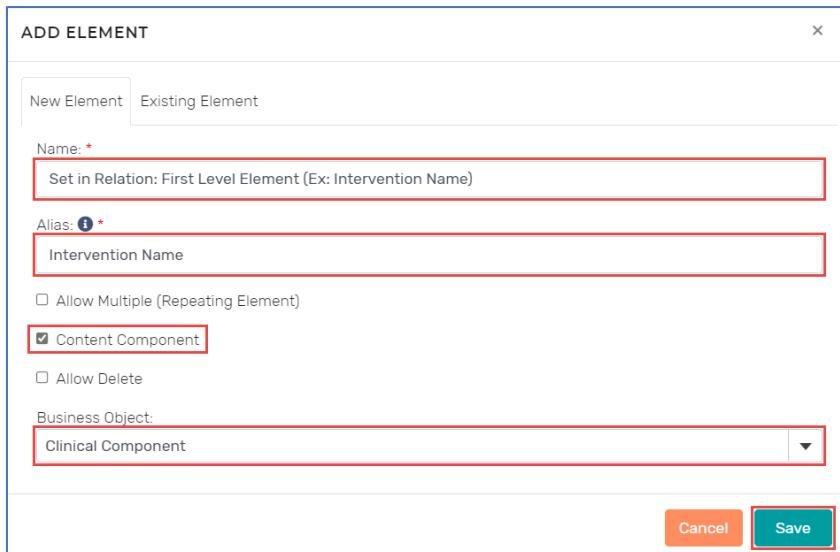
Table Type: *
Set In Relation

Cancel **Save**

5. Right-click on the newly added table set and select **Add Element to Set** option to add a first level element to this set.



6. On the **Add Element** page, enter the **Name** and **Alias**. Then click the **Content Component** checkbox. Confirm the **Business Object** selection and click **Save**.



ADD ELEMENT

New Element Existing Element

Name: *
Set in Relation: First Level Element (Ex: Intervention Name)

Alias: ⓘ *
Intervention Name

Allow Multiple (Repeating Element)

Content Component

Allow Delete

Business Object:
Clinical Component

Cancel **Save**

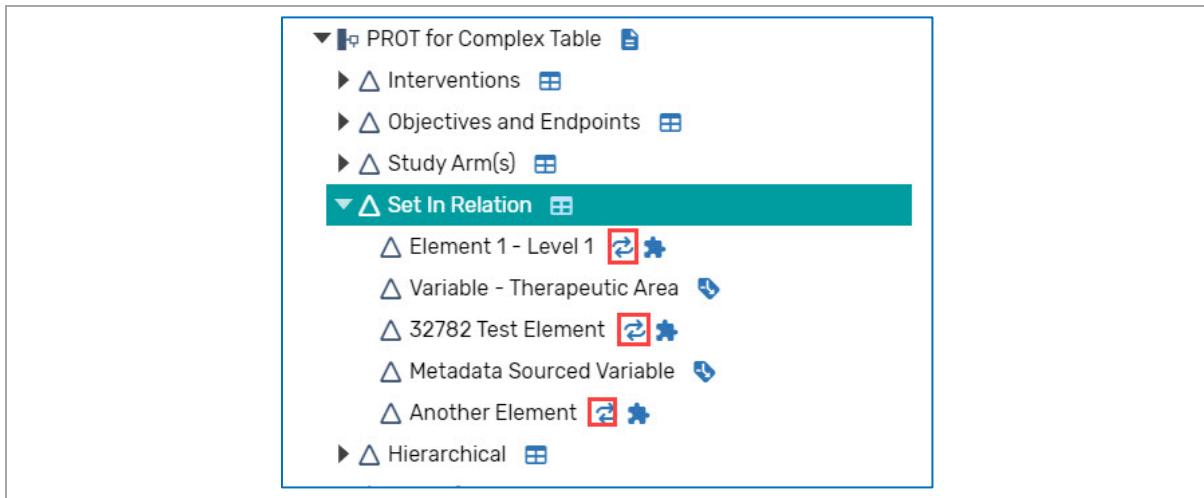
Note: All table elements inserted under a table component will always be **Allow Multiple (Repeating Element)** regardless of the checkbox appearing unchecked during time of element creation. After element is saved, the user will see the repeating icon beside the table element.

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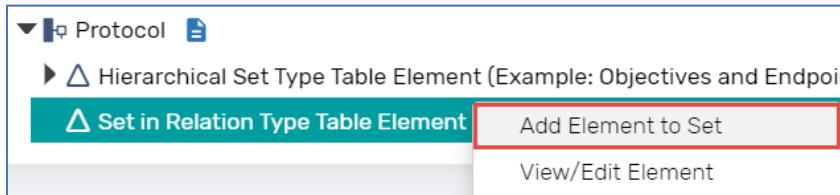
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The screenshot shows a hierarchical tree structure within a blue-bordered box. At the top level is 'PROT for Complex Table'. Below it are three items: 'Interventions', 'Objectives and Endpoints', and 'Study Arm(s)'. Under 'Objectives and Endpoints' is a sub-item 'Set In Relation'. This item has several children: 'Element 1 - Level 1', 'Variable - Therapeutic Area', '32782 Test Element', 'Metadata Sourced Variable', and 'Another Element'. The 'Element 1 - Level 1' and '32782 Test Element' items are highlighted with red boxes around their icons.

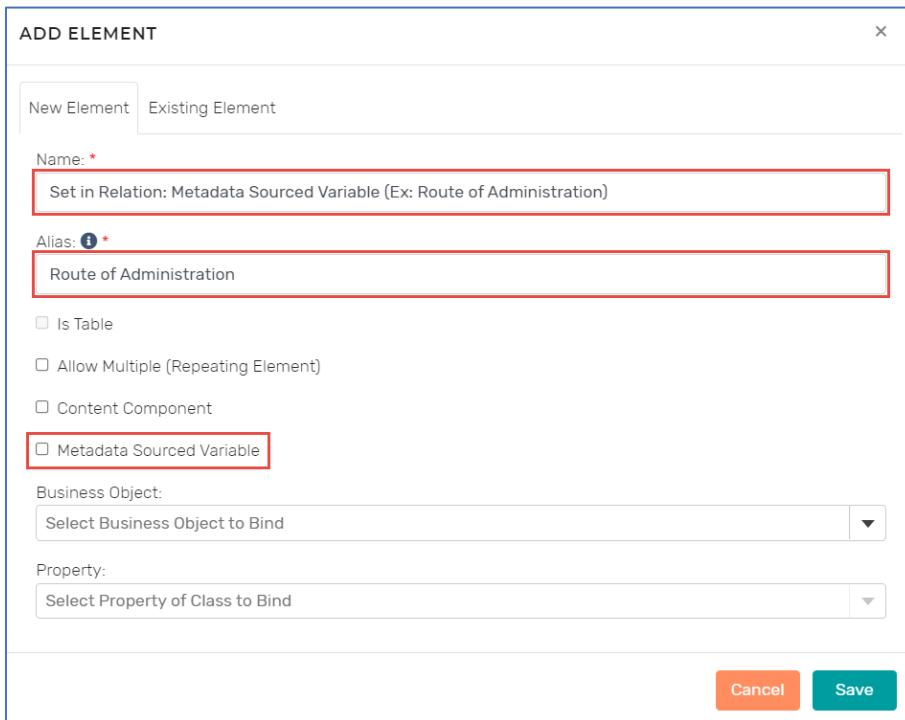
2.2.7.3 Adding a Metadata Sourced Variable to a Table Type Element in the Info Model

1. Right-click on the table placeholder element to add an element to the set.



The screenshot shows a list of table type elements. The 'Set in Relation Type Table Element' option is highlighted with a red box. A tooltip 'Add Element to Set' is displayed above the list, and a button 'View/Edit Element' is at the bottom right.

2. On the **Add Element** page, enter the **Name** and **Alias**, then check the **Metadata Sourced Variable** checkbox.



The screenshot shows the 'ADD ELEMENT' dialog box. It has tabs for 'New Element' and 'Existing Element', with 'New Element' selected. The 'Name:' field contains 'Set in Relation: Metadata Sourced Variable (Ex: Route of Administration)' and is highlighted with a red box. The 'Alias:' field contains 'Route of Administration' and is also highlighted with a red box. There are several checkboxes at the bottom left: 'Is Table', 'Allow Multiple (Repeating Element)', 'Content Component', and 'Metadata Sourced Variable', which is checked and highlighted with a red box. The 'Business Object:' section has a dropdown 'Select Business Object to Bind'. The 'Property:' section has a dropdown 'Select Property of Class to Bind'. At the bottom right are 'Cancel' and 'Save' buttons.

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3. Click on the pencil icon to open the **Metadata Catalog Explorer**.

ADD ELEMENT

New Element Existing Element

Name: *
Set in Relation: Metadata Sourced Variable (Ex: Route of Administration)

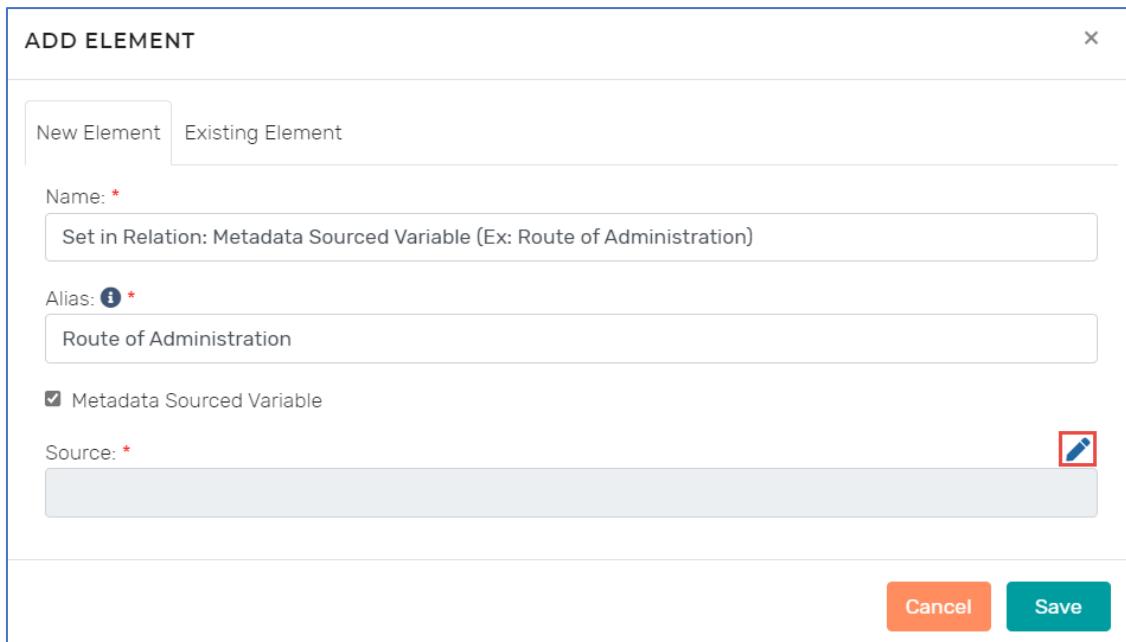
Alias: ⓘ *

Route of Administration

Metadata Sourced Variable

Source: *

Cancel Save



4. Navigate through the **Metadata Catalog Explorer**, select the desired source and click **Save**.

METADATA CATALOG EXPLORER

► 📁 Metadata

Cancel Save

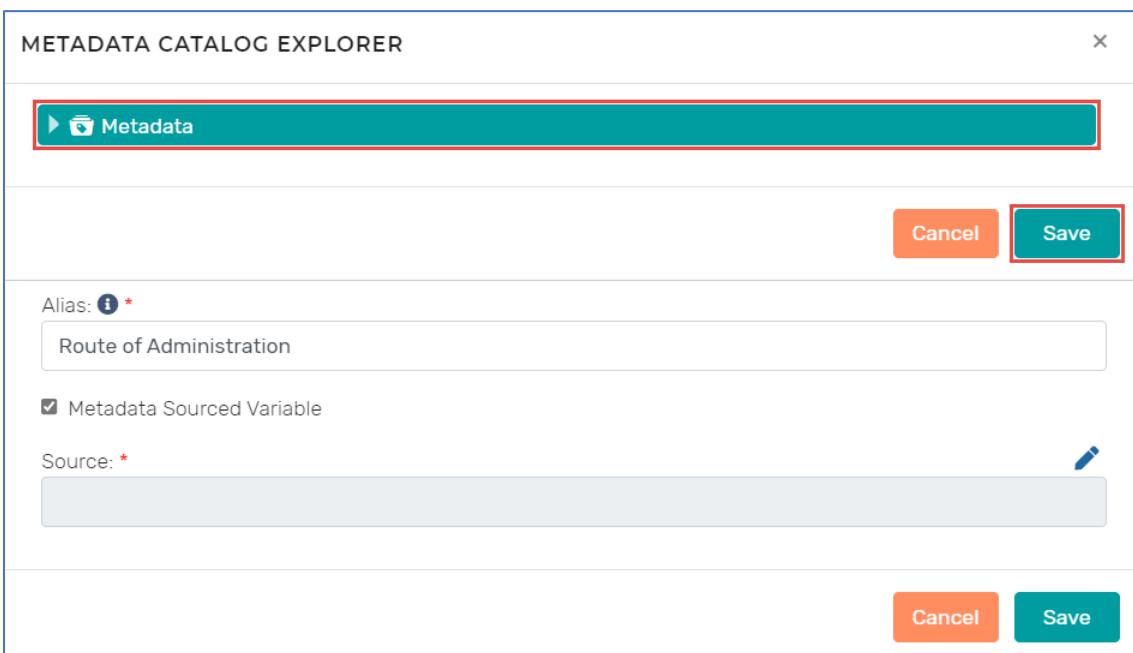
Alias: ⓘ *

Route of Administration

Metadata Sourced Variable

Source: *

Cancel Save



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5. Click **Save** on the **Add Element** page.

ADD ELEMENT

New Element Existing Element

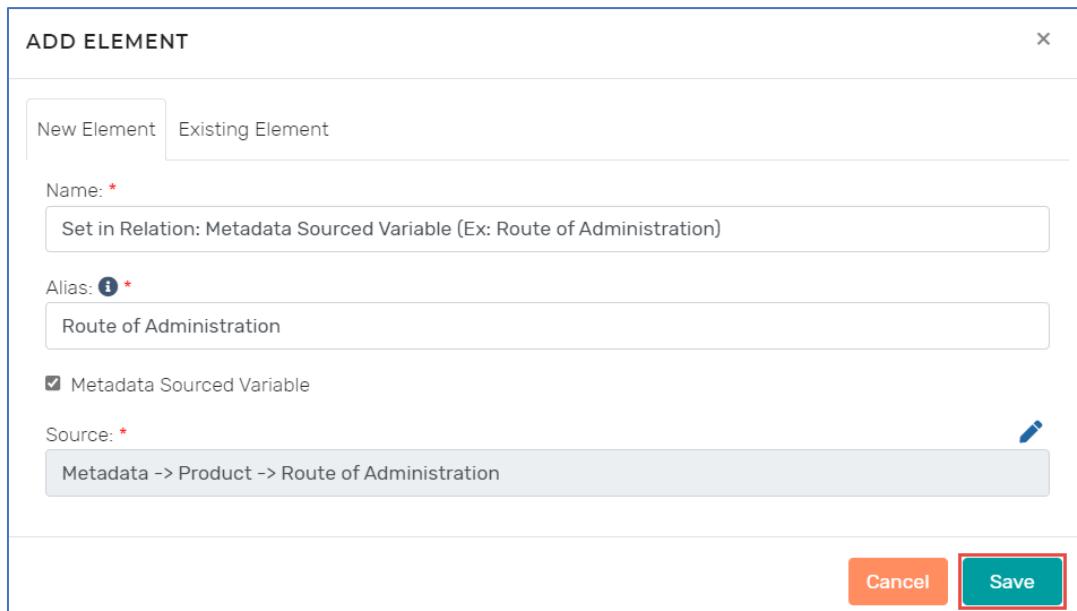
Name: * Set in Relation: Metadata Sourced Variable (Ex: Route of Administration)

Alias: * Route of Administration

Metadata Sourced Variable

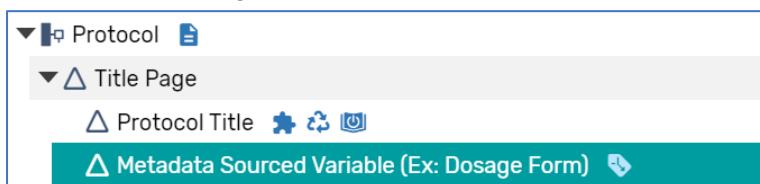
Source: * Metadata -> Product -> Route of Administration

Cancel Save

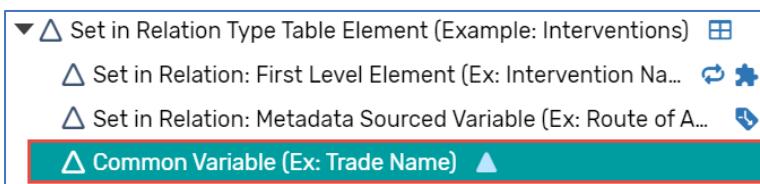


Notes:

- Metadata sourced variables are indicated by the following icon .
- Metadata sourced variables are not restricted to just table type elements and can also be added under regular info model sets and then inserted standalone in the template. However, reuse of the selected metadata sourced variable value is limited to the ones within a configured table.



- Common variables can also be added to a table type element.



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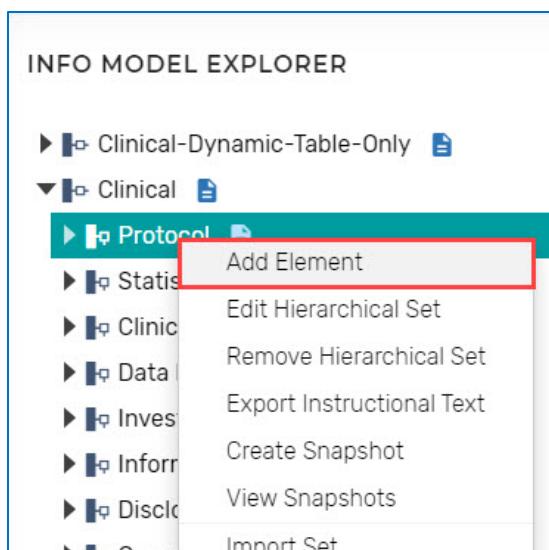
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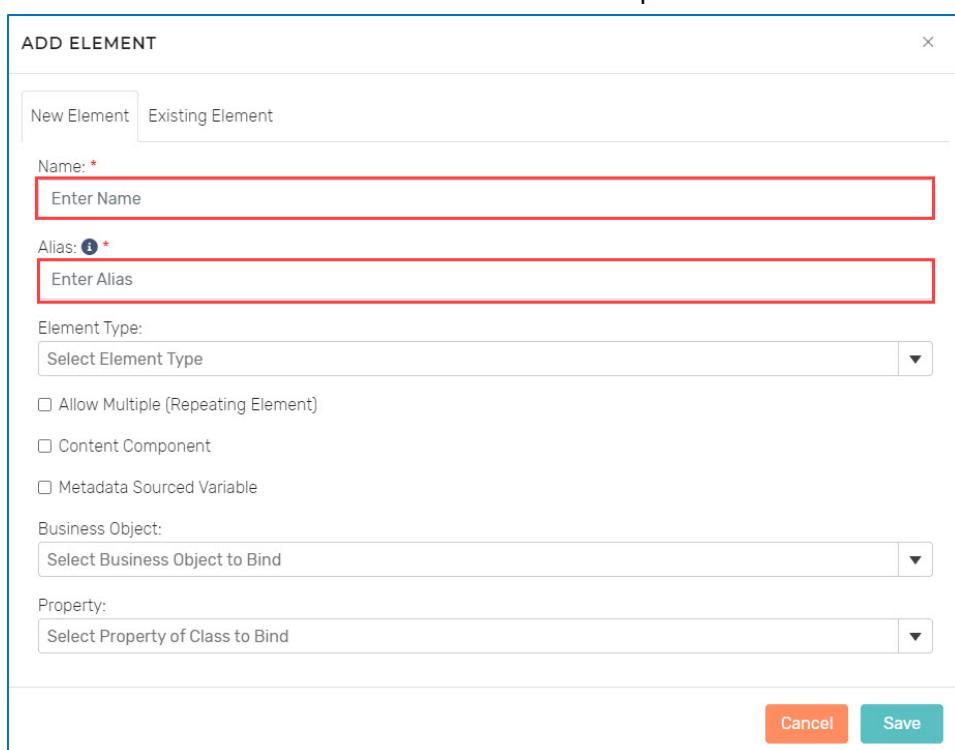
2.2.8 Adding a Component Set Element

See the steps listed below to configure an element set.

1. In the left-hand navigation pane of the Web Console, click on **Info Models**.
2. In the Info Model explorer, navigate to the applicable hierarchical set, right-click and select **Add Element**.



3. The **Add Element** pop-up window will display.
4. Enter the desired **Name** and **Alias** for the new component set.



The 'ADD ELEMENT' dialog box contains the following fields:

- New Element Existing Element
- Name: *
- Alias: i *
- Element Type:
Select Element Type
- Allow Multiple (Repeating Element)
- Content Component
- Metadata Sourced Variable
- Business Object:
Select Business Object to Bind
- Property:
Select Property of Class to Bind

Buttons at the bottom: Cancel (orange) and Save (green).

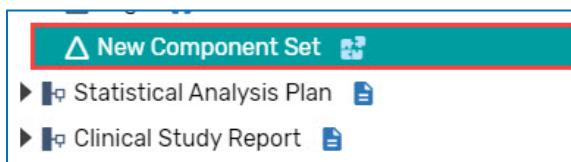
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5. Click on the Element Type drop down and select **Component Set**.
6. Click **Save**.



7. The component set is created under the applicable hierarchical set in the Info Model Explorer and the component set icon  displays next to the newly created component set.



Note: Follow the steps listed in [Section 2.2](#) to populate the newly created component set with elements, as applicable for the desired configuration of elements. If no Element Type is selected, the Business Object and Property type can still be selected to bind to the element.

2.3 ADDING INSTRUCTIONAL TEXT TO ELEMENTS

Instructional text can be associated with an element so it can appear in the *InteliNotion Word App* pane when its related/instantiated component is activated (eg, clicked in) within an open document. There is element-level instructional text, which can be added to an individual element, as well as common instructional text, which can be associated with more than 1 element.

Note: To add, edit, export or import instructional text, the user must have **Manage Instructional Text** permissions, or be a full control administrator. This feature is disabled by default and must be manually turned on. For these existing users, not having manage instructional text permission but still having C-R-U access to Instructional Text BO class can still add instructional text while adding library components. For users with only C-R-U access, the info model is read only.

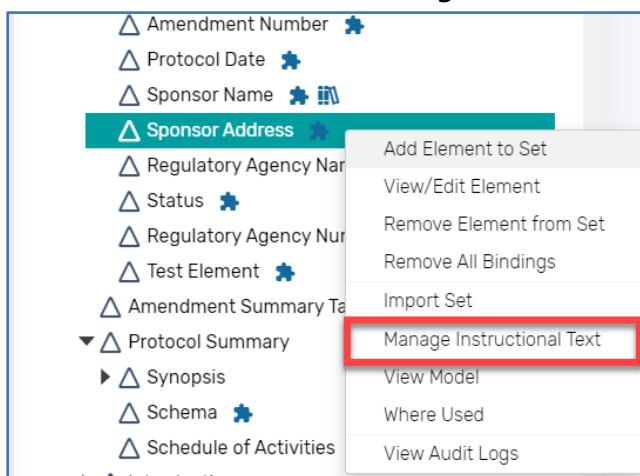
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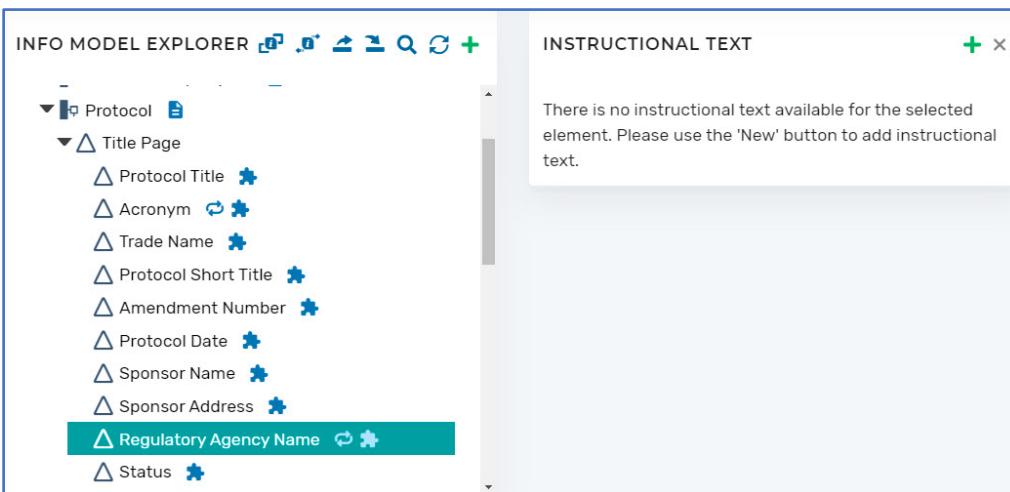
2.3.1 Element-Level Instructional Text

To add brand new instructional text:

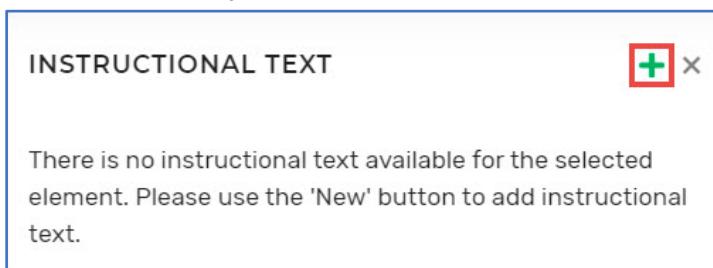
1. Right-click on the element and then click **Manage Instructional Text**.



2. The **Instructional Text** pane will open on the right-hand side.



3. If no instructional text exists yet, click the **add icon**  shown below.



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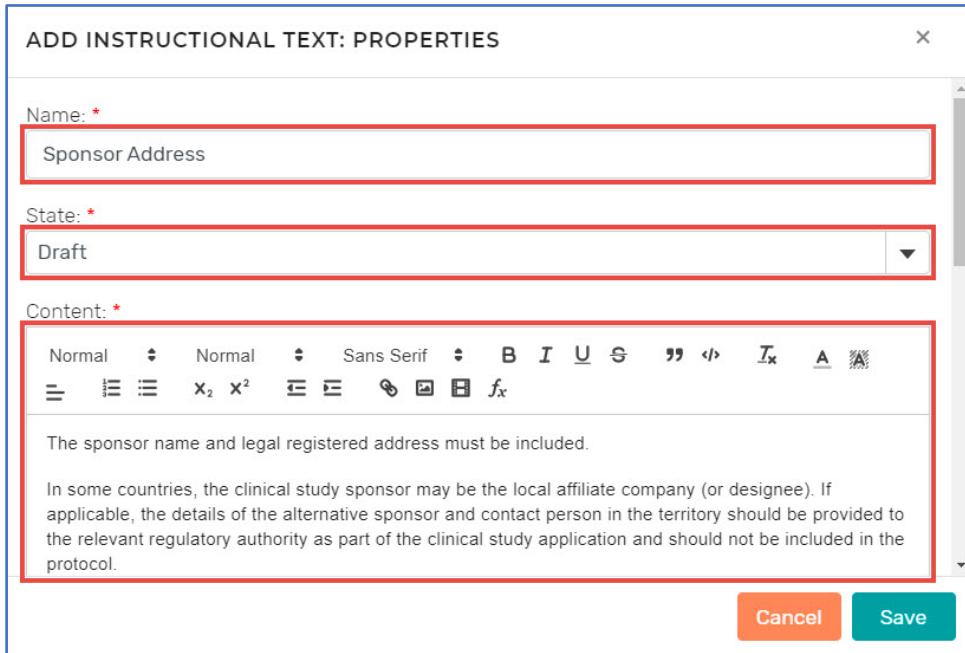
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4. Enter the required information and click **Save**.

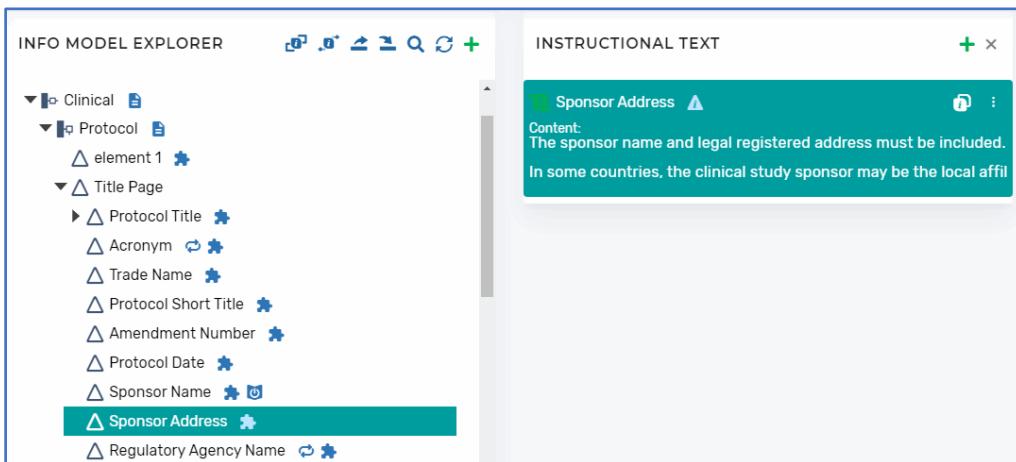
Note: Text entered in the **Name** field will be displayed above the instructional text (eg, text entered in the **Content** field) in the *InteliNotion Word App* pane.



The screenshot shows the 'ADD INSTRUCTIONAL TEXT: PROPERTIES' dialog box. It has fields for 'Name:' (containing 'Sponsor Address'), 'State:' (containing 'Draft'), and 'Content:' (containing a rich text editor toolbar and two notes about sponsor details).

Note: Populating the optional fields (eg, **Therapeutic Area** as shown above) will allow for conditional display of the instructional text according to the related document business object class property's configuration. See the **InteliNotion Application Admin Guide** for details.

5. Once the instructional text is saved, it will be listed in the **Instructional Text** pane for that element.

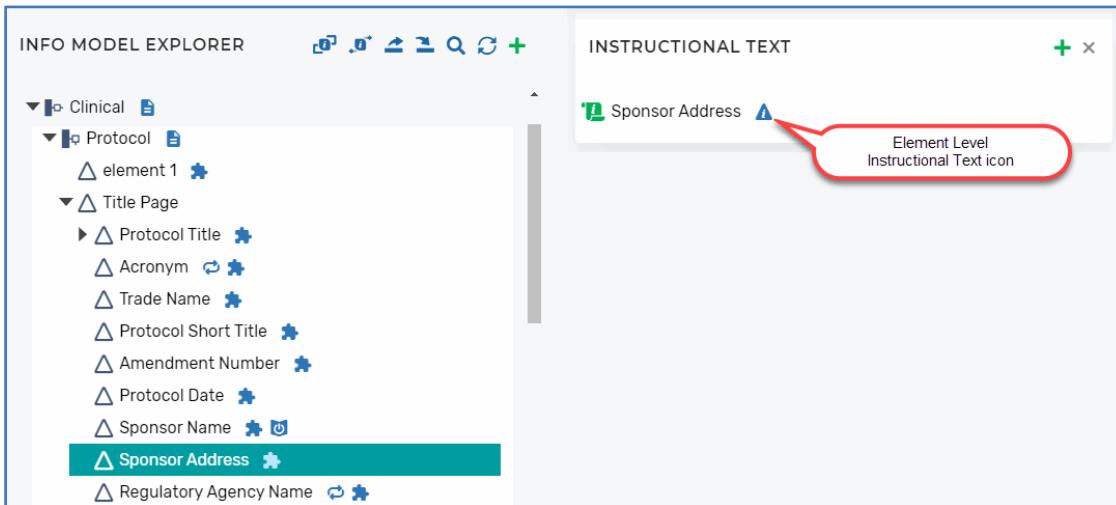


The screenshot shows the 'INSTRUCTIONAL TEXT' pane. It lists items like 'Sponsor Address' (selected), 'Protocol Title', 'Acronym', 'Trade Name', 'Protocol Short Title', 'Amendment Number', 'Protocol Date', 'Sponsor Name', and 'Regulatory Agency Name'. The 'Sponsor Address' item is highlighted, and its content is previewed in a box.

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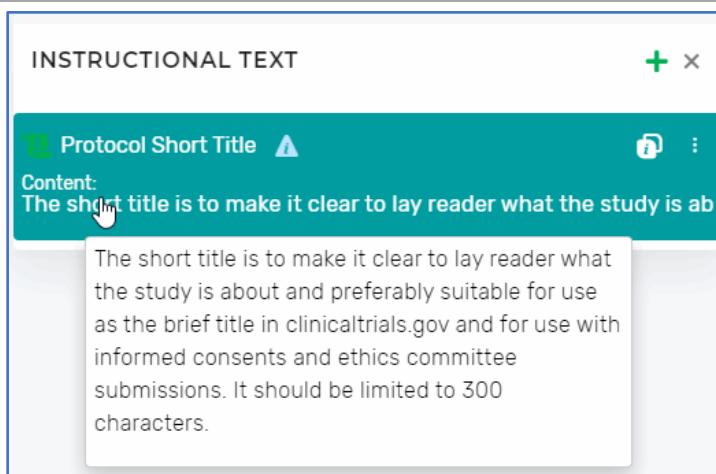
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6. The element-level instructional text can be identified by the **Information icon**  beside its name.



The screenshot shows the Intelinotion software interface. On the left, the 'INFO MODEL EXPLORER' pane lists various clinical and protocol elements, including 'Sponsor Address' which is highlighted with a teal bar at the bottom. On the right, the 'INSTRUCTIONAL TEXT' pane displays a single item: 'Sponsor Address' followed by an information icon. A red callout bubble points to this icon with the text 'Element Level Instructional Text icon'.

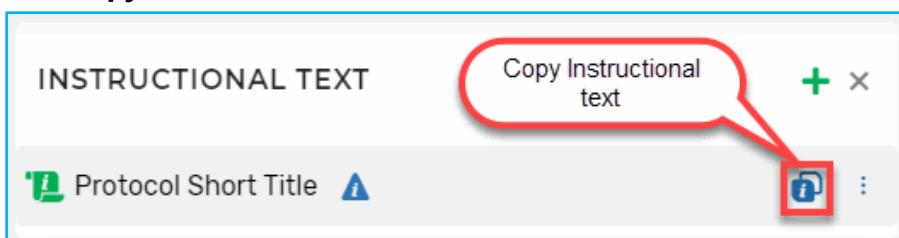
Note: The instructional text's content may be previewed if its name is clicked on and hover over the text.



The screenshot shows a detailed view of the 'Protocol Short Title' instructional text. The title is displayed in a green header bar with an information icon. Below it, a tooltip-like box shows the content: 'The short title is to make it clear to lay reader what the study is about'. A larger text area below provides a detailed explanation: 'The short title is to make it clear to lay reader what the study is about and preferably suitable for use as the brief title in clinicaltrials.gov and for use with informed consents and ethics committee submissions. It should be limited to 300 characters.'

To create new instructional text from an existing instance:

1. Hover over the existing instructional text's name; additional actions will appear beside it.
2. Click the **Copy Instructional Text icon** .

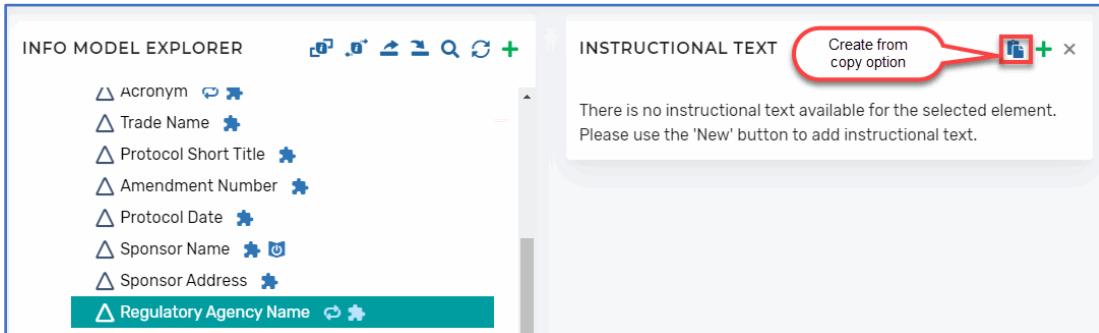


The screenshot shows the 'Protocol Short Title' instructional text again. A red callout bubble highlights the 'Copy Instructional text' icon, which is a blue square with a white 'i' symbol. Another red callout bubble points to the text 'Copy Instructional text' above the icon.

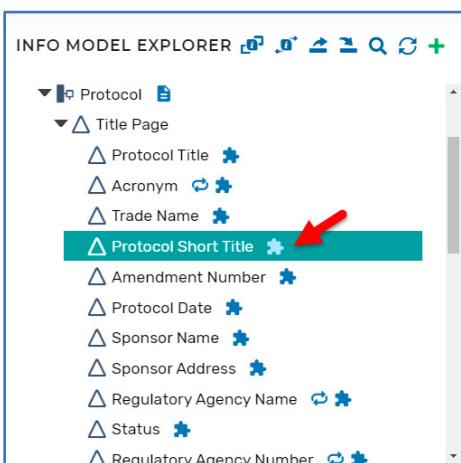
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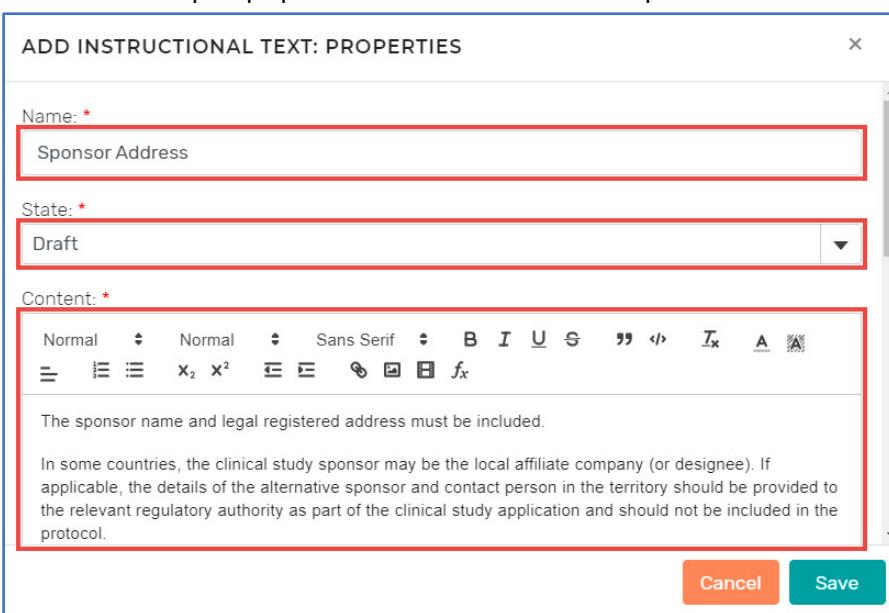
3. A **Create from Copy**  button will appear beside the **Add Instructional Text** icon.



4. If the copied instructional text is for another element, click the appropriate element on the left-hand side.



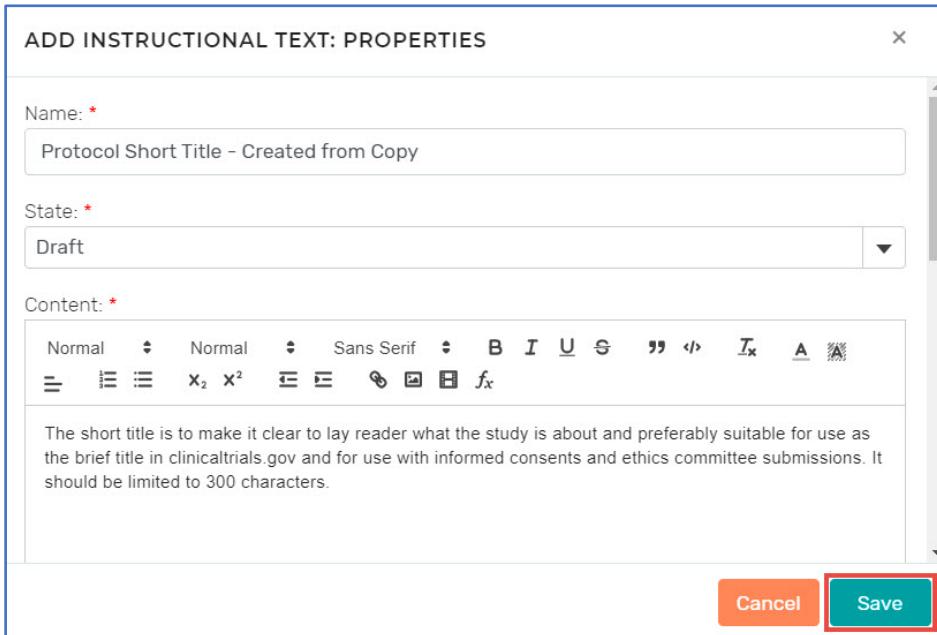
5. Click on the **Create from copy icon** . The **Add Instructional Text** form will appear on the screen with pre-populated content from the copied instructional text.



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6. Edit the **Name** of the instructional text and make any other required edits, as needed. Click **Save**.



ADD INSTRUCTIONAL TEXT: PROPERTIES

Name: *

Protocol Short Title - Created from Copy

State: *

Draft

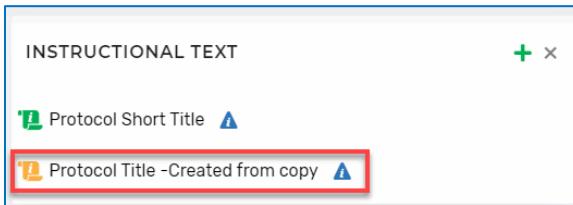
Content: *

The short title is to make it clear to lay reader what the study is about and preferably suitable for use as the brief title in clinicaltrials.gov and for use with informed consents and ethics committee submissions. It should be limited to 300 characters.

Normal Sans Serif B I U S " " Tx A

Cancel **Save**

7. Once the instructional text is saved, it will be listed in the **Instructional Text** pane for that element.



INSTRUCTIONAL TEXT

Protocol Short Title

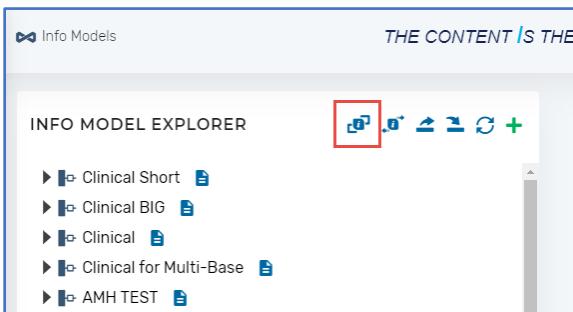
Protocol Title -Created from copy

2.3.2 Common Instructional Text

To add an instance of common instructional text and associate it with an element, follow the instructions listed in the sections below.

2.3.2.1 To Add Common Instructional Text

1. Click on the **Common Instructional Text icon** .



INFO MODEL EXPLORER

- Clinical Short
- Clinical BIG
- Clinical
- Clinical for Multi-Base
- AMH TEST

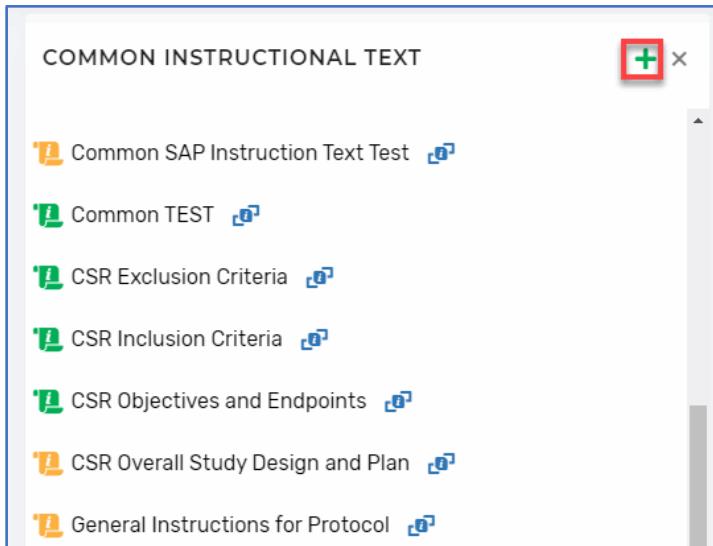
THE CONTENT IS THE

+

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2. The **Common Instructional Text** pane will open on the right-hand side.
3. Click the **add icon**  to add new common instructional text.

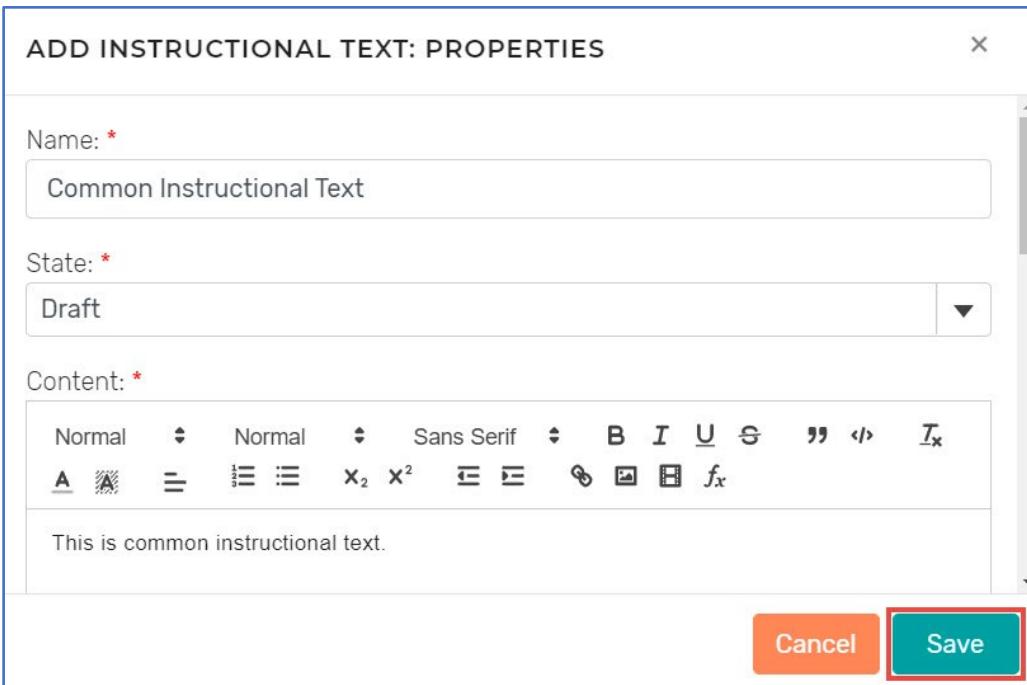


The screenshot shows a window titled "COMMON INSTRUCTIONAL TEXT". It contains a list of seven items, each with a small orange icon and a blue link:

- Common SAP Instruction Text Test [View](#)
- Common TEST [View](#)
- CSR Exclusion Criteria [View](#)
- CSR Inclusion Criteria [View](#)
- CSR Objectives and Endpoints [View](#)
- CSR Overall Study Design and Plan [View](#)
- General Instructions for Protocol [View](#)

A red-bordered plus icon is located in the top right corner of the pane.

4. Fill in all the required details in the **Add Instructional Text** form and click **Save**.



The screenshot shows a form titled "ADD INSTRUCTIONAL TEXT: PROPERTIES". It includes the following fields:

- Name: *
- State: *
- Content: *
This is common instructional text.

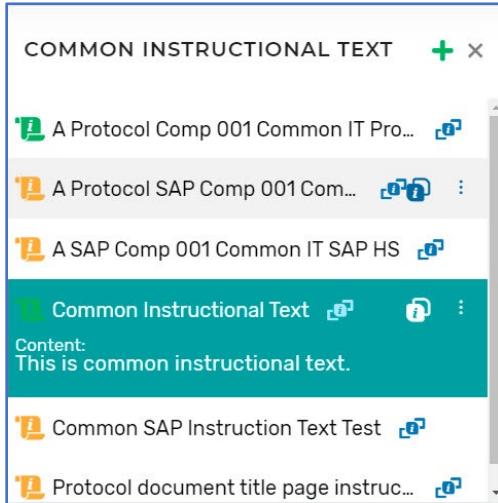
A rich text editor toolbar is visible above the content area, featuring buttons for font size, bold, italic, underline, and various symbols.

At the bottom right are two buttons: "Cancel" and "Save", with "Save" being highlighted by a red border.

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5. Once the instructional text is saved, it will be listed in the **Common Instructional Text** pane.



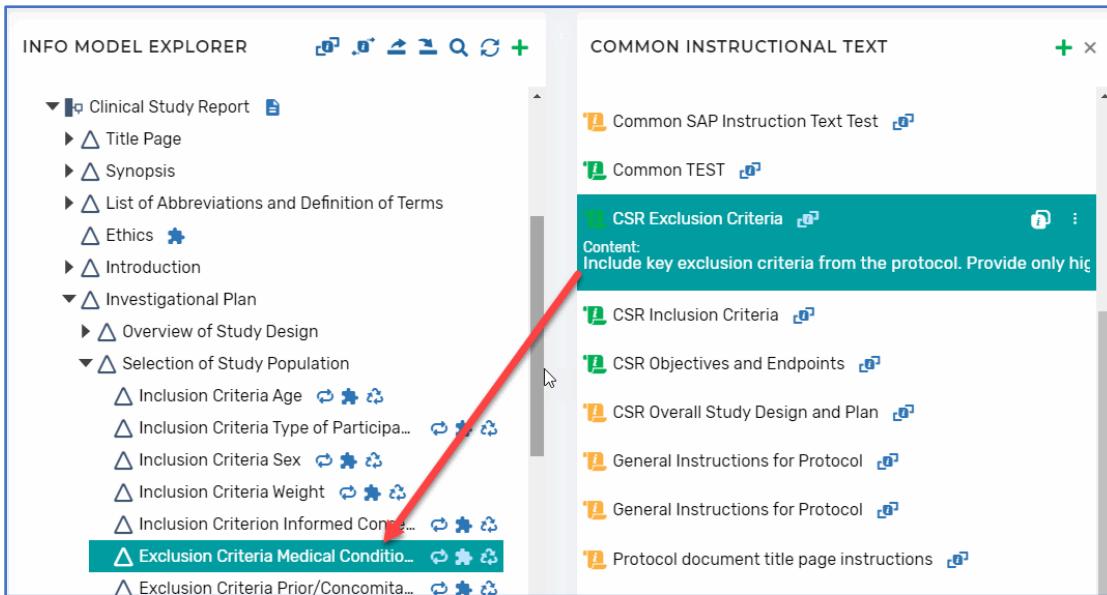
The screenshot shows the 'COMMON INSTRUCTIONAL TEXT' pane with a list of items:

- A Protocol Comp 001 Common IT Pro...
- A Protocol SAP Comp 001 Com...
- A SAP Comp 001 Common IT SAP HS
- Common Instructional Text** (selected item)
 - Content: This is common instructional text.
- Common SAP Instruction Text Test
- Protocol document title page instruc...

Note: All the actions on the common instructional text such as edit, route through lifecycle, remove, etc. can be performed in the same way as that of the element level instructional text mentioned above.

2.3.2.2 To Associate Common Instructional Text with Any Element

1. Ensure the **Common Instructional Text** pane is open by clicking on the **Common Instructional Text icon** .
2. On the left-hand side, navigate to the desired element.
3. Drag-and-drop the relevant common instructional text instance onto the desired element.

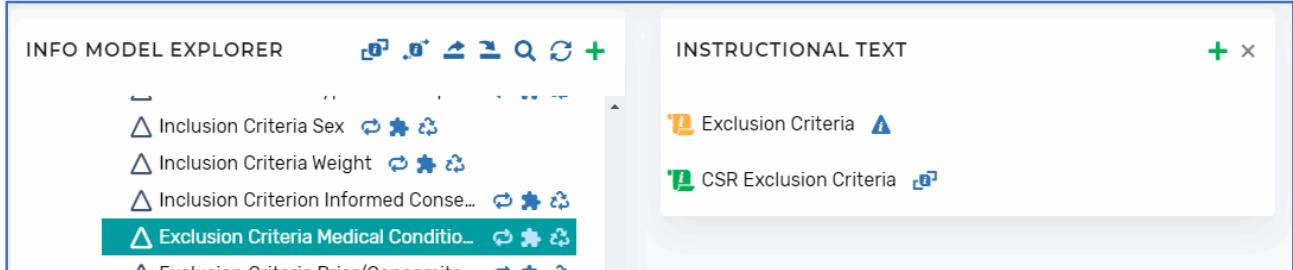


The screenshot shows the 'INFO MODEL EXPLORER' and 'COMMON INSTRUCTIONAL TEXT' panes. In the Info Model Explorer, the 'Exclusion Criteria Medical Condition...' item under 'Clinical Study Report' is highlighted. A red arrow points from this item to the 'CSR Exclusion Criteria' item in the Common Instructional Text pane, which is also highlighted.

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4. Once associated successfully, the common instructional text will be listed in the **Common Instructional Text** Pane for the selected element.
5. The common instructional text can be identified by the  icon beside its name.



The screenshot shows the Intelinotion software interface. On the left, the "INFO MODEL EXPLORER" pane lists various elements like Inclusion Criteria Sex, Inclusion Criteria Weight, Inclusion Criterion Informed Consent, and Exclusion Criteria Medical Condition. On the right, the "INSTRUCTIONAL TEXT" pane displays two items: "Exclusion Criteria" and "CSR Exclusion Criteria". The "Exclusion Criteria" item has a blue square icon with a white question mark next to it, indicating it is a common instructional text.

Note: Common instructional text can also be created from a copy following similar steps as described in [Section 2.3.1](#) above.

2.3.3 Enabling, Reordering, Updating, and Deleting Instructional Text

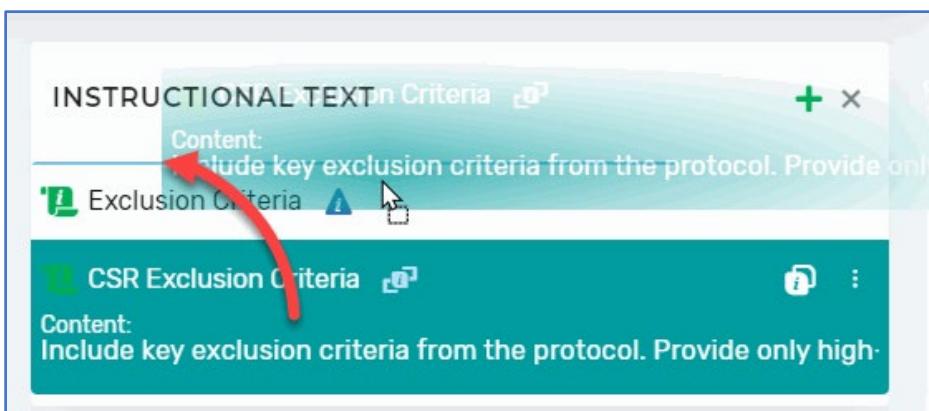
The following steps are for element-level instructional text, but the same actions can be performed for the common instructional text.

2.3.3.1 Enabling Instructional Text

Instructional text will only be displayed in the *InteliNotion Word App* pane for users if it is in an approved state. Instructional text may be either manually changed to an approved state or sent through a review and/or approval lifecycle (if configured for the instructional text business object class). If instructional text is later updated (eg, changed back to a draft state), the most recently approved version of the instructional text will still be displayed in the *InteliNotion Word App* pane for users.

2.3.3.2 Reordering Instructional Text

The instructional text presentation order in the *Word App* pane can be changed in the info model by dragging and dropping it into the desired order.



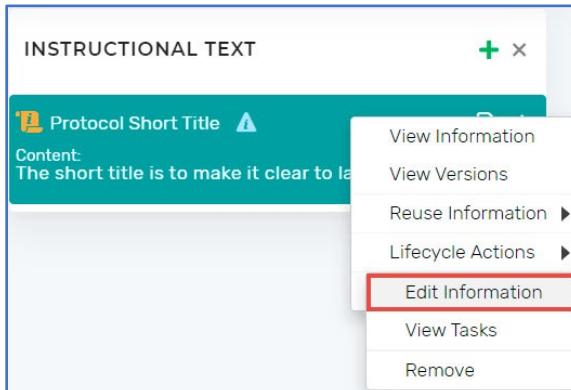
The screenshot shows the "INSTRUCTIONAL TEXT" pane with two items: "Exclusion Criteria" and "CSR Exclusion Criteria". The "Exclusion Criteria" item has a "Content:" field containing the text "Include key exclusion criteria from the protocol. Provide only high-". A red arrow points to this "Content:" field. The "CSR Exclusion Criteria" item also has a "Content:" field with similar text.

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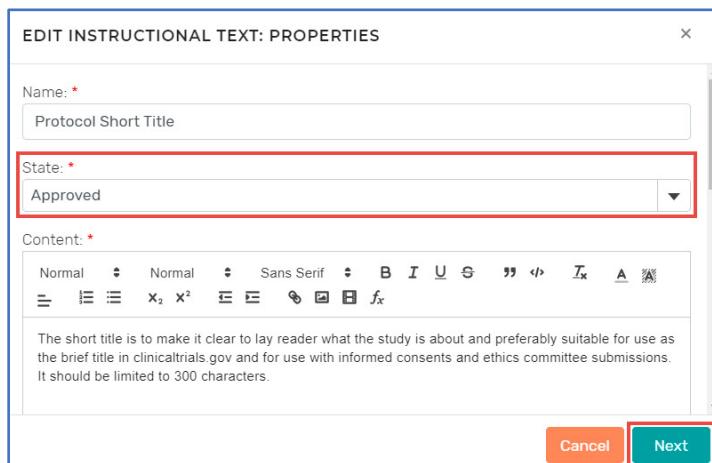
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2.3.3.3 Updating Instructional Text

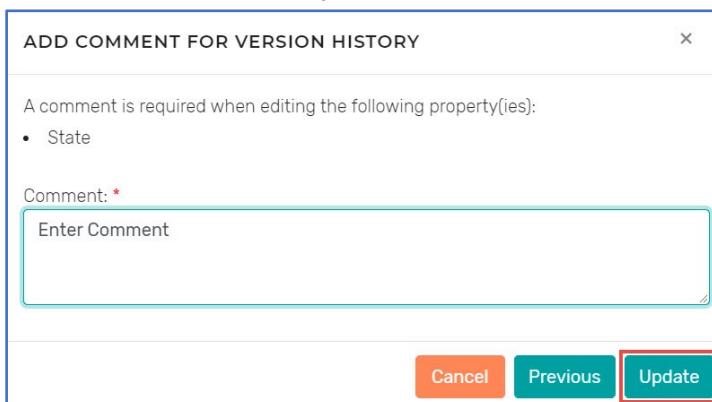
- Click on the vertical ellipsis  button beside its name and select **Edit Information**.



- Make any required edits, including manually changing the **State**, and click **Next**.



- Enter a Comment for Version History and click **Update**.



Note: If the instructional text business object class's approved state is set to **Demote to Default State**, then the selected state, as shown above, will be ignored, and the default state (eg, Draft) will be applied instead.

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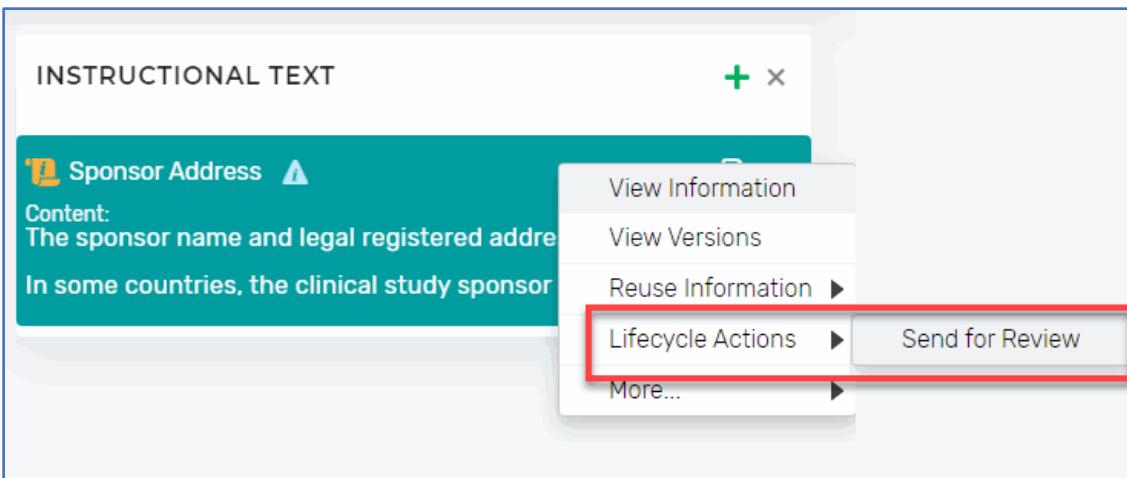
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2.3.3.4 Routing Instructional Text Through a Lifecycle

Note: A lifecycle (states and transitions) must be configured for the instructional text business object class before an instance can be routed through a lifecycle. See the **InteliNotion Application Admin Guide** for details on how to configure a lifecycle for a business object class.

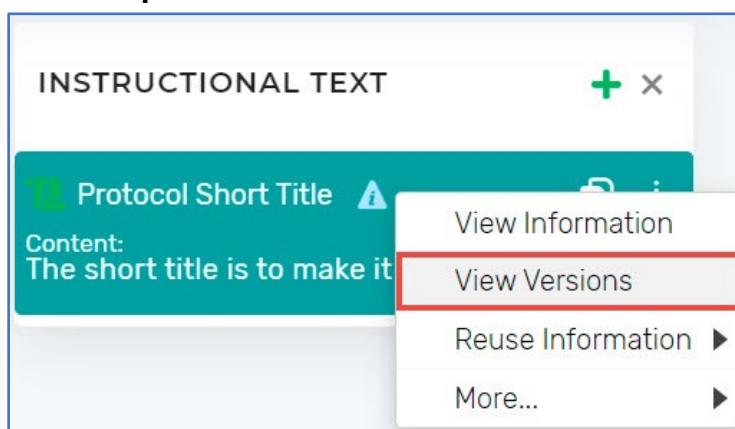
1. Click the **vertical ellipsis**  button beside the instructional text's name and under **Lifecycle Actions**, select from the available options, (eg, **Send for Review**).



2. Complete the applicable task form and subsequent review and/or approval task steps, as appropriate. See the **InteliNotion User Guide Module 9** for more details on sending and completing tasks.

2.3.3.5 Compare Two Versions of Instructional Text

1. Click the **vertical ellipsis**  button beside its name and select **View Versions**.



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2. The version history of the instructional text will appear on the screen.

VIEW VERSIONS: TRADE NAME

	Version	Modified On	Modified By	Comment	
<input type="checkbox"/>	1.0	2021-11-21 11:13 AM	Cam Mistry	Imported	<input type="button" value="..."/>
State: Approved					
<input type="checkbox"/>	0.1	2021-10-15 3:17 PM	Cam Mistry	Imported	<input type="button" value="..."/>
Name: Trade Name Owner: Cam Mistry State: Draft Content: Enter trade name, if available. Process Performance Type: Study Phase: Test: Therapeutic Area: Trade Name:					

Close **Compare Versions**

3. Select any 2 versions from the list and then the **Compare Versions** button will enable. Click on **Compare Versions**.

VIEW VERSIONS: TRADE NAME

	Version	Modified On	Modified By	Comment	
<input checked="" type="checkbox"/>	1.0	2021-11-21 11:13 AM	Cam Mistry	Imported	<input type="button" value="..."/>
State: Approved					
<input checked="" type="checkbox"/>	0.1	2021-10-15 3:17 PM	Cam Mistry	Imported	<input type="button" value="..."/>
Name: Trade Name Owner: Cam Mistry State: Draft Content: Enter trade name, if available. Process Performance Type: Study Phase: Test: Therapeutic Area: Trade Name:					

Close **Compare Versions**

Note: Only 2 versions can be compared at a time.

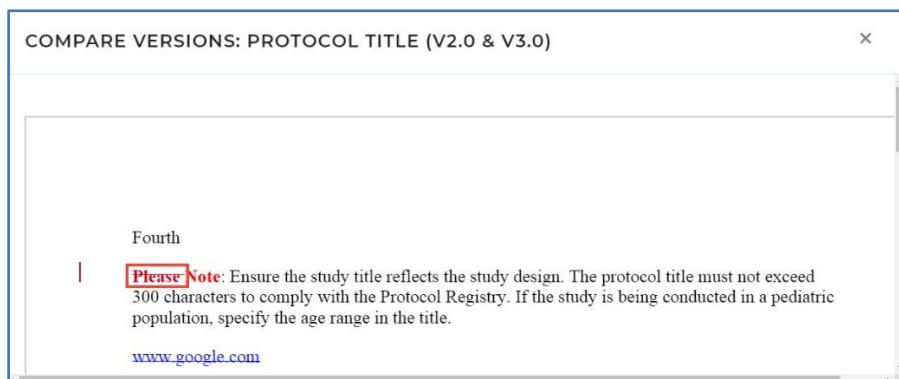
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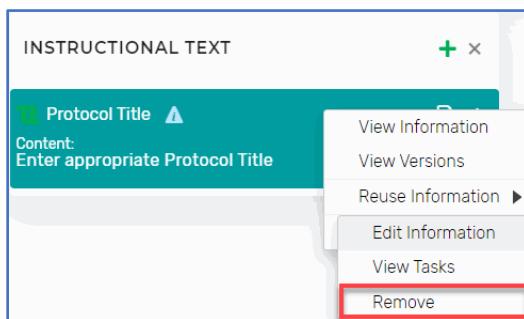
4. A comparison showing the differences between versions in track changes format will appear on the screen.



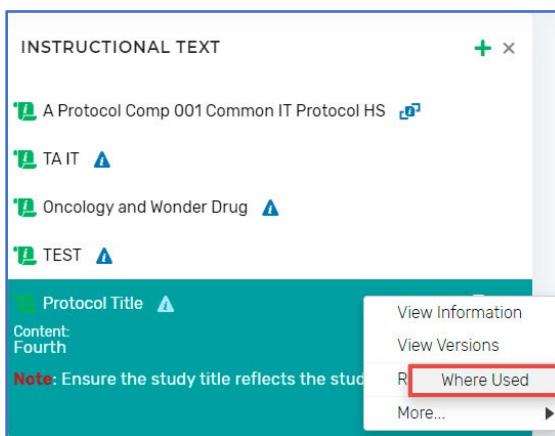
Note: The version comparison may not display any content changes if one of the version's being compared was a result of a lifecycle state change.

2.3.3.6 Remove Instructional Text

Click the **vertical ellipsis**  button beside its name. Select **More** and then **Remove**.



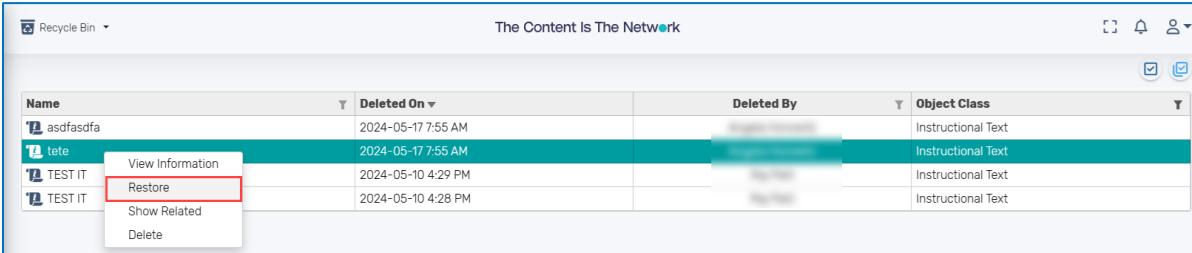
Note: Before removing instructional text, it may be helpful to see which other elements are using it. To do this, click on the **vertical ellipsis**  button beside its name, and under **Reuse Information** select **Where Used**.



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Deleted instructional text can be restored from the **Recycle Bin** by right clicking on the applicable instructional test to be restored and selecting **Restore**.



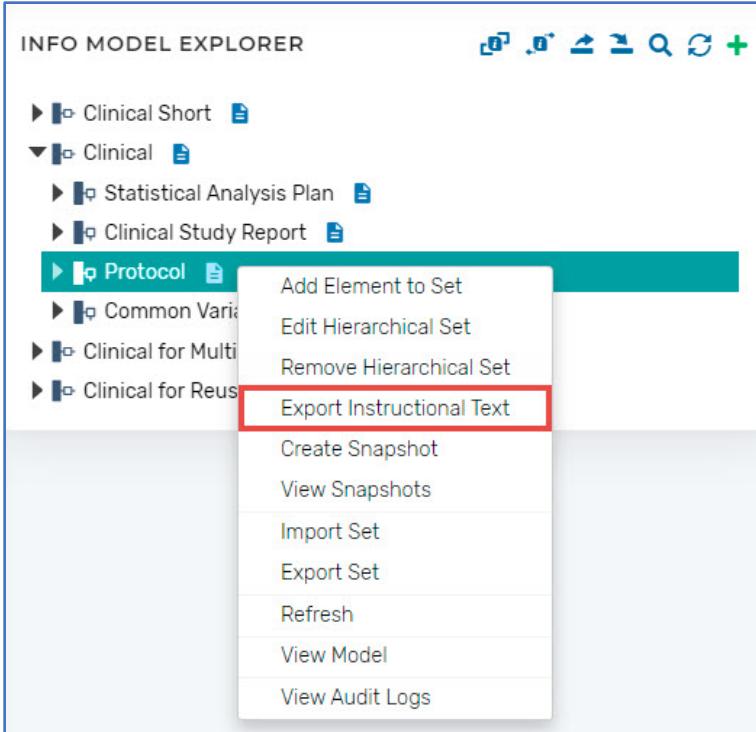
Name	Deleted On	Deleted By	Object Class
asdfasdfa	2024-05-17 7:55 AM		Instructional Text
tete	2024-05-17 7:55 AM		Instructional Text
TEST IT	2024-05-10 4:29 PM		Instructional Text
TEST IT	2024-05-10 4:28 PM		Instructional Text

2.3.4 Exporting and Importing Instructional Text

Instructional text may be exported to a docx file for any hierarchical set that contains child elements, and then imported if changes are made to the instructional text content within the exported file.

2.3.4.1 Exporting Instructional Text

1. Right-click on the hierarchical set of interest and select **Export Instructional Text**.



- ▶ Clinical Short
- ▼ Clinical
 - ▶ Statistical Analysis Plan
 - ▶ Clinical Study Report
 - ▶ Protocol
 - ▶ Common Vari
 - ▶ Clinical for Multi
 - ▶ Clinical for Reus

Note: **Export Instructional Text** allows a user to export the instructional text of a hierarchical set to a Word document.

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2. An **Instructional Text Export/Import** screen will open. Expand the **Export Jobs** section and click the **plus sign icon** .

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS

▼ Export Jobs  

Jobs not available.

➤ Import Jobs

3. Enter a **Name** for the job and a **Description**, if desired, and click **Save**.

INSTRUCTIONAL TEXT EXPORT

Name: *

Enter Name

Description:

Enter Description

Cancel

Save

4. The export job will be created, and initially shows a **Pending** status.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS

▼ Export Jobs  

Name	Created By	Created On ▾	Description	Status	Download	Remove
Protocol Instru...	Cam Mistry	2021-11-21 11:49 ...		Pending		

➤ Import Jobs

5. Once the export job finishes, a confirmation email is received. The job's status also changes to **Complete** and a **Download File icon** appears as shown below. Click the **Download File icon**  to save the file locally.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS

▼ Export Jobs  

Name	Created By	Created On ▾	Description	Status	Download	Remove
Protocol Instru...	Cam Mistry	2021-11-21 11:49 ...		Complete		

➤ Import Jobs

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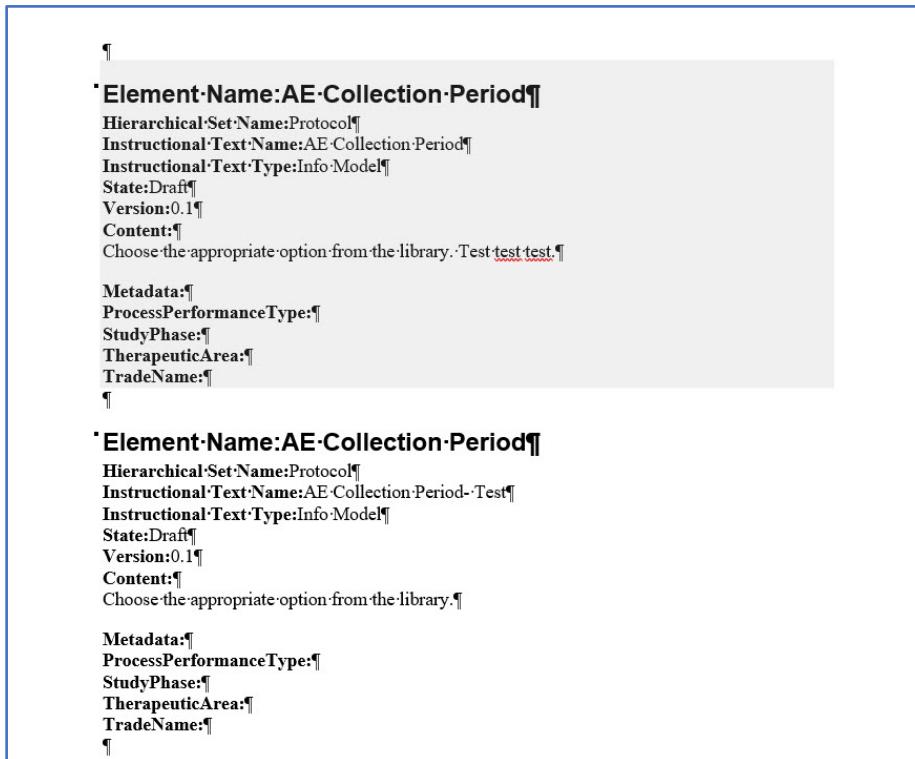
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Note: If there was an error during the export process, the job's status would display **Completed with error**. Hover over the **error icon** to view why the error occurred.

Completed with error

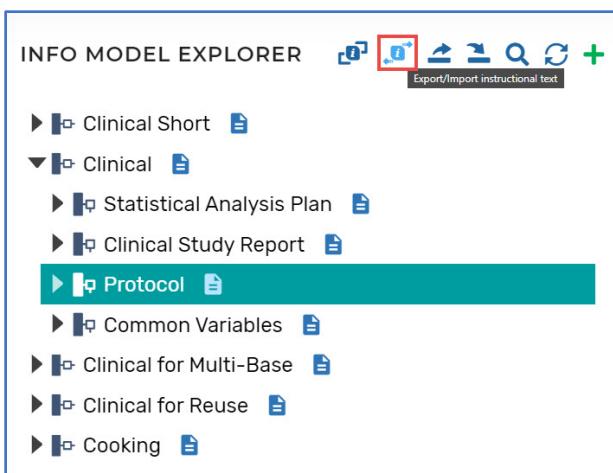


6. Open the locally saved file in *MS Word* and then edit the text within the **Instructional Text Name** and/or **Content** fields, if necessary. **Save** the updated file.



2.3.4.2 Importing Instructional Text

1. Click the **Import Instructional Text icon**



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2. On the **Instructional Text Export/Import** screen, click on the **add icon**  to create an import job.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS

- > Export Jobs
- ▼ Import Jobs  

Jobs not available.

3. Fill in the required fields and select a file to upload by clicking on **Choose Files**. The file must comply with the *InteliNotion* standard.

INSTRUCTIONAL TEXT IMPORT

Name: *

Description:

Instructional Text State:

File: *

Choose Files

Cancel
Save

4. The import job will start (eg, it will show a **Status of Pending**). An email notification will be sent to the user once completed.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS

- > Export Jobs
- ▼ Import Jobs  

Name	Created By	Created On ▾	Description	Status	Reports	Remove
Protocol Instru...	Cam Mistry	2021-11-21 12:12 ...		Pending		

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5. The import job's status will change to **Complete** and a report will be generated.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS						
> Export Jobs ▼ Import Jobs 						
Name	Created By	Created On ▾	Description	Status	Reports	Remove
Protocol Instru...	Cam Mistry	2021-11-21 12:12 ...		Complete		

Note: If there was an error during the import process, the job's status will display as either **Error** or **Completed with Error**. The report will include details about any errors that occurred.

6. The report can be opened by clicking the **Download Report icon** shown below. The report will contain information about the results of the import job.

INSTRUCTIONAL TEXT EXPORT/IMPORT JOBS						
> Export Jobs ▼ Import Jobs 						
Name	Created By	Created On ▾	Description	Status	Reports	Remove
Protocol Instru...	Cam Mistry	2021-11-21 12:12 ...		Complete		

Importing instructional text

Total number of instructional text processed: 69

Number of instructional text processed successfully: 69

Number of instructional text created successfully: 0

Number of instructional text updated successfully: 69

Number of instructional text processing failed: 0

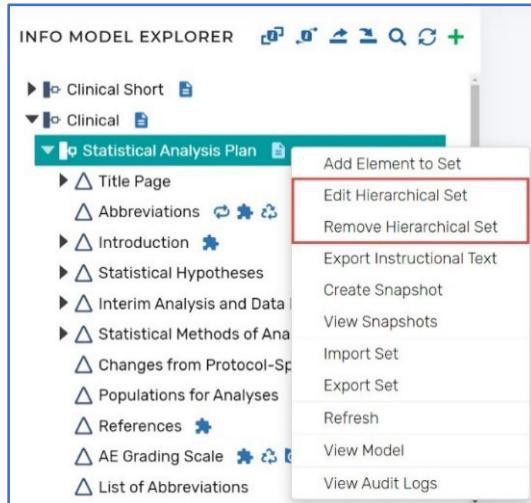
Description	Element ID	Instructional text ID	Status
Imported successfully with update	978fe76b-5d0b-4cb4-a939-51a573877bcf	ddf4067e-ce8b-4886-8ea7-39e2ae916433	Completed
Imported successfully with update	fe6ba112-d85e-4f3d-921d-c98a1553d174	7e71e65b-fc36-420c-88cd-00ec44c494ff	Completed
Imported successfully with update	fe6ba112-d85e-4f3d-921d-c98a1553d174	198ec675-6668-4d03-a777-f5fe0fd8336a	Completed
Imported successfully with update	8b594d09-919a-4a79-b43b-bdbd01855bd0	8702ec3d-35de-4cbb-b770-86bbcec2261b	Completed
Imported successfully with update	fe6ba112-d85e-4f3d-921d-c98a1553d174	044ab37d-7f3e-45c8-8941-2a6805cec18f	Completed
Imported successfully with update	fe6ba112-d85e-4f3d-921d-c98a1553d174	d07db35b-2029-4803-b5e3-038019411ab9	Completed
Imported successfully with update	fe6ba112-d85e-4f3d-921d-c98a1553d174	1f429e29-750e-4703-93de-9c9954881711	Completed
Imported successfully with update	5a93e871-0343-4d69-a74a-b797062e03d1	9661ba28-a503-48c8-9b84-cd6586f6530b	Completed
Imported successfully with update	978fe76b-5d0b-4cb4-a939-51a573877bcf	9319806a-6af7-4294-ae1f-ab3015781a96	Completed

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2.4 UPDATING AND DELETING HIERARCHICAL SETS

To update a hierarchical set, right-click on it and then click **Edit Hierarchical Set**. To delete a hierarchical set, right-click on it and then click **Remove Hierarchical Set**.



Notes

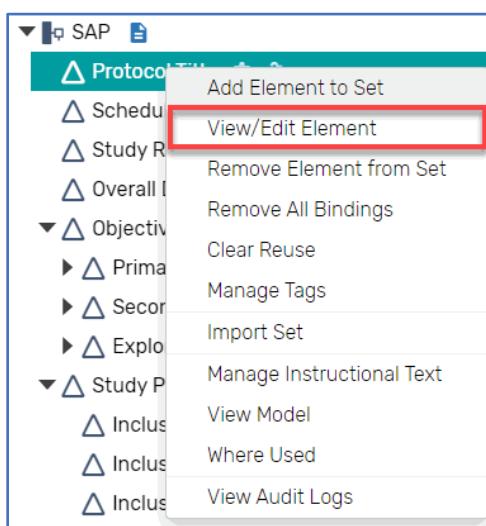
- Updating the hierarchical set **Name** will have no impact on any of its elements previously inserted into document templates.
- The selected hierarchical set **Type** cannot be changed.

2.5 UPDATING AND DELETING ELEMENTS

To update or delete an element, follow the steps listed in the sections below.

2.5.1 Updating an Element

To update an element, right-click on it and click **View/Edit Element**.



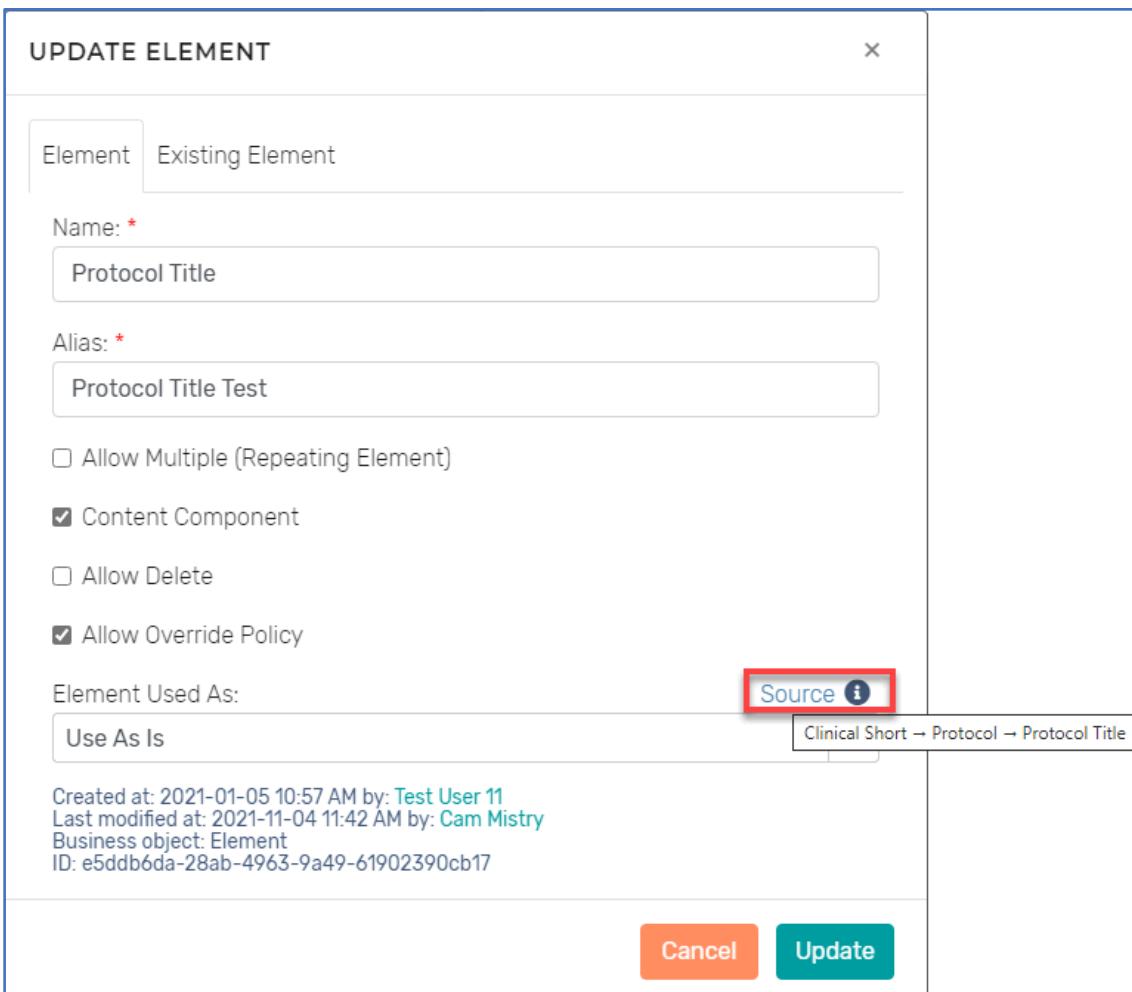
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The following types of changes are allowed when updating an element:

- Revise **Name** or **Alias**
- Uncheck or check the initial **Content Component**, **Allow Multiple**, and **Allow Delete** checkbox selections
- Change the **Business Object** selection
- Uncheck or check the initial **Allow Override Policy** checkbox selection for an as-is reused element
- Change the source of the **Element (Reuse)**

The **Update Element** window also shows the element properties, and in case of a reused element, the source, when hovering over the **Information icon**  next to **Source**.



The screenshot shows the "UPDATE ELEMENT" dialog box. In the "Element Used As:" section, there is a "Source" button with an information icon () highlighted with a red box. Below the "Source" button, a tooltip displays the hierarchical path: "Clinical Short → Protocol → Protocol Title".

Element Existing Element

Name: *
Protocol Title

Alias: *
Protocol Title Test

Allow Multiple (Repeating Element)
 Content Component
 Allow Delete
 Allow Override Policy

Element Used As:
Use As Is

Source 

Created at: 2021-01-05 10:57 AM by: [Test User 11](#)
Last modified at: 2021-11-04 11:42 AM by: [Cam Mistry](#)
Business object: Element
ID: e5ddb6da-28ab-4963-9a49-61902390cb17

Cancel Update

The reuse source of an element can be updated in the **Existing Element** tab, even for an element that did not have previously a source element (reuse) configured, by selecting or changing the hierarchical set and/or element as the source as explained in [Section 2.2.4](#).

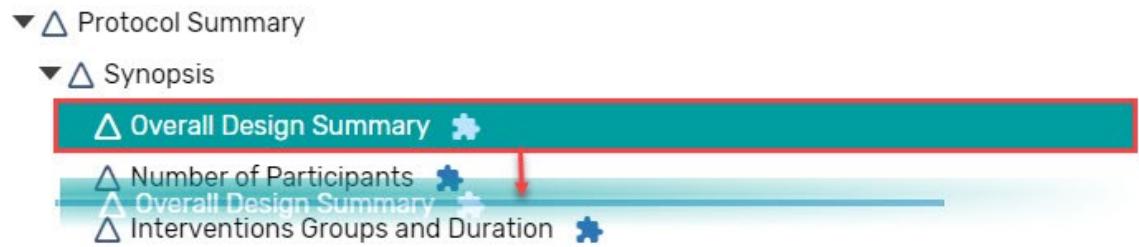
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After updating an element that had previously been inserted into a document template, the Info Model Status Report (see [Section 3.3.2](#)) will alert the template manager about this change.

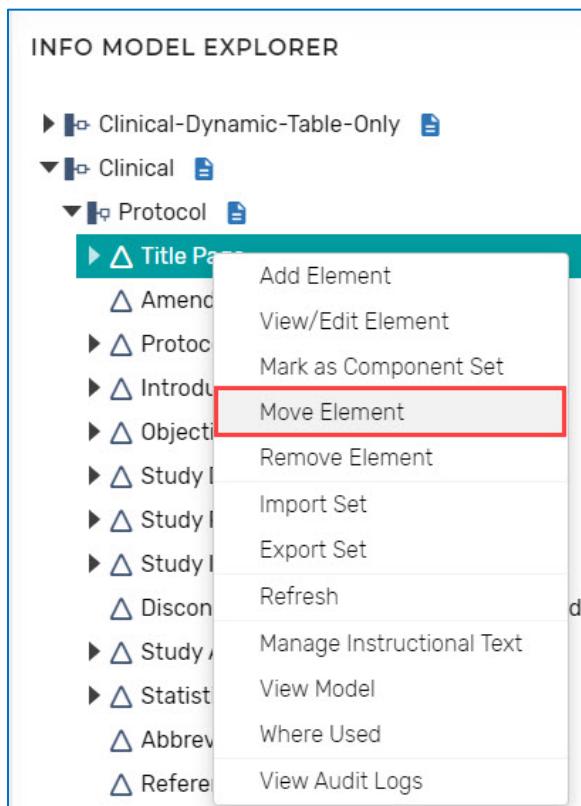
2.5.2 Move an Element within a Hierarchical Set

Previously configured document elements can be moved within a hierarchical set by dragging and dropping it to the new location.



The user can also move an element by following the steps listed below.

1. Right click on the element to be moved and choose Move Element.

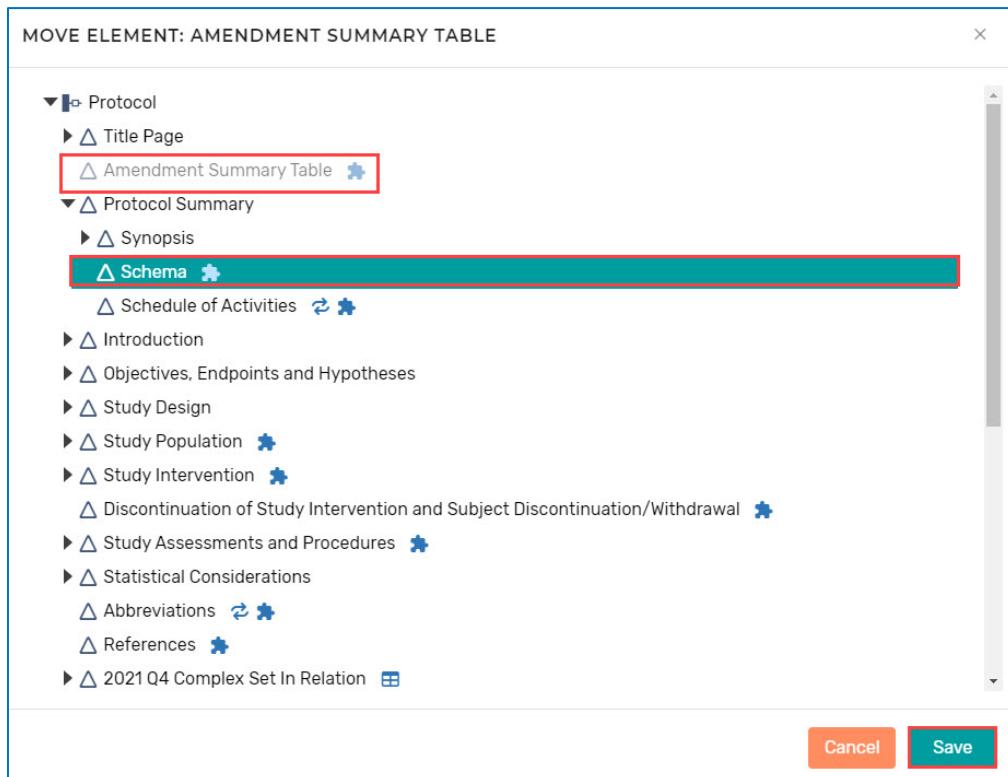


2. The **Move Element** pop-up window will display.

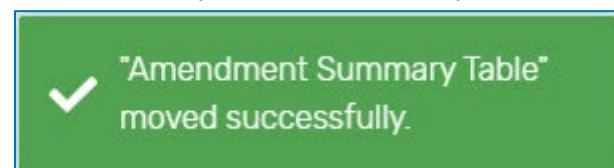
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3. Click on the new location where the element will be moved, then click **Save**.



4. The element saved successfully window will display.



5. Navigate back to the **Info Model Explorer** and observe the element in its new location.



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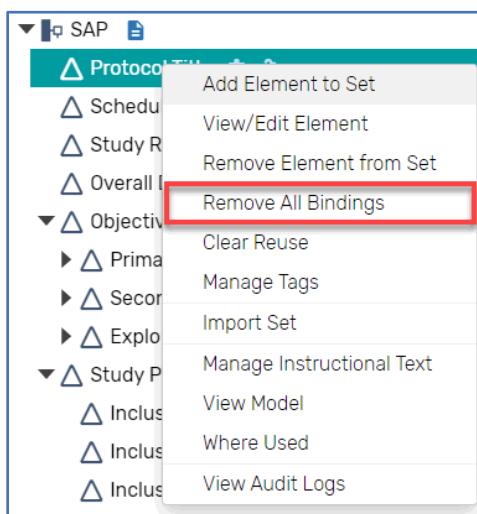
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Note: When moving an element, the following conditions apply:

- The element cannot be moved to a different Hierarchical set.
- The element cannot be moved elsewhere under the same parent element.
- The element cannot be moved under a new parent if there is an existing child element that has the same name as the element being moved.
- A reused element cannot be moved.
- The element cannot be moved such that its new parent is a reused element.
- A non-repeating element cannot be moved under a component set or table element.
- A component set or table element cannot be moved under another element.

2.5.3 Remove All Bindings

An element may also be updated by removing any object-property associations from it. To do this, right-click on it and select **Remove All Bindings**.



2.5.4 Clear Reuse of an Element

A previously reused element can be unlinked from the source using the **Clear Reuse** option from the menu (see above). Selecting this option from the dropdown menu will first display a warning and after acknowledging it will open the **Update Element** window, where the reuse was removed.

Note:

- When clearing reuse on components within a document, subsequent save, check-in, and check out events may show an error message. See **InteliNotion User Guide, Module 5, Section 1.11** for more details.

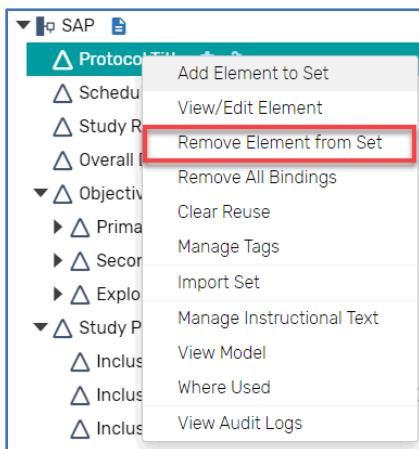
An element that was reused in a variant document can also have reuse cleared by following the steps referenced in the above bullet point.

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2.5.5 Remove Element from Set

To delete an element, right-click on it and then click **Remove Element from Set**.



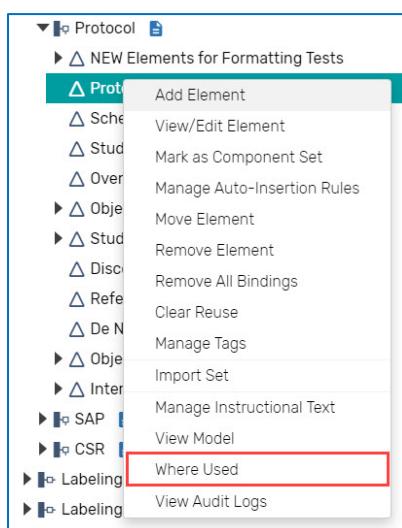
Notes:

- If the element is inserted into the latest/most current version of a document template within the system, a warning will be displayed listing all the templates where the element is used. Removing the element from the set won't remove it from the template.
- When an individual element or entire hierarchical set is deleted, any associated element-level instructional text will also be deleted. However, any common instructional text will remain in the system.

2.5.6 Viewing Where Used for an Element

If an element has been used in a template that is loaded in the system, both the element and its related (primary) hierarchical set cannot be removed. To find out where the element has been used, use the **Where Used** functionality.

1. Right-click on the element and click **Where Used**.



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2. A list of templates and hierarchical sets (including placeholder elements) wherein the element is used will be listed in a pop-up window.

WHERE USED: PROTOCOL TITLE							x
	Name	Owner	Created By	Created On	Modified By	Modified On	Version
<input type="checkbox"/>	Client 1 Protocol Template	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	1.0
<input type="checkbox"/>	Client 2 Protocol Template	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-24 3:30 PM	3.0
<input type="checkbox"/>	Client 2 Protocol Template - Var	[REDACTED]	[REDACTED]	2022-04-07 9:46 AM	[REDACTED]	2022-06-01 6:52 PM	0.5
<input type="checkbox"/>	Client 3 Protocol Template	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	1.0
<input type="checkbox"/>	PROT Template for U-Ingestion	[REDACTED]	[REDACTED]	2022-02-08 8:45 AM	[REDACTED]	2022-02-08 9:18 AM	1.0
<input type="checkbox"/>	Variant Template Test	[REDACTED]	[REDACTED]	2022-09-16 8:40 AM	[REDACTED]	2022-09-16 8:40 AM	0.1
<input type="checkbox"/>	↳ Clinical Short - Reuse Formattir	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2023-01-10 3:31 PM	0.1
<input type="checkbox"/>	↳ SAP	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	0.1
<input type="checkbox"/>	↳ CSR	[REDACTED]	[REDACTED]	2022-01-24 3:16 PM	[REDACTED]	2022-01-24 3:16 PM	0.1
<input type="checkbox"/>	↳ Protocol	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	0.1

Page Size: 10 items ▾ < < 1 > > >> 1 - 10 of 10

> Notification: ⓘ

Close Notify

3. To perform an available action on a template and/or a hierarchical set (eg, **View Information** for a template), right-click on the listed objects to **View Information**.

WHERE USED: PROTOCOL TITLE							x
	Name	Owner	Created By	Created On	Modified By	Modified On	Version
<input checked="" type="checkbox"/>	Client 1 Protocol Template	[REDACTED]	View Information	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	1.0
<input type="checkbox"/>	Client 2 Protocol Template	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-24 3:30 PM	3.0
<input type="checkbox"/>	Client 2 Protocol Template - Var	[REDACTED]	[REDACTED]	2022-04-07 9:46 AM	[REDACTED]	2022-06-01 6:52 PM	0.5
<input type="checkbox"/>	Client 3 Protocol Template	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	1.0
<input type="checkbox"/>	PROT Template for U-Ingestion	[REDACTED]	[REDACTED]	2022-02-08 8:45 AM	[REDACTED]	2022-02-08 9:18 AM	1.0
<input type="checkbox"/>	Variant Template Test	[REDACTED]	[REDACTED]	2022-09-16 8:40 AM	[REDACTED]	2022-09-16 8:40 AM	0.1
<input type="checkbox"/>	↳ Clinical Short - Reuse Formattir	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2023-01-10 3:31 PM	0.1
<input type="checkbox"/>	↳ SAP	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	0.1
<input type="checkbox"/>	↳ CSR	[REDACTED]	[REDACTED]	2022-01-24 3:16 PM	[REDACTED]	2022-01-24 3:16 PM	0.1
<input type="checkbox"/>	↳ Protocol	[REDACTED]	[REDACTED]	2022-01-17 12:04 PM	[REDACTED]	2022-01-17 12:04 PM	0.1

Page Size: 10 items ▾ < < 1 > > >> 1 - 10 of 10

> Notification: ⓘ

Close Notify

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4. If a notification needs to be sent to the creator of a template and/or hierarchical set to inform them that an action is going to be performed against that item, click the **checkbox** next to the item's **Name**, expand the **Notification** section at the bottom of the window. The owner's name will be automatically entered in the **Send To** field; add all other necessary users, enter appropriate subject and message text, then click **Notify**. An email notification will be sent to the selected creators and the owner of the object.

WHERE USED: PROTOCOL TITLE

Name	Owner	Created By	Created On	Modified By	Modified On	Version
<input checked="" type="checkbox"/> Client 1 Protocol Template			2022-01-17 12:04 PM		2022-01-17 12:04 PM	1.0
<input type="checkbox"/> Client 2 Protocol Template			2022-01-17 12:04 PM		2022-01-24 3:30 PM	3.0
<input type="checkbox"/> Client 2 Protocol Template - Var			2022-04-07 9:46 AM		2022-06-01 6:52 PM	0.5
<input type="checkbox"/> Client 3 Protocol Template			2022-01-17 12:04 PM		2022-01-17 12:04 PM	1.0
<input type="checkbox"/> PROT Template for U-Ingestion			2022-02-08 8:45 AM		2022-02-08 9:18 AM	1.0
<input type="checkbox"/> Variant Template Test			2022-09-16 8:40 AM		2022-09-16 8:40 AM	0.1
<input type="checkbox"/> Clinical Short - Reuse Formatti			2022-01-17 12:04 PM		2023-01-10 3:31 PM	0.1
<input type="checkbox"/> SAP			2022-01-17 12:04 PM		2022-01-17 12:04 PM	0.1
<input type="checkbox"/> CSR			2022-01-24 3:16 PM		2022-01-24 3:16 PM	0.1
<input type="checkbox"/> Protocol			2022-01-17 12:04 PM		2022-01-17 12:04 PM	0.1

Page Size: 10 items ▾ « < < 1 > > » 1 - 10 of 10

▼ Notification: ⓘ

Send To: ⓘ

Cam Mistry (cmistry@intelinotion.com) x Enter User(s)

Subject:

Enter Subject

Message:

Enter Message

Close **Notify**

Notes:

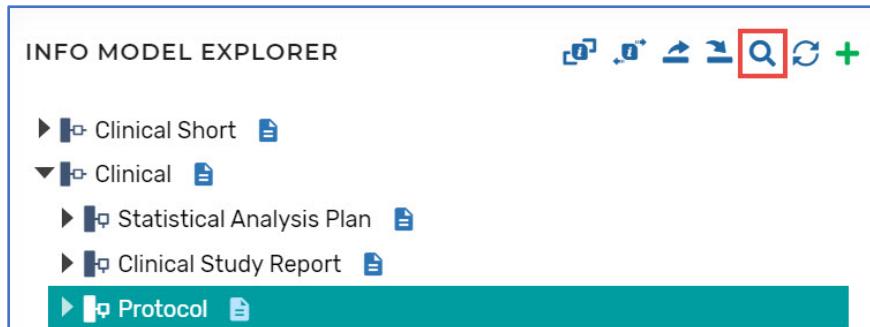
- If the owner of the selected object is not available, the user listed under the **Created By** column will be auto populated in the **Send To** field as an alternative.
- At least one user must be listed in the Send To field for the Notify button to be active.

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2.6 SEARCHING IN THE INFO MODEL EXPLORER

Hierarchical sets and elements can be searched using the search icon on the top of the pane.



A search can be performed by ID, name, or alias. The result will be displayed in a tabular form with an icon indicating if it is an element or hierarchical set.

The table can be sorted into any column by clicking on its header.

SEARCH				
<input type="text" value="Protocol"/> <button>Search</button>				
Name	Created By	Created On	Modified By	Modified On
△ Amended Protocols	Mike Redl	2020-08-03 2:28 PM	Mike Redl	2020-08-03 2:28 PM
▢ Protocol	Andrea Sullivan	2021-07-22 9:00 AM	Mike Redl	2021-08-17 6:28 AM
▢ Protocol	Andrea Sullivan	2021-07-15 12:59 AM	John Duran	2021-07-15 12:59 AM
▢ Protocol	Mike Redl	2021-07-09 9:43 AM	Mike Redl	2021-07-09 9:43 AM
△ CPT:ProtocolID	Mike Redl	2019-10-10 3:08 AM	Mike Redl	2019-10-10 4:30 AM
▢ Global Single Dose T	John Duran	2021-03-27 11:18 AM	Mike Redl	2021-03-27 11:18 AM
▢ M Protocol	John Duran	2021-03-01 4:24 PM	Mike Redl	2021-03-02 8:29 AM

Right clicking on any row will allow the user to navigate to the hierarchical set or element.

△ Protocol Short Title	Cam Mistry	2021-10-15 4:17 PM	Locate In Info Model	2021-10-15 4:17 PM
▢ Protocol Summary	Cam Mistry	2021-10-15 4:17 PM	Cam Mistry	2021-10-15 4:17 PM

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2.7 EXPORTING AND IMPORTING HIERARCHICAL SETS OR ELEMENTS

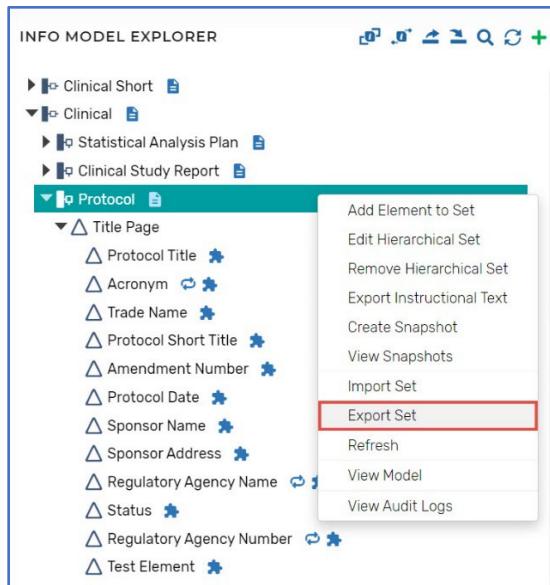
There are a few options available to export and/or import a specific hierarchical set (including all child sets and/or elements) or element. The exported file is in JSON format; similarly, a file must be in the appropriate JSON format before it can be imported.

Note: Export or import of the entire info model, including all hierarchical sets and elements, can be done by clicking the appropriate icon at the top of the **Info Model Explorer** window as shown below.



2.7.1 Exporting Hierarchical Set or Element

1. To export a hierarchical set or parent element (eg, includes at least 1 child element), right-click on it and click **Export Set**. If prompted, browse to, and select the location where the file is to be downloaded.



2. The downloaded file will be saved to the appropriate folder with a .json extension.



3. The file can be opened using a preferred text editor (eg, Notepad) or in a browser. It will contain all the elements of the selected hierarchical set or parent element and the corresponding configurations.

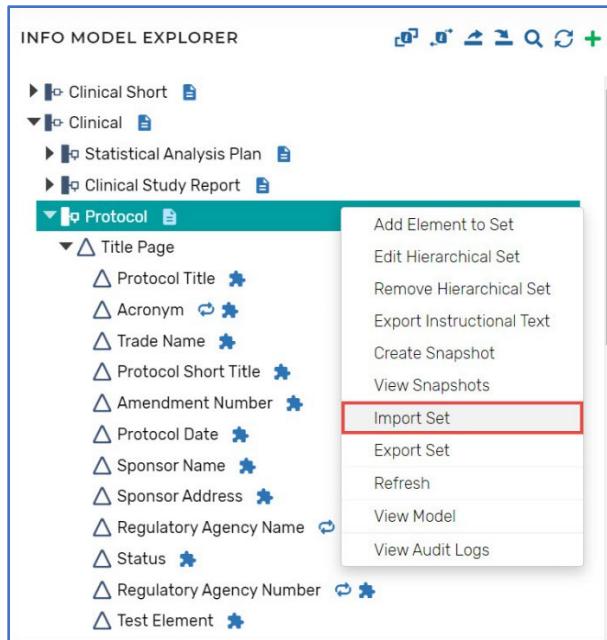
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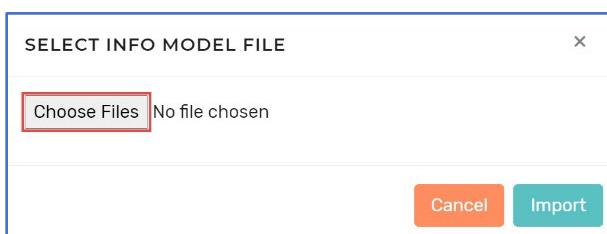
2.7.2 Importing Hierarchical Set or Element

- To import a hierarchical set or any element, right-click on the parent set or element under which the new item is to be added, and then click **Import Set**.



Notes:

- A hierarchical set can *only* be imported under another hierarchical set that does not already include any child elements. It is not permitted to add or import a hierarchical set that would be a sibling of an element under the same hierarchical set.
 - A table element can be selected for export or import directly via the info model page (at either the element or hierarchical set level).
 - Once a hierarchical set has been imported, the related validation report will inform the user if elements are present in the target environment, but not the imported set. This is also true if the target environment's set is missing AI rules or instructional text when compared to the set/element being imported.
- Browse to and select the file to be imported. The import file must be compliant with the *InteliNotion* structure.



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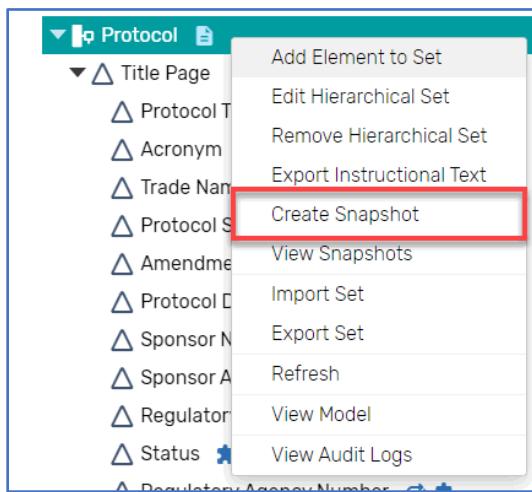
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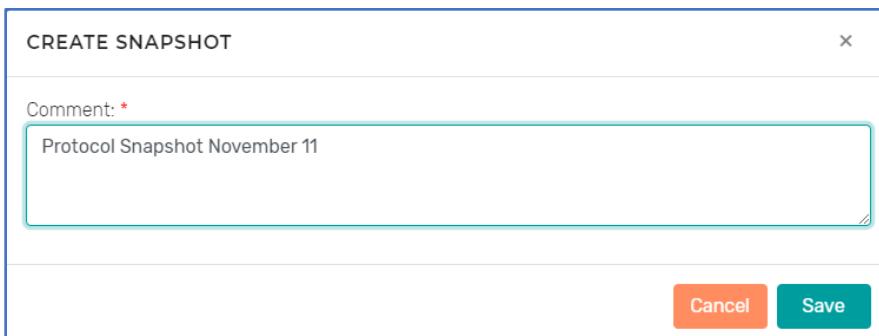
Note: Exporting and importing hierarchical sets and/or elements is intended to help expedite the creation of new info model structures. To export system-level configurations including the info model, metadata, templates, etc., so that they can be migrated from one *InteliNotion* environment into another, refer to the **InteliNotion Application Admin Guide** for detailed instructions.

2.8 CREATE AND VIEW SNAPSHOT OF MODEL

1. To create a snapshot of a Hierarchical Set, right-click on the set and **select Create Snapshot**.



2. On the **Create Snapshot** screen, enter a comment.

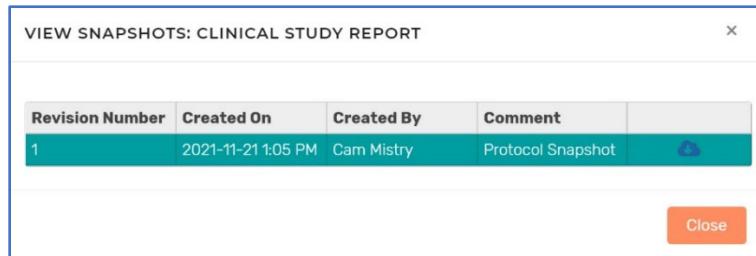
A screenshot of the 'CREATE SNAPSHOT' dialog box. The title bar says 'CREATE SNAPSHOT'. Below it is a 'Comment:' field with a red asterisk, containing the text 'Protocol Snapshot November 11'. At the bottom are two buttons: 'Cancel' (orange) and 'Save' (green).

3. A **Snapshot Created Successfully** pop-up will display.

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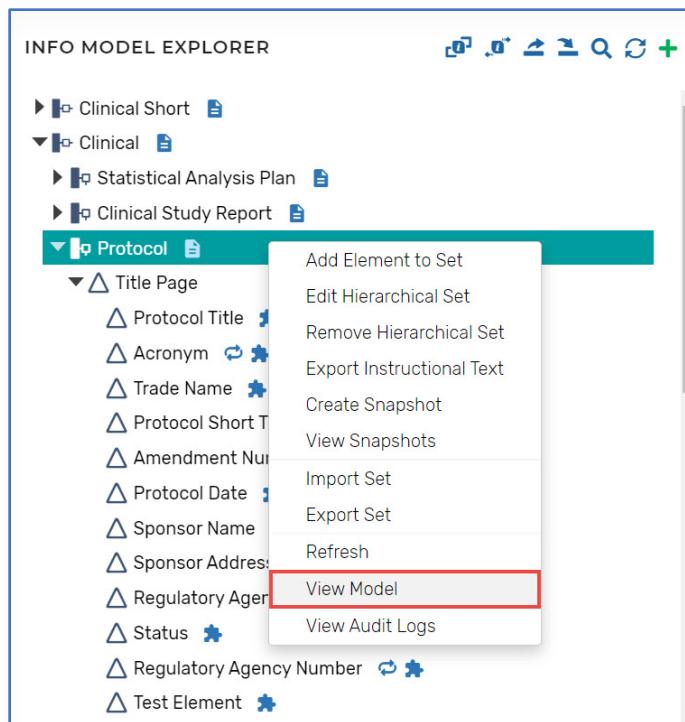
4. To view the snapshot, select **View Snapshots** from the dropdown menu and on the **View Snapshot** screen click on the download file icon.



5. A json file containing all the hierarchical set properties and setting on that point of time will be downloaded.

2.9 VIEWING THE MODEL

A graphical view of any hierarchical set, including its child sets and related elements, can be displayed within the system. Information such as source and reuse policy are included within the view. To open the graphical view of a hierarchical set, select **View Model** from its right-click menu; there are 2 views available – **Local View** (default) and **Incremental View**.

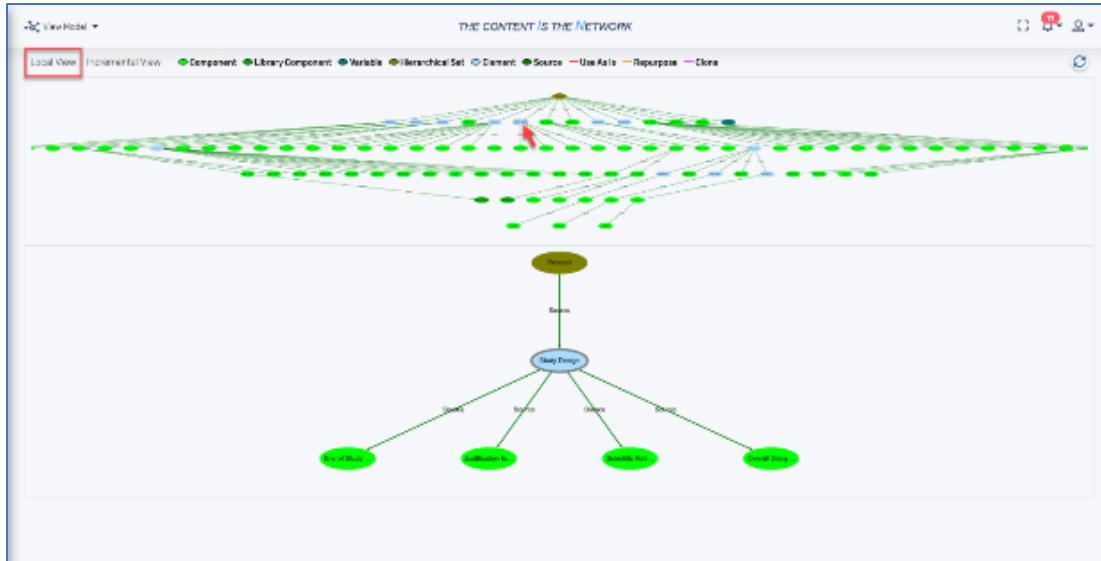


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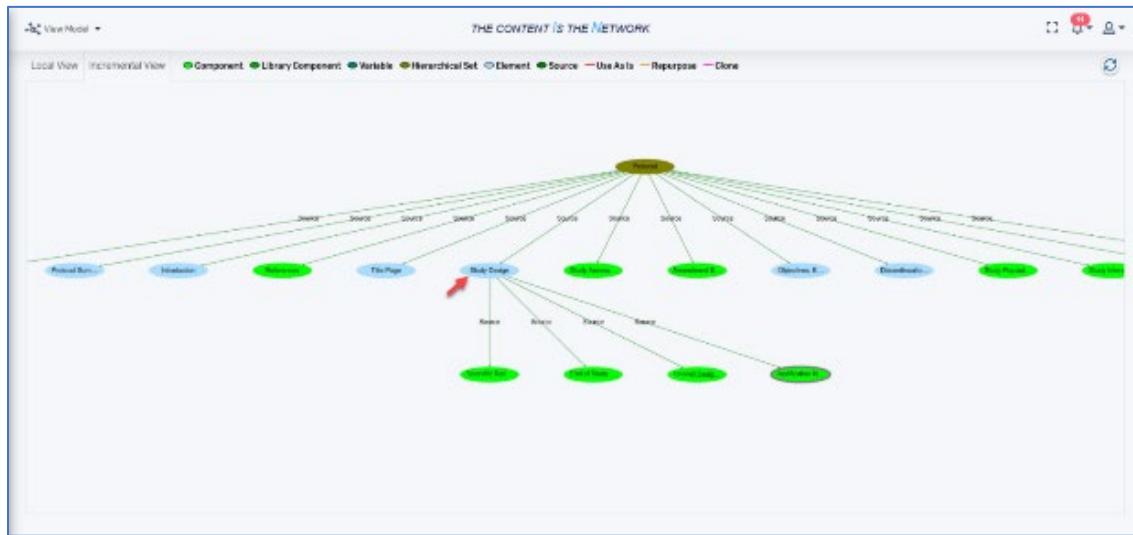
2.9.1 Local View

While this representation can be very complex depending on if a parent hierarchical set is selected, the graphic is zoomable with the center wheel of the mouse. When 1 of the nodes (eg, **Study Design**) is clicked on, a focused representation for that node will be shown on the bottom half of the screen.



2.9.2 Incremental View

In this view, only 1 level of nodes is displayed initially, but clicking on 1 of them will incrementally show (if possible) more and more nodes until there are no more child nodes to display.



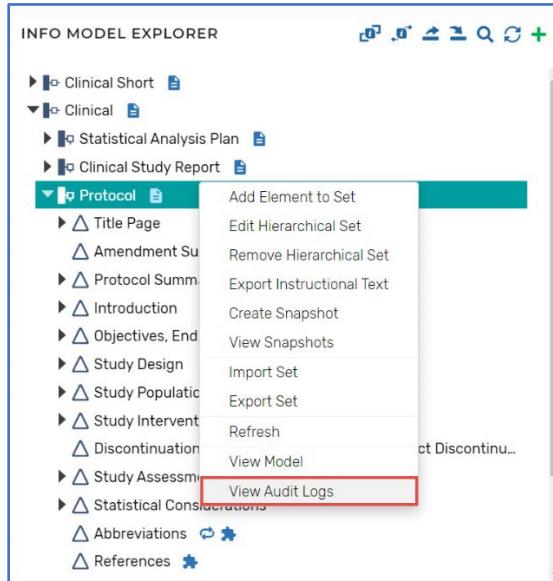
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Note: A user can view some of the properties of the nodes (hierarchical sets or elements/components) by hovering the mouse over them.

2.10 INFO MODEL AUDIT LOGS

Info model actions performed in the system will be audited automatically. To view the audit logs, right-click on any item in the info models' hierarchical tree and click **View Audit Logs**.



The following events will create an audit log event for the info models:

- Hierarchical set creation, update, or deletion
- Element creation, update, or deletion

VIEW AUDIT LOGS: AMENDMENT SUMMARY TABLE				
Event Name	Object Name	Event Time	User Name	Object ID
Create Relationship	△ Amendment Su...	2020-06-23 2:18 ...	John Duran	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-06-12 10:10 ...	Andrea Sullivan	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-06-01 2:42 ...	Mike Redl	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-05-26 1:04 ...	Mike Redl	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-03-18 10:31 ...	John Duran	8379117a-9947-40...
Update Object	△ Amendment Su...	2020-03-18 10:30 ...	Andrea Sullivan	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-02-26 1:49 A...	Andrea Sullivan	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-02-13 2:49 P...	Mike Redl	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2020-01-10 4:11 PM	Mike Redl	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2019-11-20 10:08 ...	John Duran	8379117a-9947-40...
Create Relationship	△ Amendment Su...	2019-08-22 2:25 A...	John Duran	8379117a-9947-40...

Page Size: 25 items < < 1 > >> 1 - 11 of 11

Close

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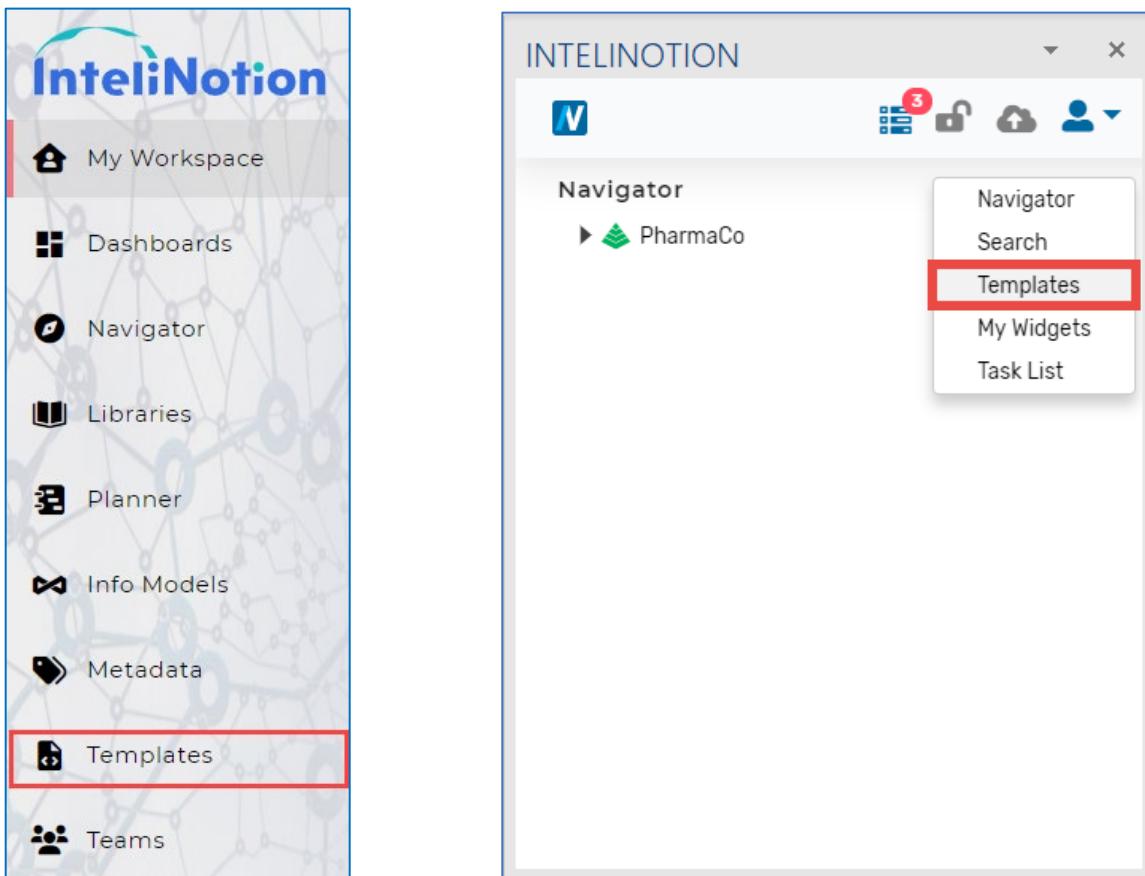
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3. CONFIGURING DOCUMENT TEMPLATES

The document templates are docx files that include elements (inserted from the info model) that define what content should be included in a document, and in what location; when a document is generated from a template, any content reuse policies can then be applied according to the info model.

Available document templates can be accessed by clicking the **Templates** option in the left-hand navigation pane of the *Web Console* OR in the options under the **vertical ellipsis** ⏮ button of the *InteliNotion Word App*.



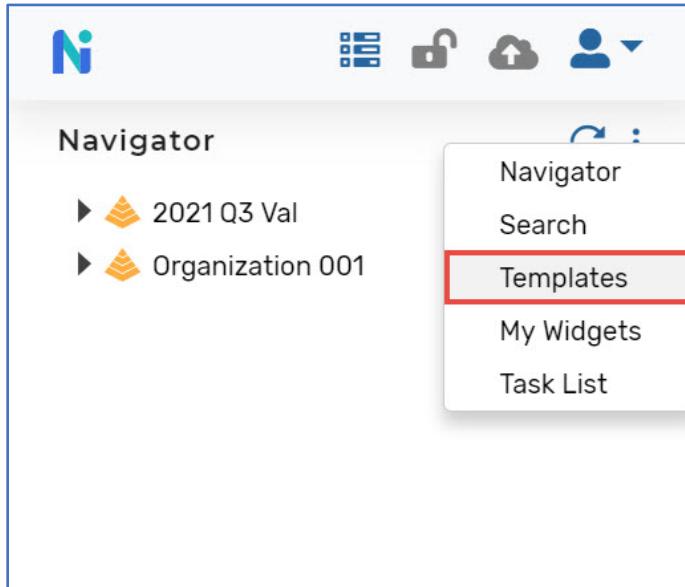
Note: To ensure the style and any formatting applied to the content in the (library) component remains unchanged after it is reused, either via auto-insertion during document generation, or user-insertion while authoring, the same style(s) should be imported/available in the document or template itself.

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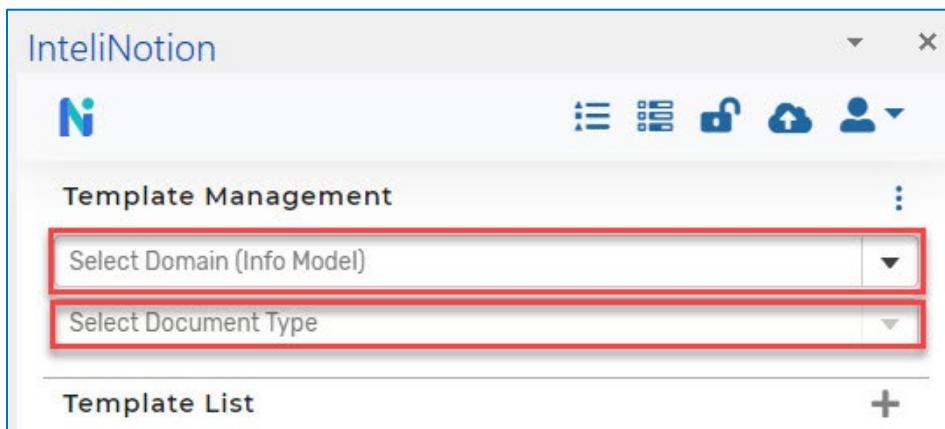
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3.1 CONFIGURING A DOCUMENT TEMPLATE VIA THE WORD APP

1. Click on the vertical ellipsis  button in the *InteliNotion Word App* and select **Templates**.



2. Select the relevant **Info Model - Hierarchical Set Name** and **Document Type** and click the **add icon**  to add a template.

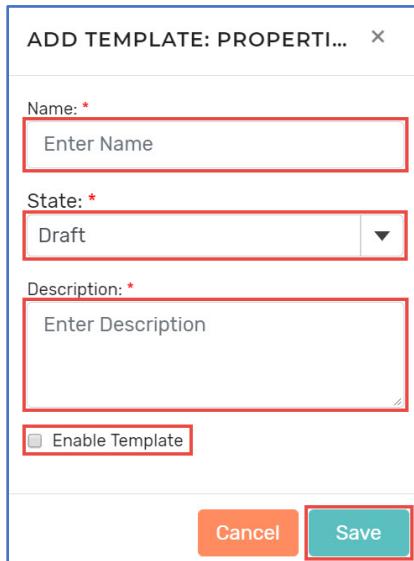


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- Fill in the required form details and click **Save**. The following special characters are not allowed in the **Name**: \, /, :, #, %, *, ?, <, >, |, ".

Note: If the **Enable Template** checkbox is left unchecked, the template will be hidden from the list of available templates that any user will see when generating a document, even if it is in an approved state.



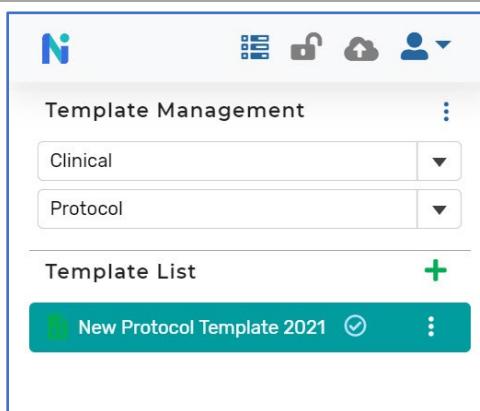
The dialog box has a title bar 'ADD TEMPLATE: PROPERTY...' with a close button. It contains three input fields with red borders: 'Name: *' with placeholder 'Enter Name', 'State: *' with placeholder 'Draft', and 'Description: *' with placeholder 'Enter Description'. Below these is a checkbox labeled 'Enable Template' which is unchecked. At the bottom are two buttons: 'Cancel' (orange) and 'Save' (green).

- The app will display a progress indicator while it is opening the new template.



- The template will open in the same window of *MS Word* automatically.

Note: A new template will be empty of any content.



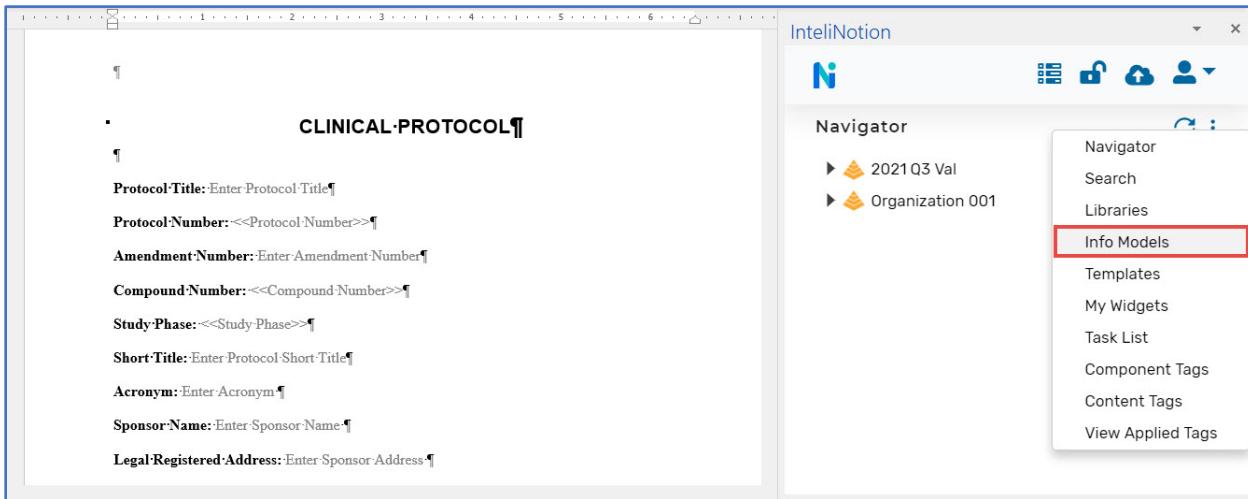
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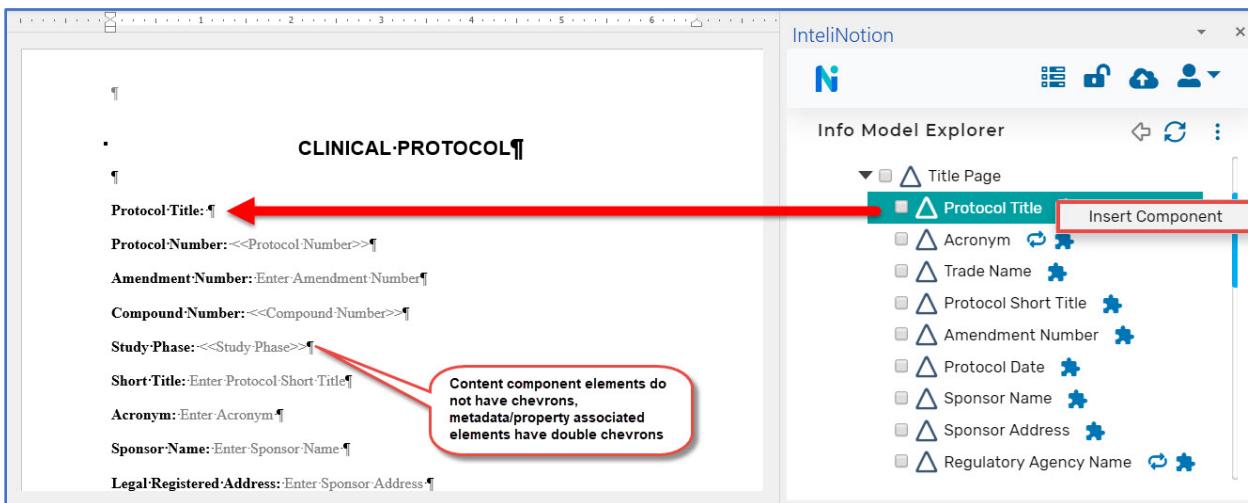
6. Insert any document-level content (eg, header/footer, section headings, etc.) and import any preferred styles into the template, as appropriate.

Note: The **InteliNotion ribbon** provides **Text Tools** to manage styled text within the template or a generated document.

7. Click on the **vertical ellipsis** button in the *InteliNotion Word App* and select **Info Models**.



8. Expand the hierarchical set for the related document type (or another set, if appropriate), locate the element to be inserted into the template, right-click on it, and click **Insert Component**.



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Notes:

- Multiple elements can be inserted 1 at a time by clicking the checkbox next to the element names and then clicking the arrow button at the top-right corner of the *InteliNotion Word App* pane.
- If 2 or more repeating components are configured in a parent-child manner, they must be added within a tabular format for the child components to be automatically added if/when the parent component is added.
- If repeating components are configured in a parent child relationship and are intended to use in a tabular format, refer to [Section 2.2.7.1](#).

9. Repeat Step 7 until all required elements are inserted into the header, body, and footer section of the template.

Note: It is recommended to limit the number of inserted elements to below 250, to ensure optimal performance while authoring a document generated from the template. As the number of components increases the response/processing time may also increase.

10. Save and check in the template using the **Save icon** .

3.1.1 Adding a Table Type Element to a Template

As an authorized user it is possible to select a table sub-element in the info model and insert it as follows:

- Insert BOTH the table sub-element along with its 'parent' table element (ie, as part of a table) AND the sub-element standalone (ie, outside of a table, directly in the template)
- Insert ONLY the table sub-element standalone without also inserting it along with its 'parent' table element being inserted elsewhere
- For Set in Relation table - Insert any table sub-element
- For Hierarchical table - User cannot insert a 'child' sub-element (eg, endpoint) without first inserting its related 'parent' sub-element (eg, objective)

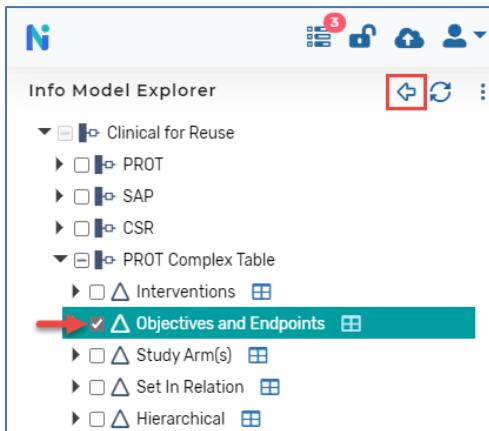
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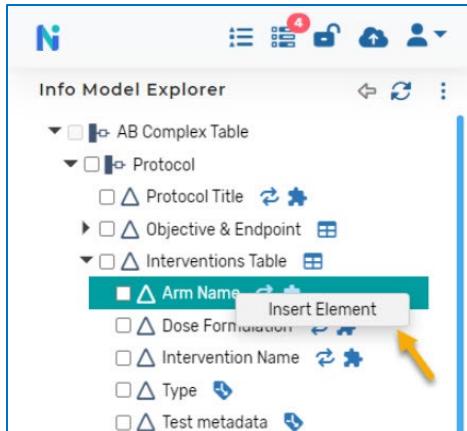
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There are three ways in which a table type element can be inserted into a template:

- Select table type element from the Info Models view of the *IN Word* app
- Insert the table type element by using the Insert selected element (arrow) button. The table will be inserted into the template with all child elements included and row layout by default.



- Insert the table type element directly into the template (outside of an existing table) by navigating to the applicable element in the *IN Word* app info model explorer, right clicking, and selecting **Insert Element**.



Notes:

If inserting a table element directly into a template, it is possible to insert both the table sub-element along with its 'parent' table element (ie, as part of a table) and the sub-element outside of a table

- If inserting a table element directly into a template, it is possible to insert only the table sub-element standalone without also inserting it along with its 'parent' table element being inserted elsewhere in the template.

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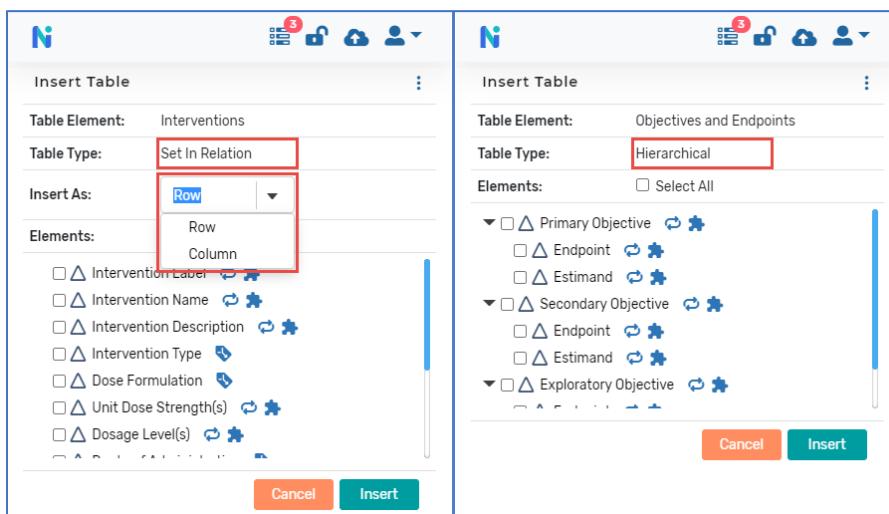
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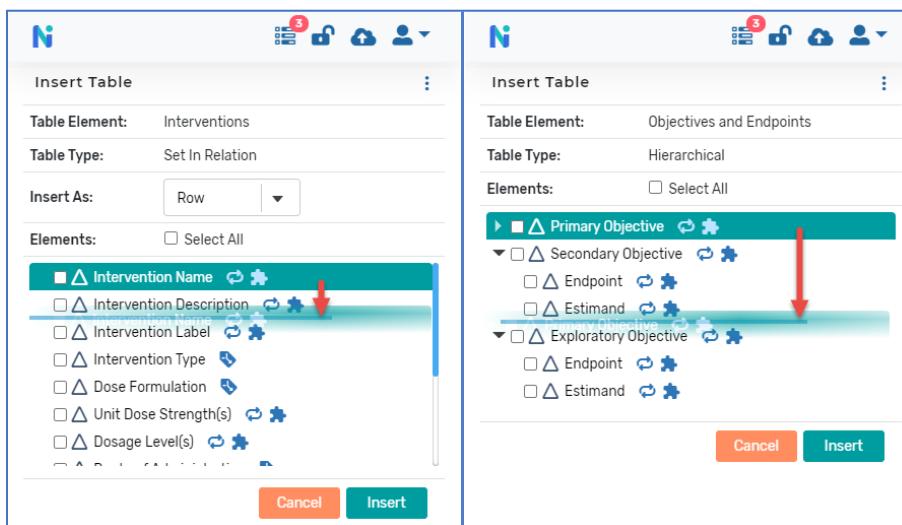
- Insert the table type element using the context menu (right-click select 'Insert table') which will open a new 'Insert Table' view.

From within the 'Insert Table' view, the user should be able to see the following information about the table type element:

- Name of the table type element
- Table type
- Drop-down for "Insert As" (for the 'Set in Relation' type only) with 'Column' and 'Row' values



Note: In the context menu, the user can also change the order of how the elements are inserted into the template by clicking and dragging a set of element(s) as needed.



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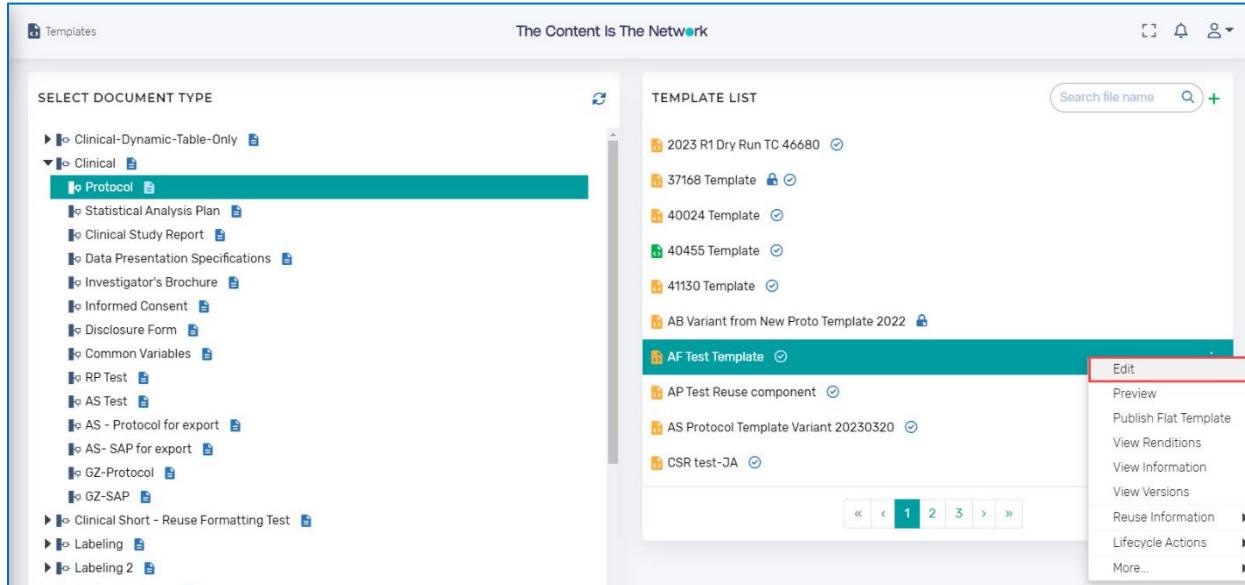
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Note: See **InteliNotion User Guide, Module 5, Section 1.8** for further details on the utilities of table tools.

3.1.2 Adding a Component Set to a Template

Follow the steps listed below to add a component set to a template.

1. In the left-hand navigation pane, click on **Templates**.
2. Navigate to the document type to be updated and click on it. The **Template List** for that document will appear on the right.
3. In the **Template List**, click on the ellipsis for the template to be edited and select **Edit**.



4. Once the template is open in *Word*, place the cursor in the desired location of the new component set.

Primary Objectives	Endpoints	Estimands
Enter Primary Objectives	Enter Endpoints	Enter Estimands
Secondary Objectives	Endpoints	Estimands
Enter Secondary Objectives	Enter Endpoints	Enter Estimands
Exploratory Objectives	Endpoints	Estimands
Enter Exploratory Objectives	Enter Endpoints	Enter Estimands

Enter References

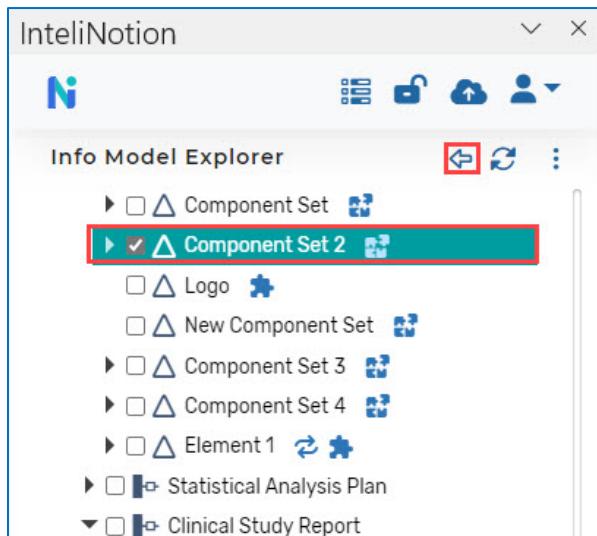
5. In the *IN Word* app, click on ellipsis and select **Info Model**.

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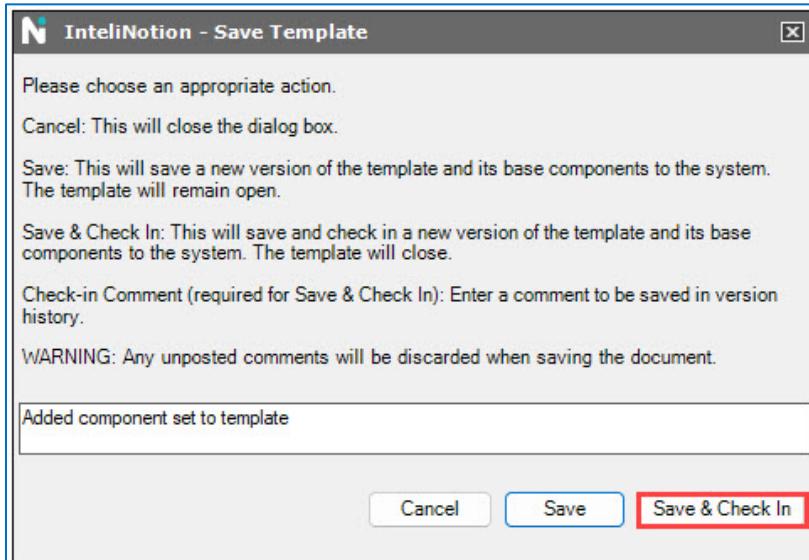
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6. Navigate to the component set to be added to the template, right click on it, and select **Insert Component Set** or select the check box next to component set and click on the arrow icon at the top of the Info Model Explorer.



Note: If components from the set need to be reordered, drag and drop them in the desired order before insertion.

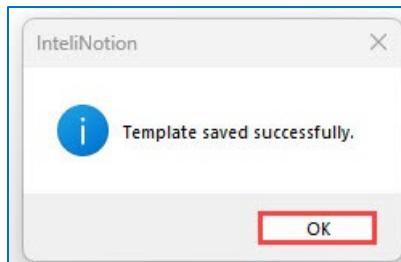
7. Click the **Save Document** icon in the InteliNotion toolbar.
8. The **Save Template** window will appear. Enter a comment and click the **Save and Check in** button to save the template.



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9. A pop-up will appear informing the user the template was saved successfully. Click **Okay** and exit out of Word.



3.1.3 Changing the Behavior of an Inserted Component

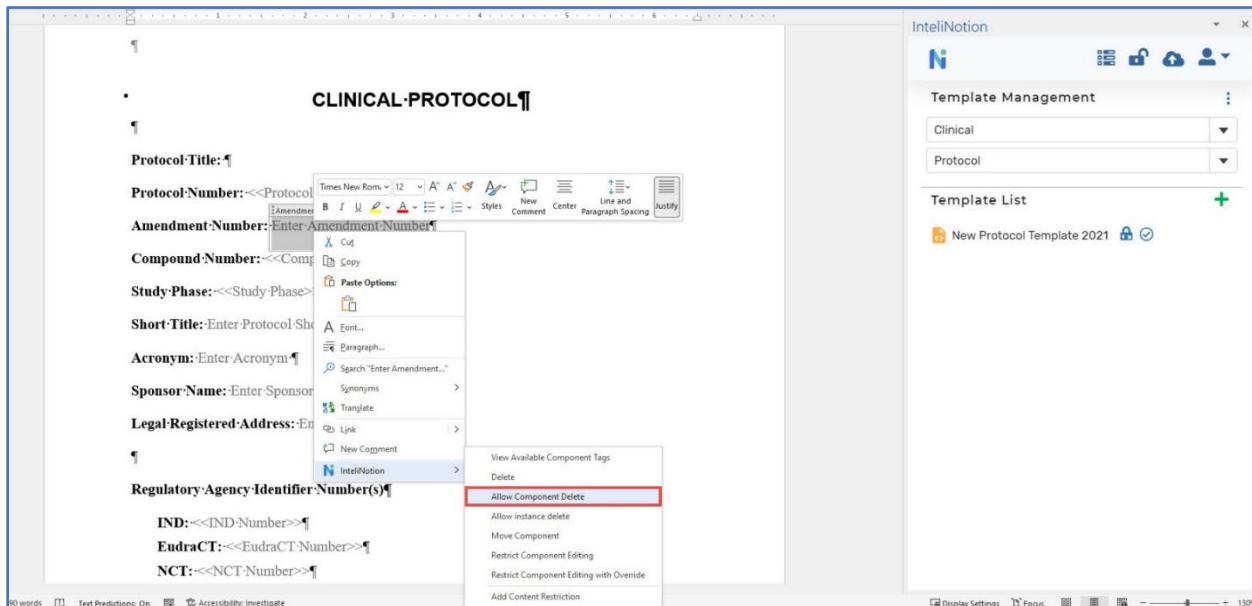
After an element/component has been inserted into a template, a few actions may be performed on it:

- Change the delete policy set at the info model level for the inserted component.
- Insert an additional instance of a component and apply a different delete policy.
- Add content to create a base component. Once a base component is created, certain content restrictions can be applied to the content therein.

The following subsections outline the steps needed to complete the actions above.

3.1.3.1 Changing the Delete Policy for an Inserted Component

To change the component's delete policy, right-click on the component in the document, hover over the **InteliNotion** option, and click either **Allow Component Delete** or **Restrict Component Delete** (the available option will be based on the info model's policy).



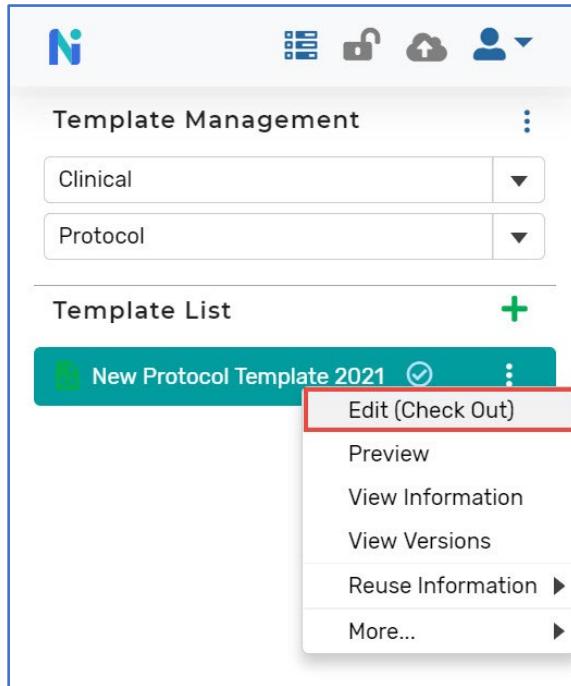
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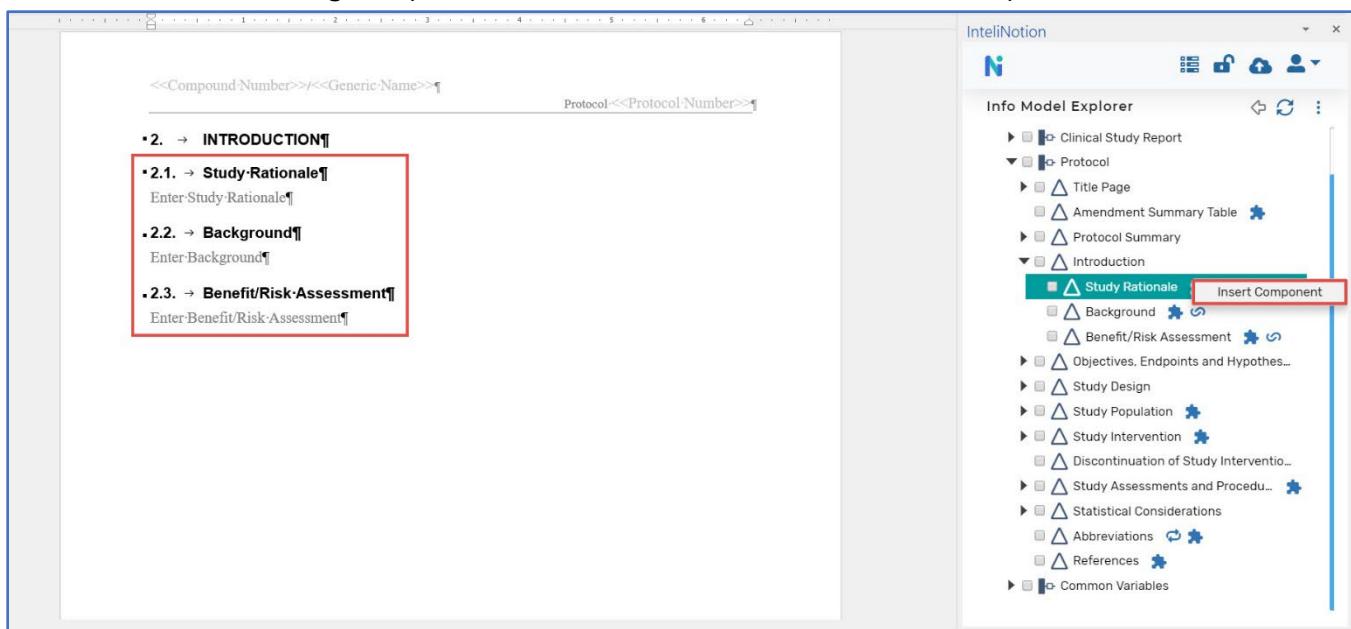
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3.1.3.2 Changing the Delete Policy for an Additional Component Instance

1. **Edit (Check Out)** a template from the Web Console or *InteliNotion Word App*.



2. Click on the **vertical ellipsis** button in the *InteliNotion Word App* and select **Info Models**. Choose an existing component and insert it several times into the template.

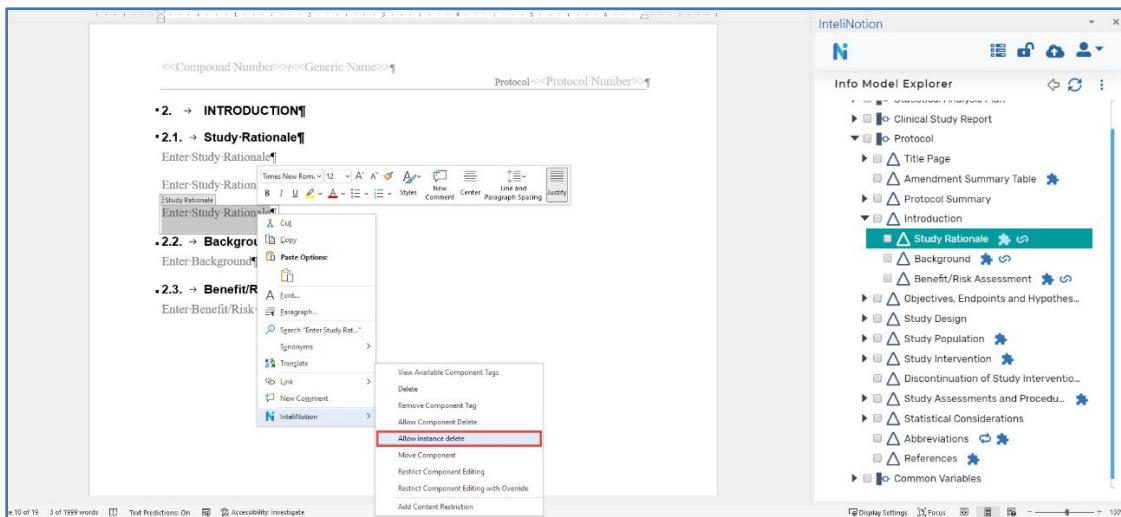


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3. Right-click on the second instance of the component, hover over the **InteliNotion** option, and click **Allow Instance Delete**.



4. Click in the third instance of the component and type in some text. Click on the **Save icon**



• 2. → INTRODUCTION¶

• 2.1. → Study-Rationale¶

Enter-Study-Rationale¶

Study Rationale
Test-Text¶

• 2.2. → Background¶

Enter-Background¶

• 2.3. → Benefit/Risk-Assessment¶

Enter-Benefit/Risk-Assessment¶

5. The other components will now update to show the reflected text.

• 2. → INTRODUCTION¶

• 2.1. → Study-Rationale¶

Test-Text¶

Test-Text¶

Test-Text¶

• 2.2. → Background¶

Enter-Background¶

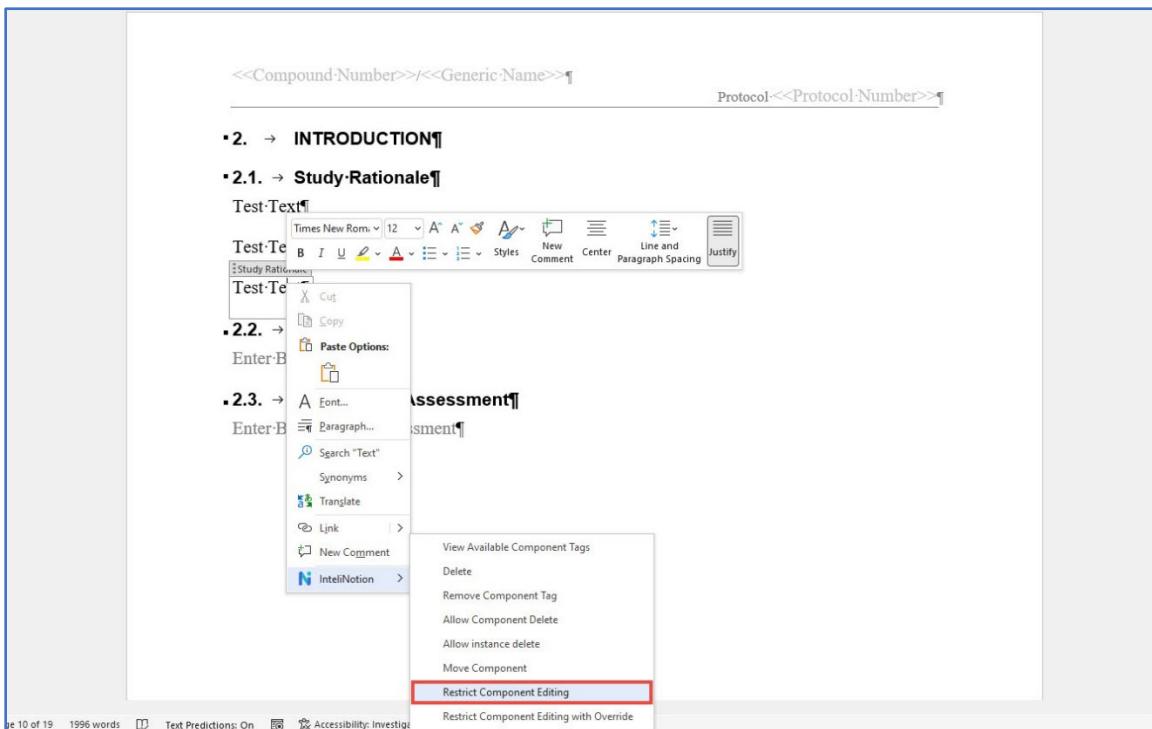
• 2.3. → Benefit/Risk-Assessment¶

Enter-Benefit/Risk-Assessment¶

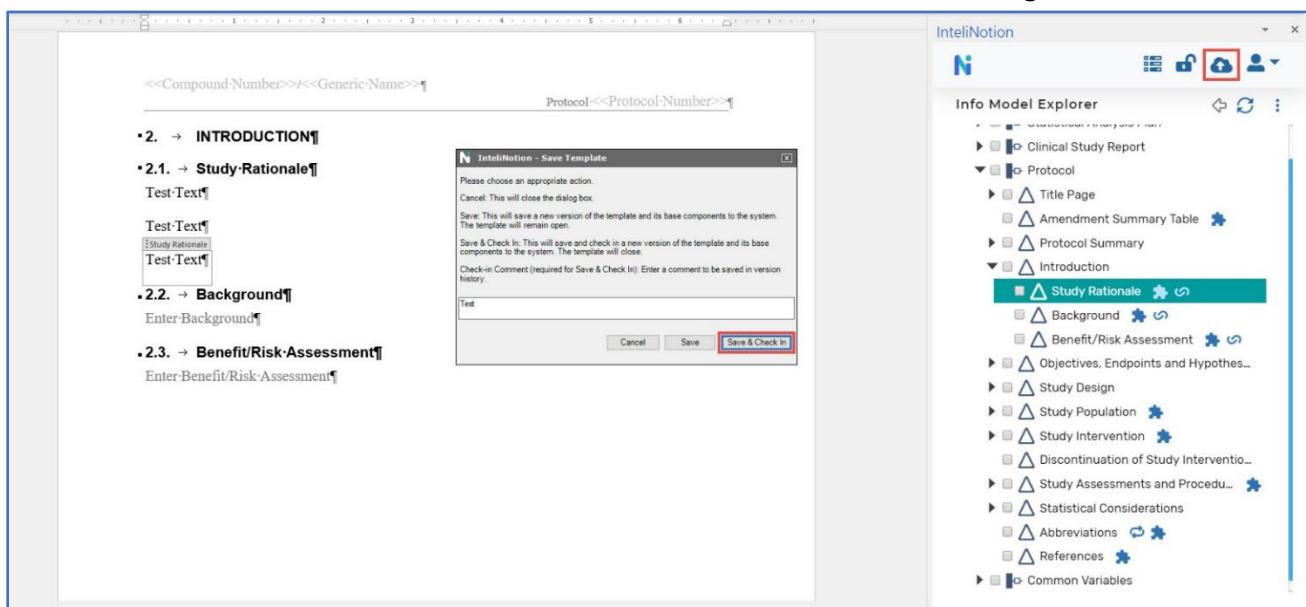
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6. Right-click on the third instance of the component, hover over the **InteliNotion** option, and click **Restrict Component Editing**.



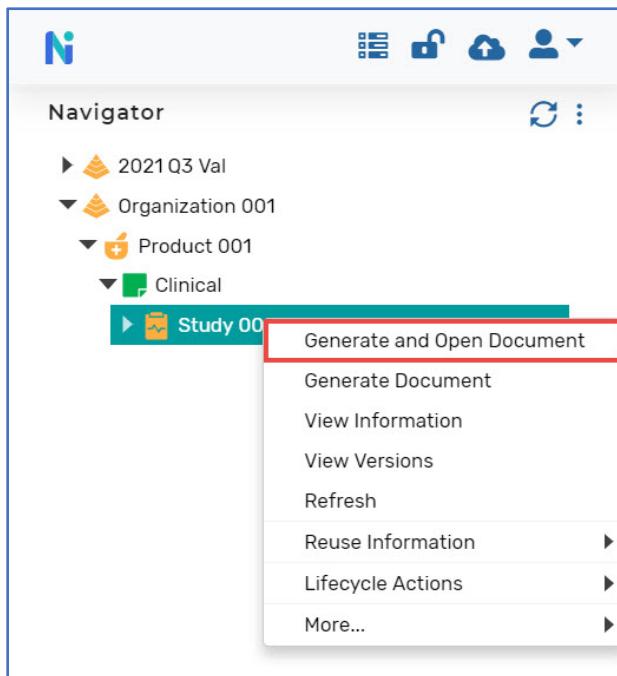
7. Click on the **Save icon**  **. Save & Check In** the document after adding a comment.



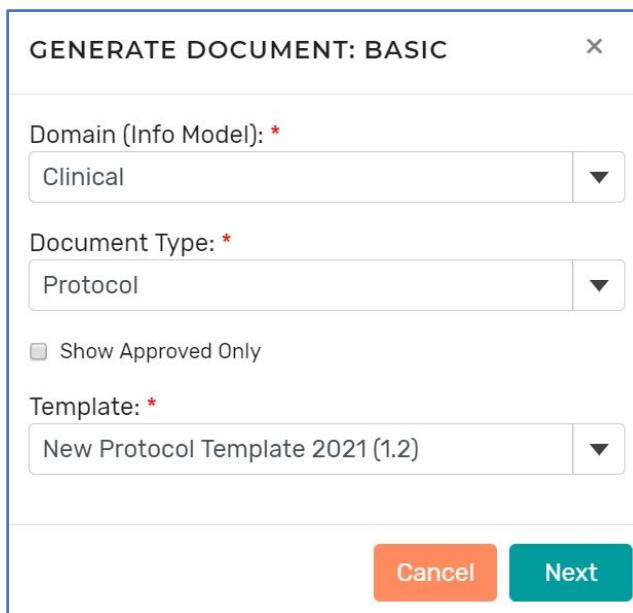
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8. Right-click on **Generate and Open Document** at the location in **Navigator** where the new document created from the template will be located.



9. Fill in the information to populate the document from the template that was created.



GENERATE DOCUMENT: BASIC

Domain (Info Model): *
Clinical

Document Type: *
Protocol

Show Approved Only

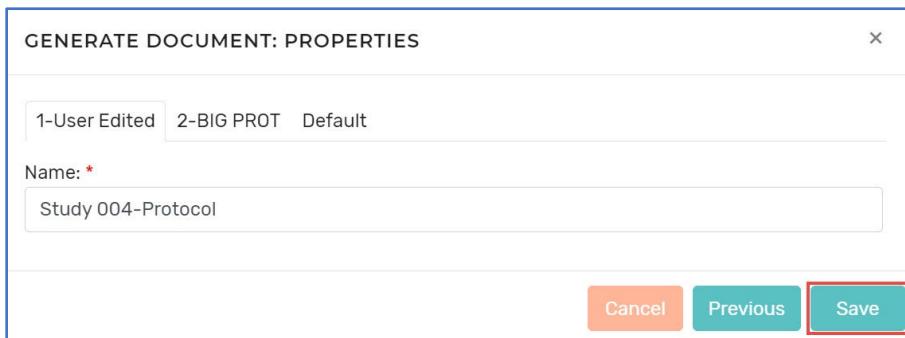
Template: *
New Protocol Template 2021 (1.2)

Cancel Next

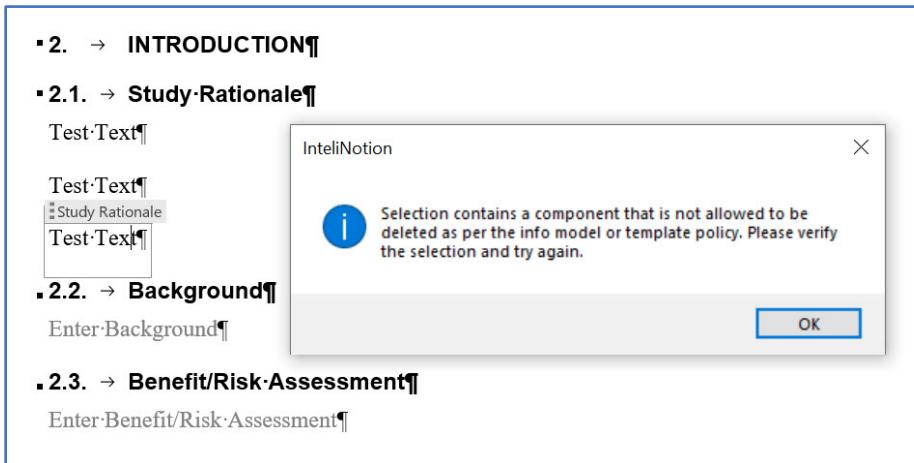
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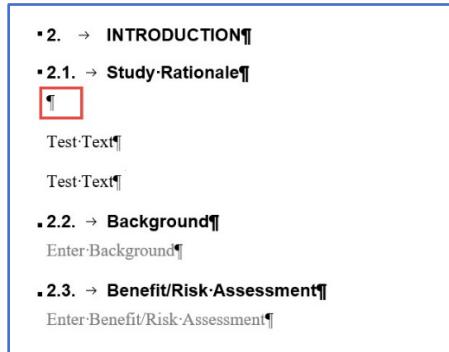
10. Complete the **Generate Document: Properties** tab and click **Save** to generate the document.



11. Right-click on the first instance of the component and hover over the **InteliNotion** option, then click **Delete**. The user will receive a notification that they are unable to delete the component per the info model policy.



12. Right-click on the second instance of the component and hover over the **InteliNotion** option, then click **Delete**. The user will be allowed to delete the component based on the info model delete policy.



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13. Right-click on the third instance of the component and try to edit the text. The user will not be allowed to edit the component based on the info model delete policy.

3.1.3.3 Applying Content Restrictions to a Component

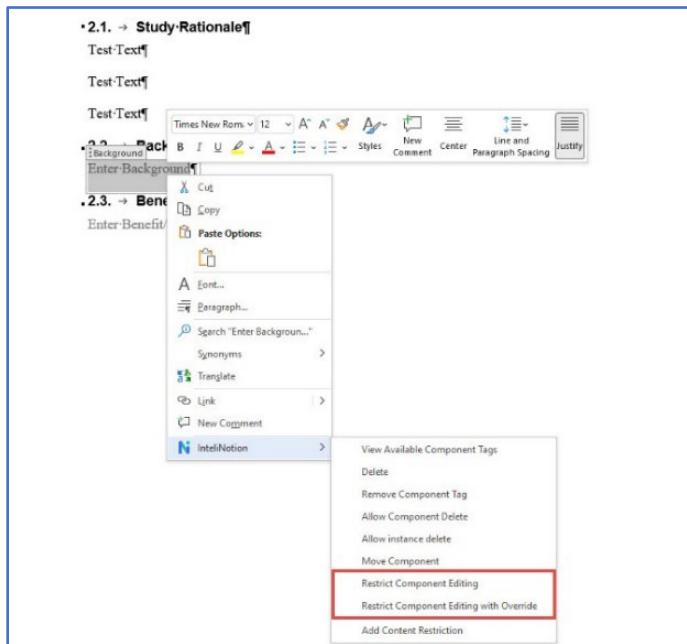
Content restrictions can be added within a base component once it has been created. To create a base component, enter text or other content into an inserted element/component, and save the template. Refer to the **InteliNotion User Guide**, Module 5 for details on how to save or save and check in a document (this is the same process for a template).

Note: When copying and pasting content within a content control, be sure to verify that MS Word's Design Mode (on the developer ribbon) is off. If content with its surrounding content control is copied and pasted into an empty component while Design Mode is on, then the content will be inserted within the component's placeholder text.

Once a base component has been created, a content restriction can be applied to all its content or a selected area.

To restrict editing for all content within the component, right-click on the component in the document, hover over the **InteliNotion** option, and click either of the following options:

- **Restrict Component Editing** - editing of the content by a user is never allowed in the generated document.
- **Restrict Component Editing with Override** - editing of the content is not allowed in the generated document; however, the user can choose to override the edit restriction after entering a change rationale.



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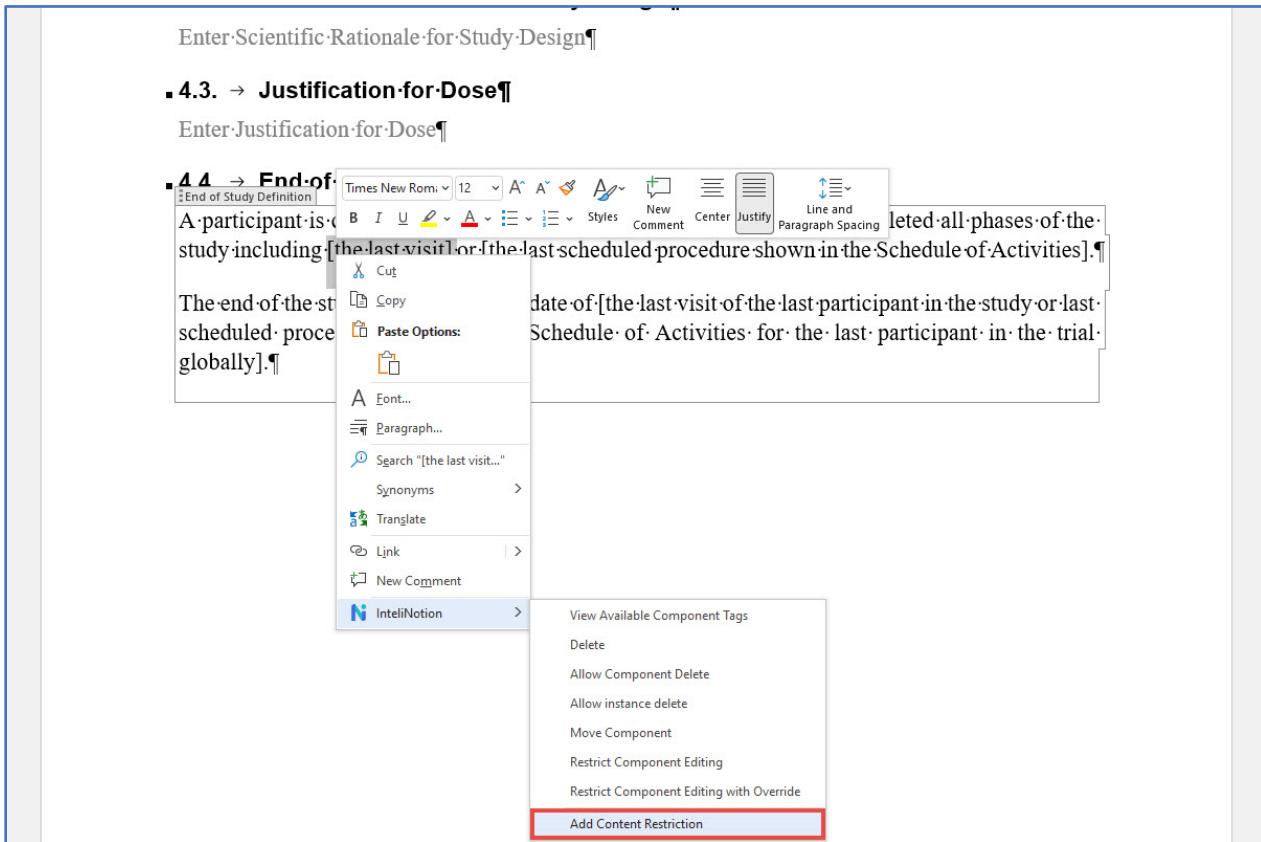
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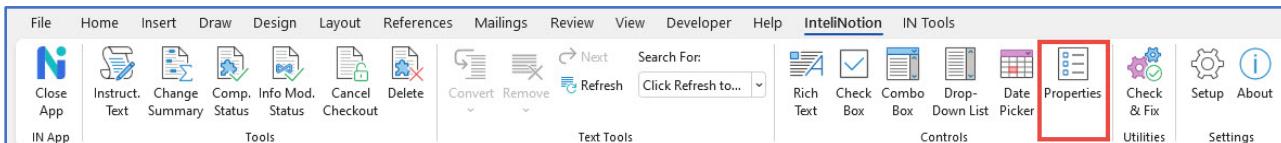
Note: To remove the component editing restriction, right-click on the component in the document, hover over the **InteliNotion** option, and click **Allow Component Editing**.

To restrict editing and/or deletion for selected content within the component follow the steps listed below:

1. Highlight/select the desired content.
2. Right-click on the highlighted area, hover over the **InteliNotion** option, and click **Add Content Restriction**.



3. The highlighted content is inserted into a content control box. Click on the **Properties** option under the Controls section of the *InteliNotion* ribbon to configure the content restriction.



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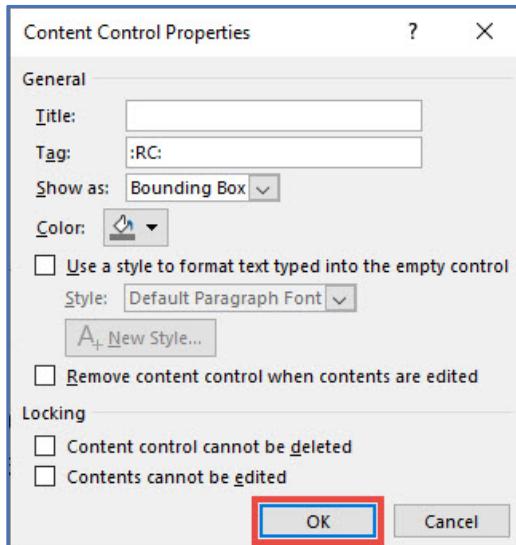
4.4 → End-of-Study-Definition¶

A participant is considered to have completed the study if he/she has completed all phases of the study including [the last visit] or [the last scheduled procedure shown in the Schedule of Activities].¶

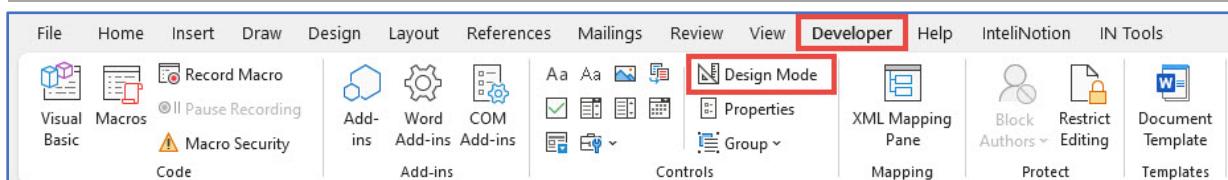
The end-of-the-study is defined as the date of [the last visit of the last participant in the study or last scheduled procedure shown in the Schedule of Activities for the last participant in the trial globally].¶

Note: To apply a content restriction to the last paragraph within a component, an extra empty paragraph must be inserted temporarily after the last paragraph so that it can be selected, and the restriction applied. Thereafter, the extra empty paragraph should be removed.

4. Configure content control properties (to prohibit deletion and/or editing) and click **OK**.



Note: If MS Word's **Design Mode** (on the developer ribbon) is turned on, the system will automatically turn it off when saving a document, component, or template to the system.



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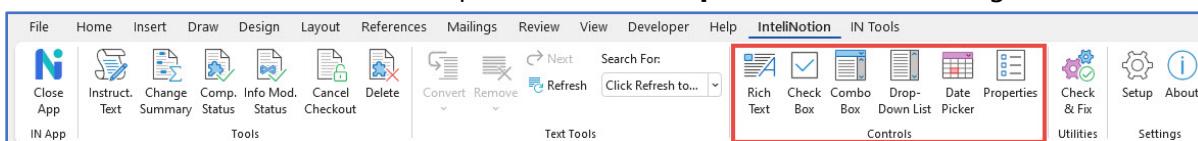
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3.1.4 Applying Content Controls in a Template

The following types of content controls are available on the *InteliNotion* ribbon:

- **Rich Text** – to restrict content editing or deletion for content outside a component (eg, a section heading within the document itself). Use the **Properties** button to update the editing or deletion policy (like a content restriction, refer to [Section 2.5.1](#)).
- **Check Box** – to insert a check box. Use the **Properties** button to change the check box symbol, if needed.
- **Combo Box** – to insert a drop-down list of values, which also allows for the user to specify a new one. Use the **Properties** button to add the values.
- **Drop-Down List** – to insert a drop-down list of fixed values. Use the **Properties** button to add the values.
- **Date Picker** – to insert a date picker. Use the **Properties** button to change the date format.



Note: These **Content Controls** are only available if the user has **Templates** or **Libraries** functional permission enabled.

All controls, excluding **Rich Text**, can be inserted either within a component or directly in the template/document itself. After inserting a control, use the **Properties** button to configure its settings, as appropriate.

To remove a control, a user can complete one of the following two actions:

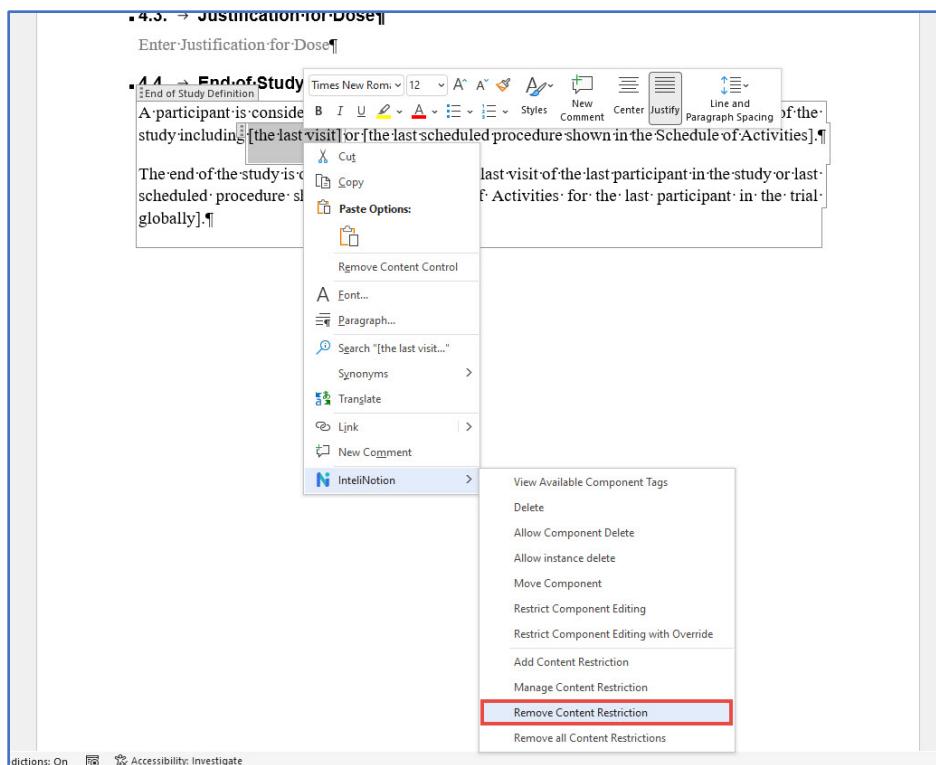
- Highlight the control (click the 3 dots on the left-hand side), right-click and select **Remove Content Control**.



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Note: This option will leave the content contained within a **Rich Text** control in the document, as well as the checkbox.

- Highlight the control (click the 3 dots on the left-hand side) and click **Delete** on the keyboard.

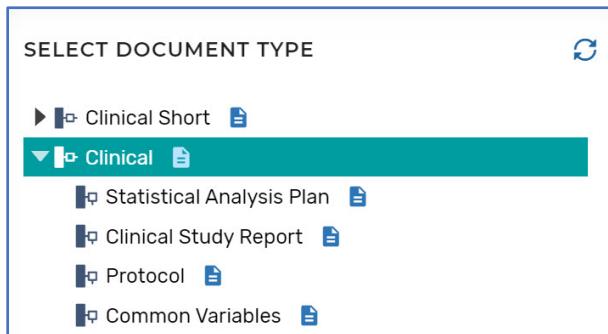
Note: This option will also remove the content contained within a **Rich Text** control.

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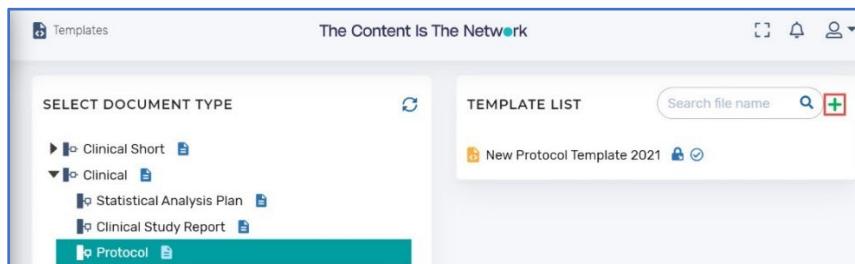
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3.2 CONFIGURING DOCUMENT TEMPLATES VIA THE WEB CONSOLE

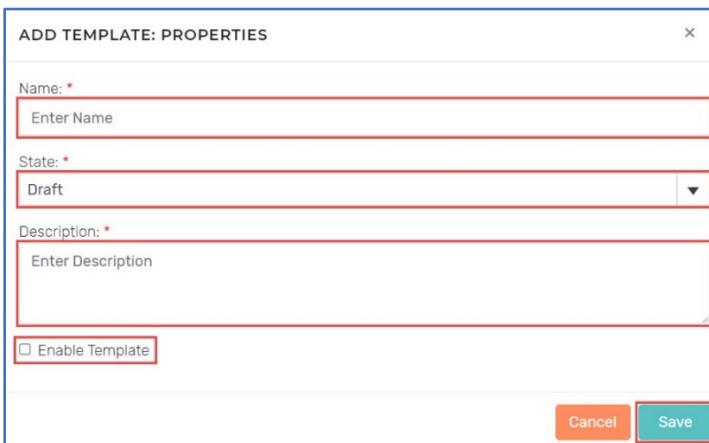
1. Click the **Templates** option in the left-hand navigation pane of the *Web Console*.
2. A hierarchical set structure based on the info model's configuration will display.



3. Select the relevant document type and click on the **add icon**  to add a new template for that document type.



4. Fill in the required form details and click **Save**.



The dialog has the following fields:

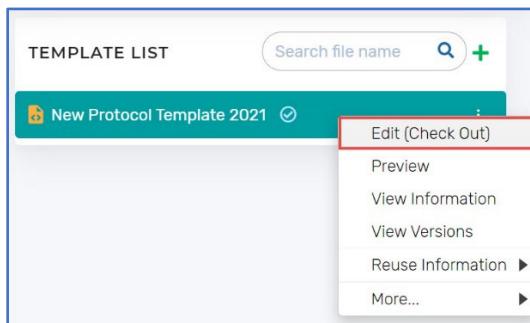
- Name: * (Input field: Enter Name)
- State: * (Select dropdown: Draft)
- Description: * (Input field: Enter Description)
- Enable Template (unchecked)

Note: As mentioned above, if the **Enable Template** checkbox is left unchecked, the template will be hidden from the list of available templates that any user will see when generating a document, even if it is in an approved state.

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5. Click on the **vertical ellipsis**  **button** beside the newly created template's name and select **Edit (Check Out)**.



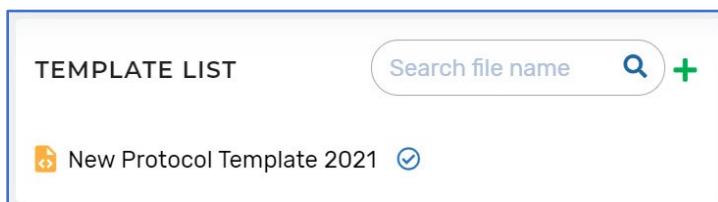
Note: If the template (empty docx file) does not open automatically, it may be opened from the designated *InteliNotion* download location.

6. Follow the steps outlined in [Section 3.1](#) above to complete the template creation. If needed, change or apply content restrictions for the inserted components following the steps outlined in [Section 3.1.3](#) above.

3.3 ENABLING TEMPLATES FOR USE

Admin-type users with the appropriate level of permission in the system will be able to view and select a template that is still in a draft state. Typical users (eg, authors), however, will not be able to view and select a template unless it is in an approved state. In either case, the template's **Enable Template** checkbox must be checked for any version of the template, regardless of its state, to be available for any user's selection.

Enabled templates will display a **Visual Indicator icon**  in both the *Web Console* and *InteliNotion Word App*.



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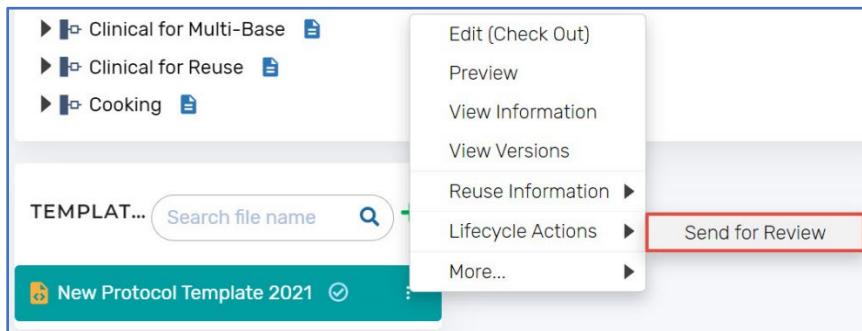
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3.3.1 Routing a Template Through a Lifecycle

The template is like a document, in that it can be routed through a lifecycle (assuming it has one configured). See the **InteliNotion Application Admin Guide** for details on how to configure a lifecycle for a business object class.

Note: A lifecycle (states and transitions) must first be configured for the Template business object class before an instance can be routed through a lifecycle. See the **InteliNotion Application Admin Guide** for details on how to configure a lifecycle for a business object class.

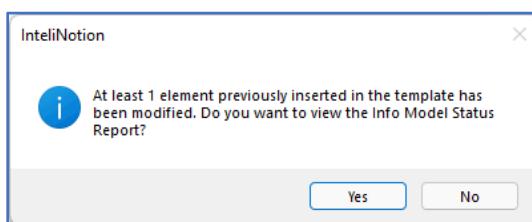
1. Click on the **vertical ellipsis**  button beside the template's name, and under **Lifecycle Actions**, select from the available options, (eg, **Send for Review**).



2. Complete the applicable task form and subsequent review and/or approval task steps, as appropriate. See the **InteliNotion User Guide Module 9** for more details on sending and completing tasks.

3.3.2 Info Model Status Report

Changes made to the info model may impact the templates related to it. If any change was made to an element in the info model, opening an existing template based on it will alert the user with a pop-up window; click **Yes** to open the Info Model Status Report (IMSR).



IMSR will list the elements grouped in 3 categories:

- **Modified:** Lists the Elements that were modified in the Info Model.
 - **Deleted:** Components that were removed from the Info Model
 - **Configuration:** Existing component with changes in the configuration (the addition or removal of a component tag is not currently detected as a configuration change)

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- **New:** Any element that previously did not exist in the Info Model
- **Not Modified:** Elements that have not changed since the template creation or last template update
- **Not inserted:** Elements that were in the info model but not present in the template

Info Model Status Report: New CSR Template 2021							
Name	Element ID	Reuse Policy	Source/Library	Inserted By	Inserted At	Change Type	
Status: Modified (39 items)							
Abbreviations	cd6dab66-fc8d-475...	Repurpose	Clinical -> Protocol -			Configuration	
Acronym	b166bb5c-1eae-4f1...	Use As Is	Clinical -> Protocol -			Configuration	
Compound Num...	0eebeeda-f92b-46...					Deleted	
Endpoint	f1aafb5f-3f18-499e...	Repurpose	Clinical -> Protocol -			Configuration	
Endpoint	f2891df4-d171-41af...	Repurpose	Clinical -> Protocol -			Configuration	
Endpoint	f18b9c3d-5dd2-44...	Repurpose	Clinical -> Protocol -			Configuration	
EudraCT Numb...	efeb90a7-7396-4e1...					Deleted	
Exclusion Criteria	b43eeb86-d35b-4c...	Repurpose	Clinical -> Protocol -			Configuration	
Exclusion Criteria	1b0d1664-07d9-40...	Repurpose	Clinical -> Protocol -			Configuration	
Exclusion Criteria	f02e3525-fe6b-483...	Repurpose	Clinical -> Protocol -			Configuration	
Exclusion Criteria	562355d7-7c6-4ba...	Repurpose	Clinical -> Protocol -			Configuration	
Exclusion Criteria	a1cc16d8-679a-49c...	Repurpose	Clinical -> Protocol -			Configuration	
Generic Name	09553a14-7255-44...					Deleted	
Hypotheses	56c56e5e-7cc2-417...	Repurpose	Clinical -> Protocol -			Configuration	
Inclusion Criteria	33f9f3ca-ccaa-4ca...	Repurpose	Clinical -> Protocol -			Configuration	

Note: Elements configured as variable will have a triangle  icon listed next to the name

Right-clicking on any of these rows will show a few menu options:

- **View Information:** (available for **Deleted**, **Configuration**, **Not Modified** and **Not Inserted** elements) will show the element information in a pop-up window.

Info Model Status Report: Template US 27231							
Name	Element ID	Reuse Policy	Source/Library	Inserted By	Inserted At	Change Type	
Status: Not Modified (11 items)							
Unit Dose Strength	e93b9256-e...					New	
Use	a29a8e6e-15...					New	
Status: Not Inserted (1 items)							
Title	e26d649e-8...					Not Inserted	

VIEW INFORMATION

Name	Hypotheses
Object Class	ClinicalComponent
Property	Content
Allow Multiple (Repeating Element)	No
Allow Delete	No
Source (Hierarchical Set Level)	-
Reuse Policy	-
Allow Override Policy	No
Auto-Insertion Rules	-

Created at: 2018-08-14 9:34 AM by: Mike Redl
 Last modified at: 2021-10-18 10:58 AM by: Andrea Sullivan
 Element type: Component
 Business object: Element
 Element ID: 56c56e5e-7cc2-417a-4d17a-4d17a-4d17a-4d17a

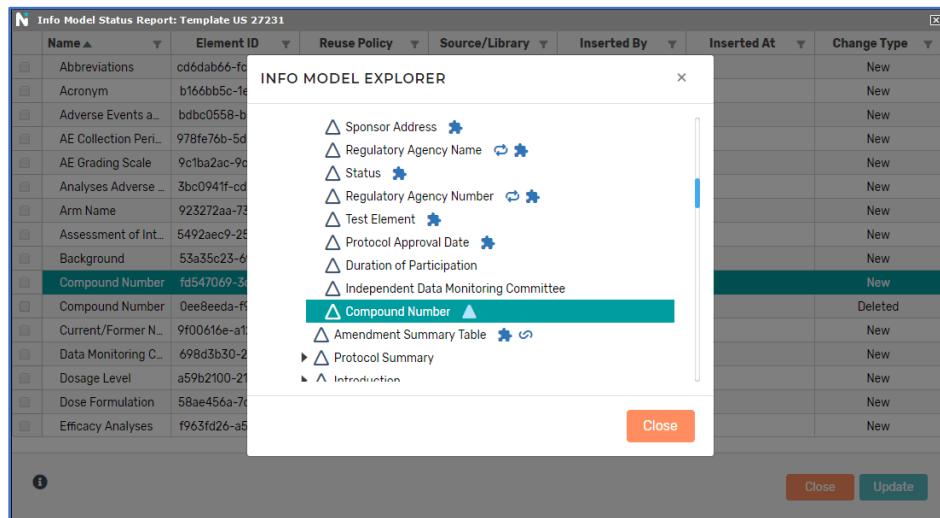
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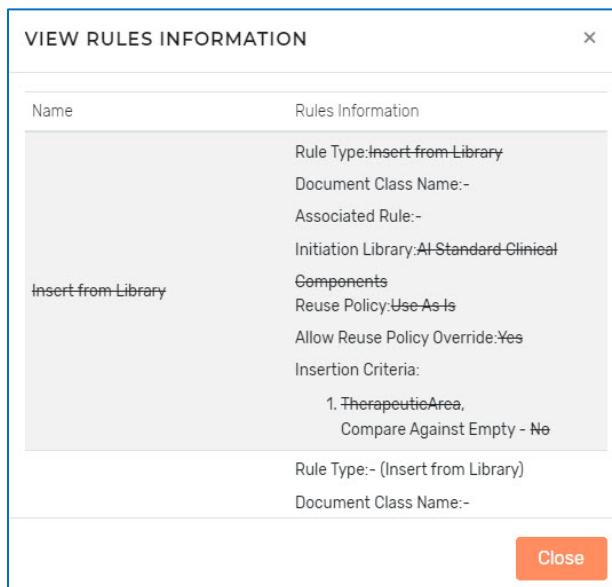
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Note: If Auto Insertion Rules are configured, the reuse information will be available in a pop-up window via the IMSR.

- **Insert Element:** (available for **New** and **Not Inserted** elements) Inserts the element in the current cursor position
- **Locate in Info Model Explorer:** Opens a scrollable window highlighting the element in the hierarchical set, with the right-click option of **view/edit element**



- **View Rules Information:** For elements that have rules associated to them (eg, auto-inserted Library components) will display the configured rule. For rules that were updated since they were last inserted in the template, the changes will be listed with the **Name** of the rule that has been changed, and the **Rules Information**



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Elements that were **Deleted** or had **Configuration** changes can be selected by placing a checkmark in the first column and can be updated in the template once the **Update** button is selected in the IMSR.

Info Model Status Report: US29228						
Name	Element ID	Reuse Policy	Source/Library	Inserted By	Inserted At	Change Type
Status: Modified (10 items)						
<input checked="" type="checkbox"/> AE Grading Scale	9c1ba2ac-9cbf-4dc...		Library			New
<input checked="" type="checkbox"/> Analyses Adverse ...	3bc0941f-cd21-408...		Library			New
<input checked="" type="checkbox"/> element 1	3617d6b9-376f-45e...		Library			New
<input checked="" type="checkbox"/> End of Study Defi...	cff1f5d15-3d68-4719...		Library			New
<input checked="" type="checkbox"/> Endpoint	6479393e-da83-417...					Deleted
<input checked="" type="checkbox"/> Endpoint	948355d5-9dd8-41...					New
<input checked="" type="checkbox"/> Endpoint	823b68dd-5957-4e...		Library			Configuration
<input checked="" type="checkbox"/> Estimand	c5a93d57-05b0-49...		Library			New
<input checked="" type="checkbox"/> Estimand	3eeff2e6d-c6bb-474...					New
<input checked="" type="checkbox"/> Estimand	4251cdfe-7144-485...					New
Status: Not Modified (1 items)						
<input checked="" type="checkbox"/> LibraryComponent	f06a7204-0cd6-42...		Library	Mike Redl	2021-10-21 9:23 AM	
Status: Not Inserted (104 items)						
<input checked="" type="checkbox"/> Abbreviations	cd6dab66-fc8d-475...					Not Inserted
<input checked="" type="checkbox"/> Acronym	b166bb5c-1eae-4f1...					Not Inserted
						Close Update

Deleted elements will be removed from the template and configuration changes will be applied to the existing selected elements (eg, if the reuse policy was changed from as-is to repurpose, the component will be unlocked and vice versa). If the **Close** button is selected, the IMSR will close, and no changes will be made to the template.

Info Model Status Report: US29228						
Name	Element ID	Reuse Policy	Source/Library	Inserted By	Inserted At	Change Type
Status: Modified (10 items)						
<input checked="" type="checkbox"/> AE Grading Scale	9c1ba2ac-9cbf-4dc...		Library			New
<input checked="" type="checkbox"/> Analyses Adverse ...	3bc0941f-cd21-408...		Library			New
<input checked="" type="checkbox"/> element 1	3617d6b9-376f-45e...		Library			New
<input checked="" type="checkbox"/> End of Study Defi...	cff1f5d15-3d68-4719...		Library			New
<input checked="" type="checkbox"/> Endpoint	6479393e-da83-417...					Deleted
<input checked="" type="checkbox"/> Endpoint	948355d5-9dd8-41...					New
<input checked="" type="checkbox"/> Endpoint	823b68dd-5957-4e...		Library			Configuration
<input checked="" type="checkbox"/> Estimand	c5a93d57-05b0-49...		Library			New
<input checked="" type="checkbox"/> Estimand	3eeff2e6d-c6bb-474...					New
<input checked="" type="checkbox"/> Estimand	4251cdfe-7144-485...					New
Status: Not Modified (1 items)						
<input checked="" type="checkbox"/> LibraryComponent	f06a7204-0cd6-42...		Library	Mike Redl	2021-10-21 9:23 AM	
Status: Not Inserted (104 items)						
<input checked="" type="checkbox"/> Abbreviations	cd6dab66-fc8d-475...					Not Inserted
<input checked="" type="checkbox"/> Acronym	b166bb5c-1eae-4f1...					Not Inserted
						Close Update

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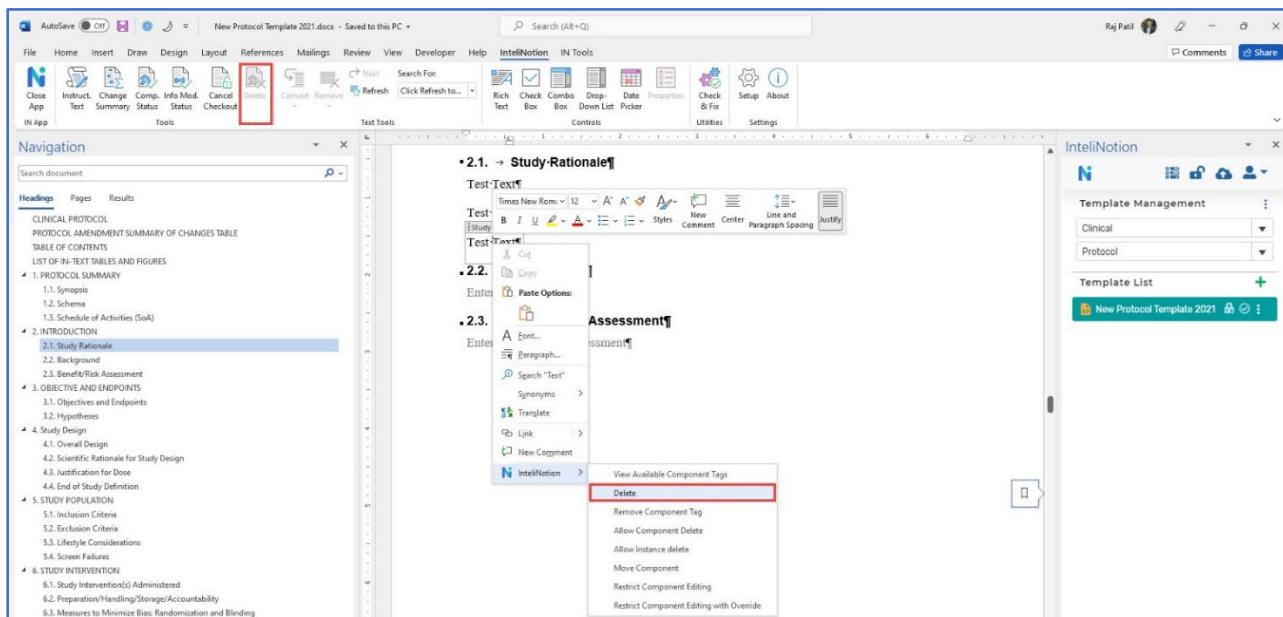
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The IMSR will show the same report if the template is later reopened, or the **Info Model Status** button is clicked on the *InteliNotion* ribbon.

Note: If the template checkout is canceled, no change will be saved to the template and the IMSR will show the same report when the template is reopened.

3.3.3 Updating a Template

1. A template can be updated by adding new elements (see Section 3.1) or removing existing elements, as appropriate. To delete an inserted element/component from the template, right-click on the component in the template, hover over the **InteliNotion** option, and click **Delete Component**. Alternatively, click in the component, then click the **Delete** button under the **Tools** section of the *InteliNotion* ribbon.

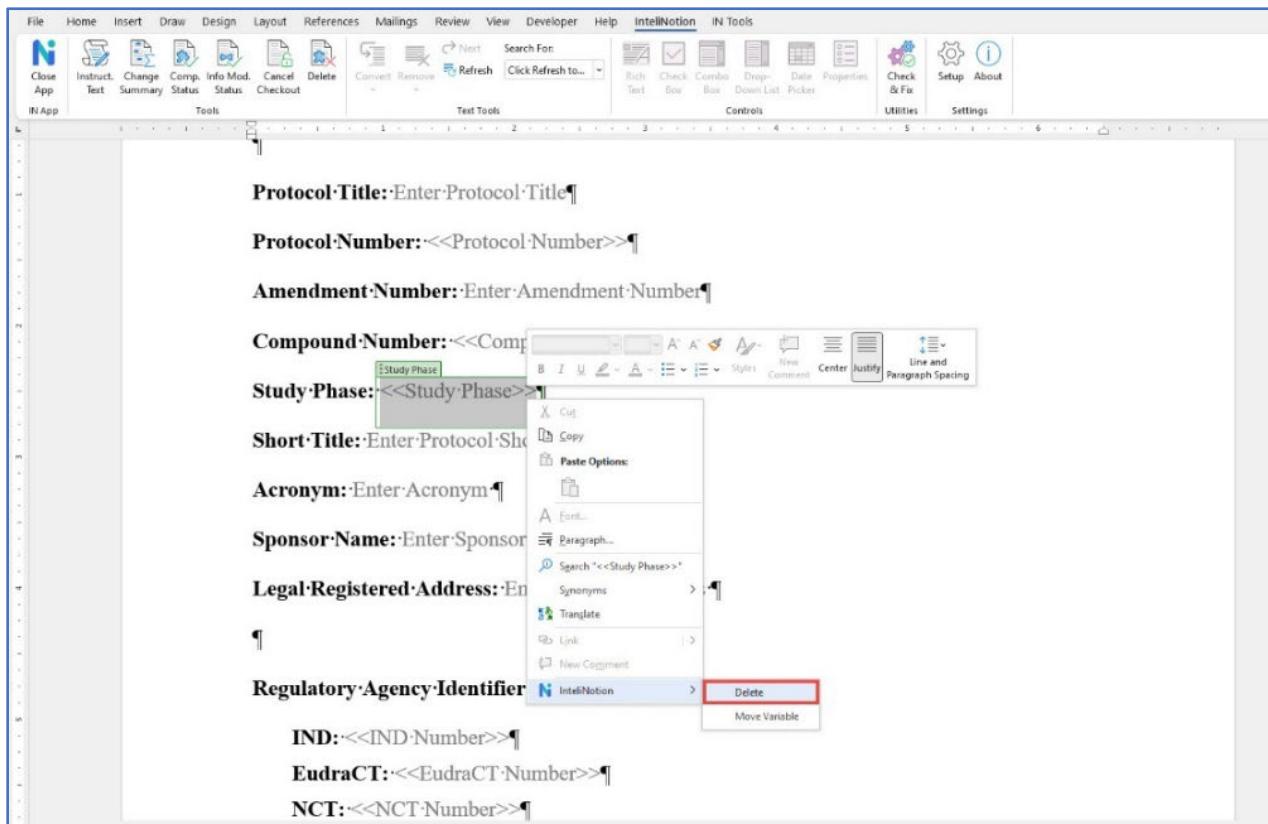


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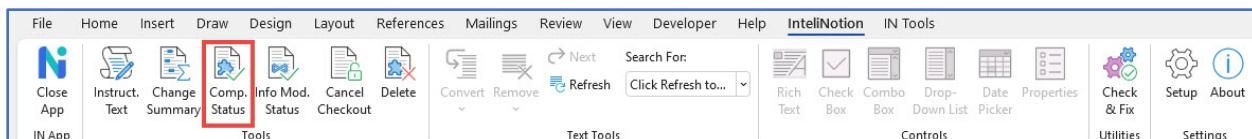
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2. The ability to delete or move a variable is available when a user right-clicks on the item and hovers over the *InteliNotion* menu.



3. If a base component is updated outside of the template's context (ie, as a standalone component), the user will be notified of this change and asked to launch the **Component Status Report** after first editing/checking out the template. All components included in the template are listed in the **Component Status Report**. If working in an open template, this report can be launched by clicking the **Component Status** button in the *InteliNotion* ribbon.



4. The **Component Status Report** lists all components included in a template by **Component Name, Reuse Type, State, and Version**. Any base components will be listed under the **Not Modified** or **Modified** section; any empty components will be listed in the **Not Created** section. A user can navigate to a specific component by clicking on it in the list. If a component is listed in the **Modified** section, the user can take relevant action to

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either accept, ignore, or defer incorporation of the updated component into the template (see the **InteliNotion User Guide Module 8** for details on how to take these actions).

Component Name	Reuse Type	State	Version	Change Type	Action
Status: Not Modified (63 items)					
Protocol Title 		Draft	0.2		
Amendment Num... 		Draft	0.2		
Protocol Short Title 		Draft	0.2		
Acronym 		Draft	0.2		
Sponsor Name 		Draft	0.2		
Sponsor Address 		Draft	0.2		
Status 		Draft	0.2		
Protocol Date 		Draft	0.2		
Amendment Sum... 		Draft	0.2		
Rationale Summa... 		Draft	0.2		
Objective 		Draft	0.2		
Endpoint 		Draft	0.2		
Objective 		Draft	0.2		
Endpoint 		Draft	0.2		
Hypotheses 		Draft	0.2		

Notes:

A component may be listed in the Modified section even though no content change was made during co-authoring.

- A component included in the Modified section may also appear in the Not Modified section, based on the status of the current component in the document.
- For Change Type:

Component = The component was replaced in the parent document

- Content = The current component's content was modified
- Parent Content = The parent component's content was modified
- Content and Parent Content = The current component's content, as well as the parent component's content, was modified

The latest state and version for the component is displayed in parentheses, if applicable.

- Use **Ctrl** + click to select multiple individual items or **Shift** + click to select a range of items
- Ensure **Enable Rules** is turned on for a templates business object by the System Administrator to view the Component Status Report for templates configured within the system.

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MANAGE OBJECT TEMPLATE

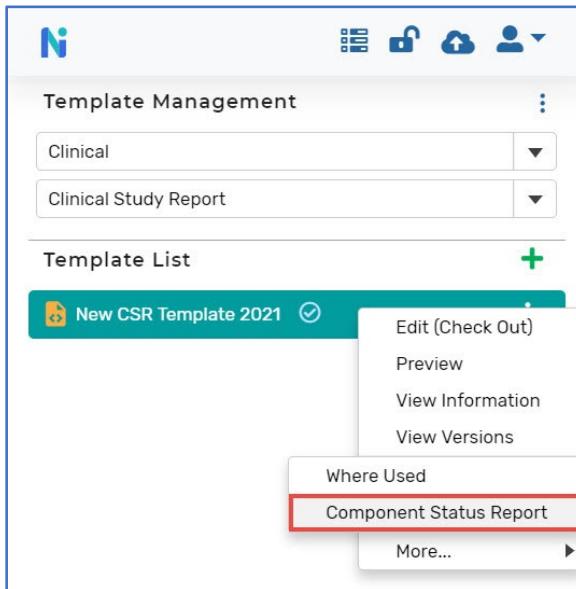
Basic Properties States Rules

Enable Rules

Document Sta...	Component State in Document	Current Component State	Policy	Lock for Editing	Auto Content Refres...
Draft	Draft	Draft	Use As Is	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Draft	Draft	Approved	Use As Is	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Draft	Approved	Approved	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Draft	Approved	Draft	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Approved	Draft	Draft	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Approved	Draft	Approved	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Approved	Approved	Approved	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Approved	Approved	Draft	Use As Is	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Close **Update Object**

- It is also possible to check the status of base components without opening the template. In either the *Web Console* or *InteliNotion Word App*, click the **vertical ellipsis**  button next to a template's name, and under **Reuse Information**, select **Component Status Report**. If necessary, the user can take relevant action to either accept, ignore, or defer incorporation of an updated component into the template via this method (the user will be required to create a new version of the template after accepting any changes).



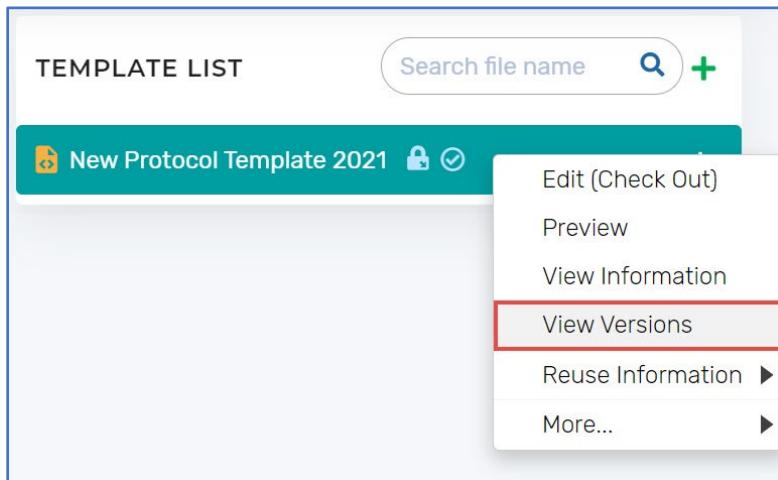
Note: If updating a template with track changes on, the user will be alerted if any modification (ie, inserting component from a library) will not be marked as a change.

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3.3.4 Compare Two Versions of a Template

1. Click on the vertical ellipsis  button beside its name and select **View Versions**.



2. The version history of the selected template will appear on the screen.

VIEW VERSIONS: 2023 R1 PROT

	Version	Modified On	Modified By	Comment	Size	
<input type="checkbox"/>	1.2	2023-03-29 11:23 AM	Bill Label	2023 R1 PV Setup - Test Case 39574: Create PROT Template with Complex Tables	32.44 KB	
<input type="checkbox"/>	1.1	2023-03-29 11:20 AM	Bill Label		8.72 KB	
		State: Draft				
<input type="checkbox"/>	1.0	2023-03-29 11:20 AM	Bill Label		8.72 KB	
		Name: 2023 R1 PROT Owner: Bill Label State: Approved Description: 2023 R1 PROT Enable Template: true				

Close **Compare Versions** **Purge Version(s)**

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3. Select any 2 versions from the list and the **Compare Versions** button will enable. Click on **Compare Versions**.

VIEW VERSIONS: 2023 R1 PROT

	Version	Modified On	Modified By	Comment	Size	
<input checked="" type="checkbox"/>	1.2	2023-03-29 11:23 AM	Bill Label	2023 R1 PV Setup - Test Case 39574: Create PROT Template with Complex Tables	32.44 KB	⋮
<input checked="" type="checkbox"/>	1.1	2023-03-29 11:20 AM	Bill Label		8.72 KB	⋮
			State: Draft			
<input type="checkbox"/>	1.0	2023-03-29 11:20 AM	Bill Label		8.72 KB	⋮
			Name: 2023 R1 PROT Owner: Bill Label State: Approved Description: 2023 R1 PROT Enable Template: true			

Close
Compare Versions
Purge Version(s)

Note: Only 2 versions can be compared at a time.

4. A comparison showing the differences between versions in tracked changes format will appear on the screen.

COMPARE VERSIONS: NEW PROTOCOL TEMPLATE 2021 (V0.1 & V1.2)

<<Compound Number>>/<<Generic Name>>

Protocol <<Protocol Number>>

2. INTRODUCTION

2.1. Study Rationale

Test Text

Test Text

Enter Study Rationale Test Text

2.2. Background

Enter Background

2.3. Benefit/Risk Assessment

Enter Benefit/Risk Assessment

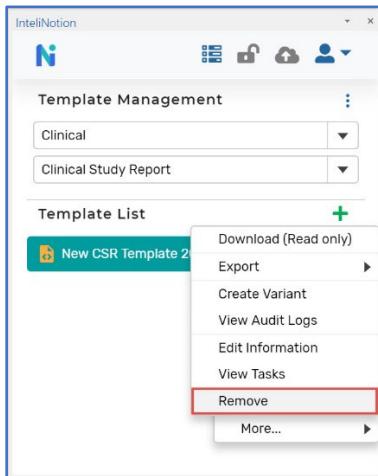
Note: The version comparison may not display any content changes if one of the version's being compared was a result of a lifecycle state change.

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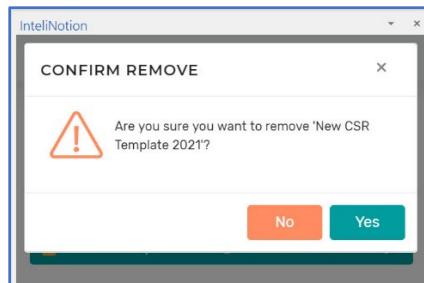
3.3.5 Deleting a Template

1. Click on the **vertical ellipsis :** button beside the applicable template name and under **More**, click **Remove**.



Note: Before removing a template, it may be helpful to see which documents were generated using it. To do this, click on the **vertical ellipsis :** button beside its name, and under **Reuse Information**, select **Where Used**.

2. A pop-up will appear asking the user if he/she is sure they want to remove the template.



Notes:

- Authorized users shall be able to delete one or more older versions of a template.
- Users shall be able to select one or more versions (on the version history page) for deletion. Users are warned by the system before deletion is performed.
- A warning popup message will appear if any of the selected template versions were used to generate documents (and still exist in the system). The user shall be able to see the list of documents.
- If a document's related template has been deleted, this information will be indicated when viewing the document's information.

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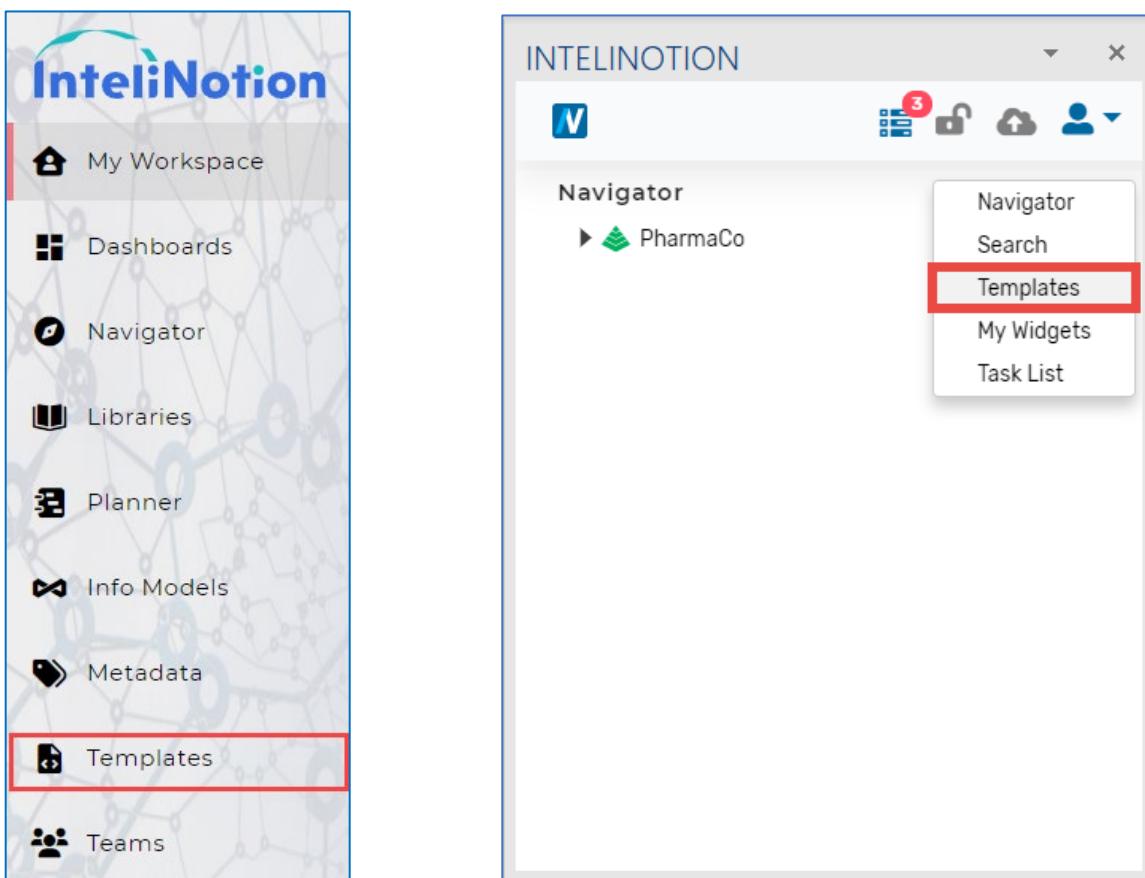
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4. CREATING A VARIANT OF A DOCUMENT TEMPLATE

A variant can be created for any existing document template. When a variant is created, the user can elect to include or exclude elements (inserted from the info model into the original template) as well as change the reuse and/or delete policy of those elements, if appropriate.

Available document templates can be found by clicking the **Templates** option in the left-hand navigation pane of the *Web Console* or within the **vertical ellipsis**  **button** options of the *InteliNotion Word App*.



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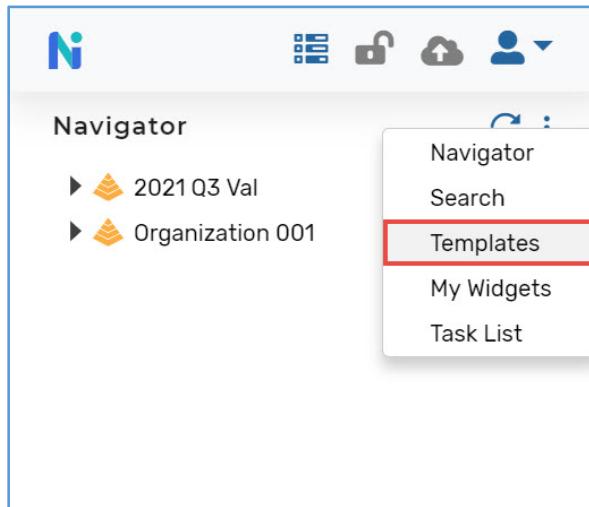
Notes:

As an authorized user, after a new template variant is generated, the user shall be able to determine the source template from which the variant was created.

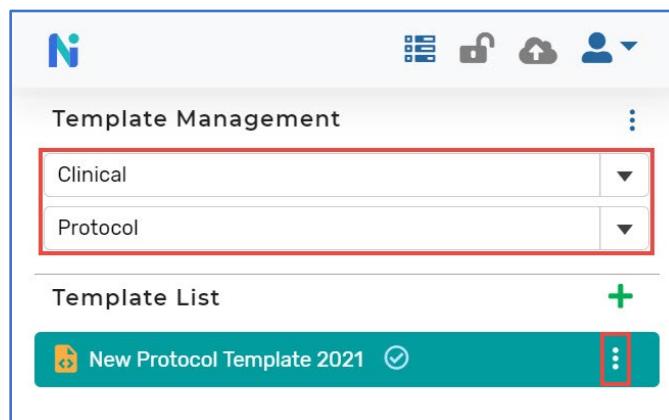
- The user can see the Source Template in the **View Information** pane of the template variant.
- The user can check the template variant's version history and see a comment added to the first version (eg, 0.1) that indicates that it was created as a variant using another template, with the other template's name included.

4.1 CREATING A TEMPLATE VARIANT VIA THE WORD APP

1. Click on the **vertical ellipsis :** button in the *InteliNotion Word App* and select **Templates**.



2. Select the appropriate **Info Model - Hierarchical Set Name** and **Document Type** and click on the **vertical ellipsis :** button beside the name of an existing template.

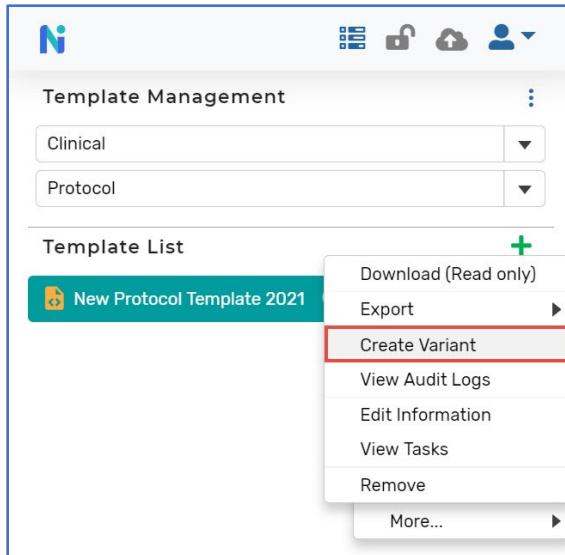


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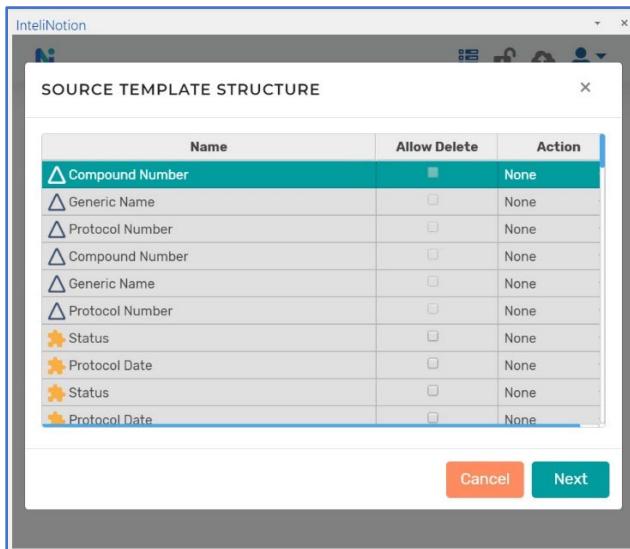
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3. Under **More**, click **Create Variant**.



4. A **Source Template Structure** pop-up window will open within the *InteliNotion Word App* pane, wherein appropriate delete policy changes and/or actions (eg, remove) can be taken on the existing elements in the source template.



Note: The *InteliNotion Word App* can be resized to see the entire **Source Template Structure** pop-up box.

5. Check or un-check the **Allow Delete** policy checkbox to either allow or disallow the deletion of that element/component in the document generated with the template variant.

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6. Click the dropdown arrow within the **Action** column to take appropriate action on the element in the template variant, as follows:

- **None** - The existing element will be included in the template variant
- **Remove** - The existing element will be removed from the template variant

Name	Allow Delete	Action
△ Compound Number	<input type="checkbox"/>	None ▾
△ Generic Name	<input type="checkbox"/>	None ▾
△ Protocol Number	<input type="checkbox"/>	None ▾
△ Compound Number	<input type="checkbox"/>	None ▾
△ Generic Name	<input type="checkbox"/>	None ▾
△ Protocol Number	<input type="checkbox"/>	None ▾
★ Status	<input checked="" type="checkbox"/>	None ▾
★ Protocol Date	<input type="checkbox"/>	None ▾
★ Status	<input type="checkbox"/>	Remove
★ Protocol Date	<input type="checkbox"/>	None ▾
★ Protocol Title	<input checked="" type="checkbox"/>	None ▾
△ Protocol Number	<input type="checkbox"/>	None ▾
★ Amendment Number	<input type="checkbox"/>	None ▾
△ Compound Number	<input type="checkbox"/>	None ▾
△ Study Phase	<input type="checkbox"/>	None ▾
★ Protocol Short Title	<input type="checkbox"/>	None ▾

Cancel Next

Notes:

- An action can also be applied to multiple elements at once, as follows:

For individual elements – click on the row of one element in the **Source Template Structure** box. While pressing the **Ctrl** key on the keyboard, click on the row of the other relevant elements to select them. Then, right-click on one of the selected elements and choose the appropriate action.

For a range of components – click on the row of one element in the **Source Template Structure** box. While pressing the **Shift** key on the keyboard, click on the row of the last element in the range to select all the elements in that range. Then, right-click on one of the selected elements and choose the appropriate action.

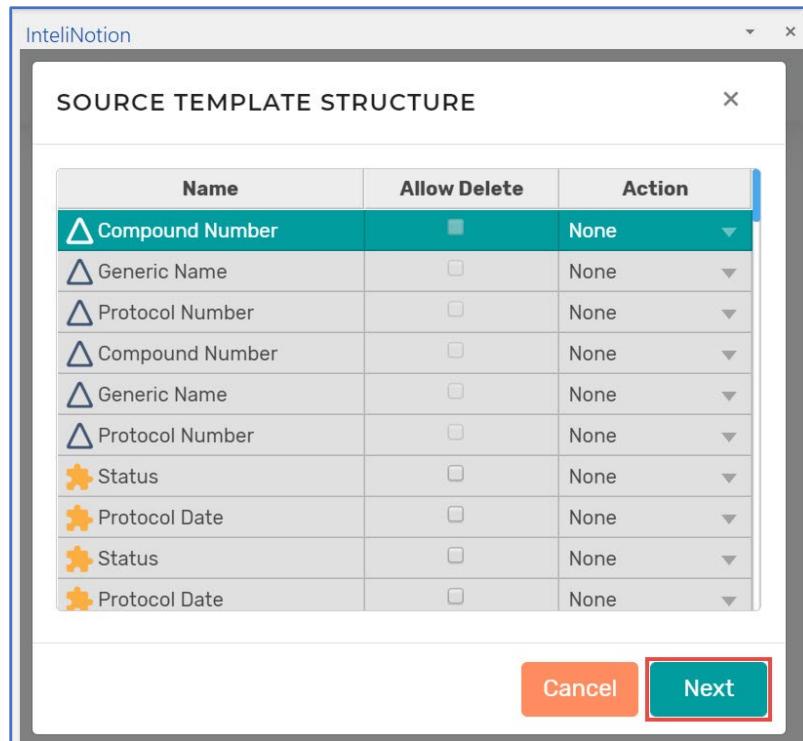
- Any elements that were bulk selected for action **None** will be included in the template and either be locked or not locked for editing as per the info model's reuse policy.
- Any elements that were bulk selected for action **Remove** will no longer exist in the template (ie, were deleted).

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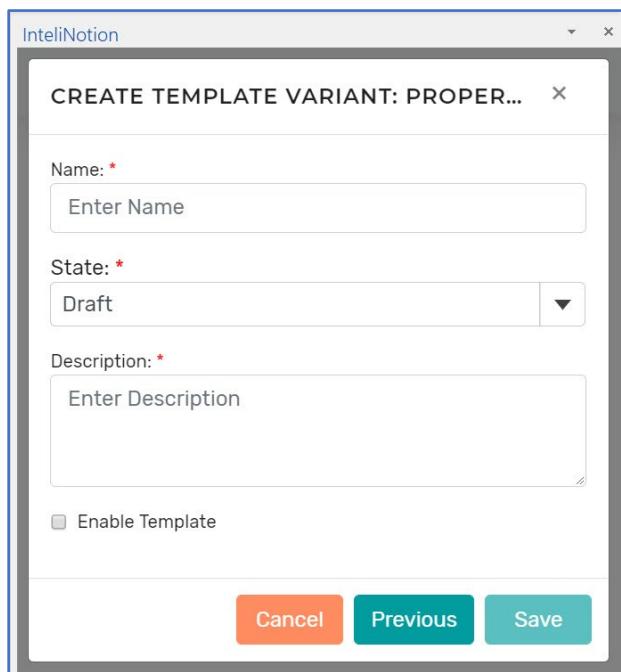
7. Repeat steps 1 – 6 until all elements have been updated, as needed. Click **Next**.



The screenshot shows a modal dialog titled "SOURCE TEMPLATE STRUCTURE". It contains a table with three columns: "Name", "Allow Delete", and "Action". The table lists ten items, each with a small icon (triangle or puzzle piece) and a name: Compound Number, Generic Name, Protocol Number, Compound Number, Generic Name, Protocol Number, Status, Protocol Date, Status, and Protocol Date. The "Allow Delete" column has checkboxes; the first item has its checkbox checked. The "Action" column has dropdown menus, all currently set to "None". At the bottom right of the dialog are two buttons: "Cancel" and "Next", with "Next" being highlighted with a red border.

Name	Allow Delete	Action
Compound Number	<input checked="" type="checkbox"/>	None
Generic Name	<input type="checkbox"/>	None
Protocol Number	<input type="checkbox"/>	None
Compound Number	<input type="checkbox"/>	None
Generic Name	<input type="checkbox"/>	None
Protocol Number	<input type="checkbox"/>	None
Status	<input type="checkbox"/>	None
Protocol Date	<input type="checkbox"/>	None
Status	<input type="checkbox"/>	None
Protocol Date	<input type="checkbox"/>	None

8. Fill in the required form details and click **Save**.



The screenshot shows a modal dialog titled "CREATE TEMPLATE VARIANT: PROPER...". It contains fields for "Name:" (with placeholder "Enter Name"), "State:" (set to "Draft"), "Description:" (with placeholder "Enter Description"), and a checkbox for "Enable Template". At the bottom right are three buttons: "Cancel", "Previous", and "Save", with "Save" being highlighted with a red border.

Name: *Enter Name

State: *Draft

Description: *Enter Description

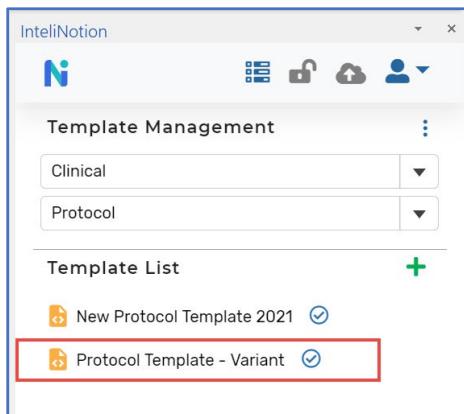
Enable Template

Cancel Previous Save

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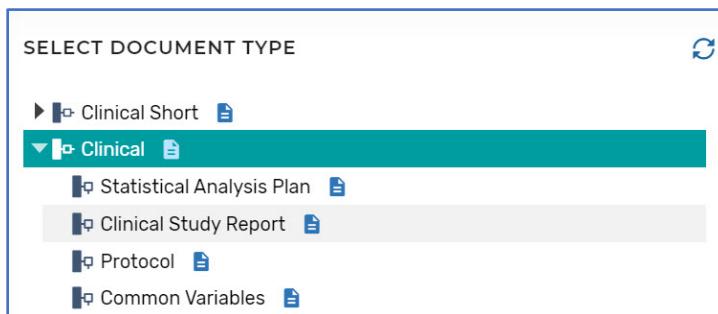
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- After the template variant creation has been completed, the new template will appear in the template list.

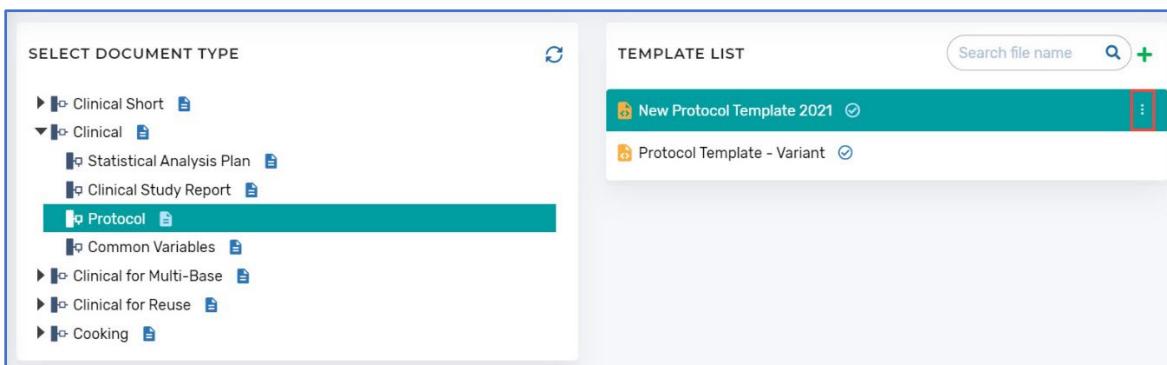


4.2 CREATING A TEMPLATE VARIANT VIA THE WEB CONSOLE

- Click the **Templates** option in the left-hand navigation pane of the *Web Console*.
- A hierarchical set structure based on the configuration done in the info model will display.



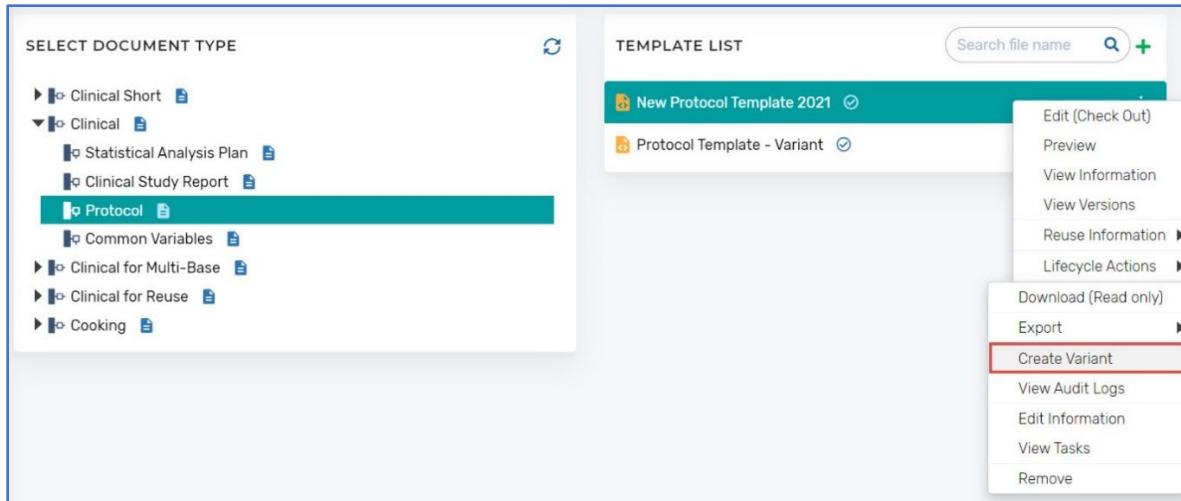
- Expand to select the appropriate document type (hierarchical set) on the left-hand side, and then click on the **vertical ellipsis**  button beside the name of an existing document template.



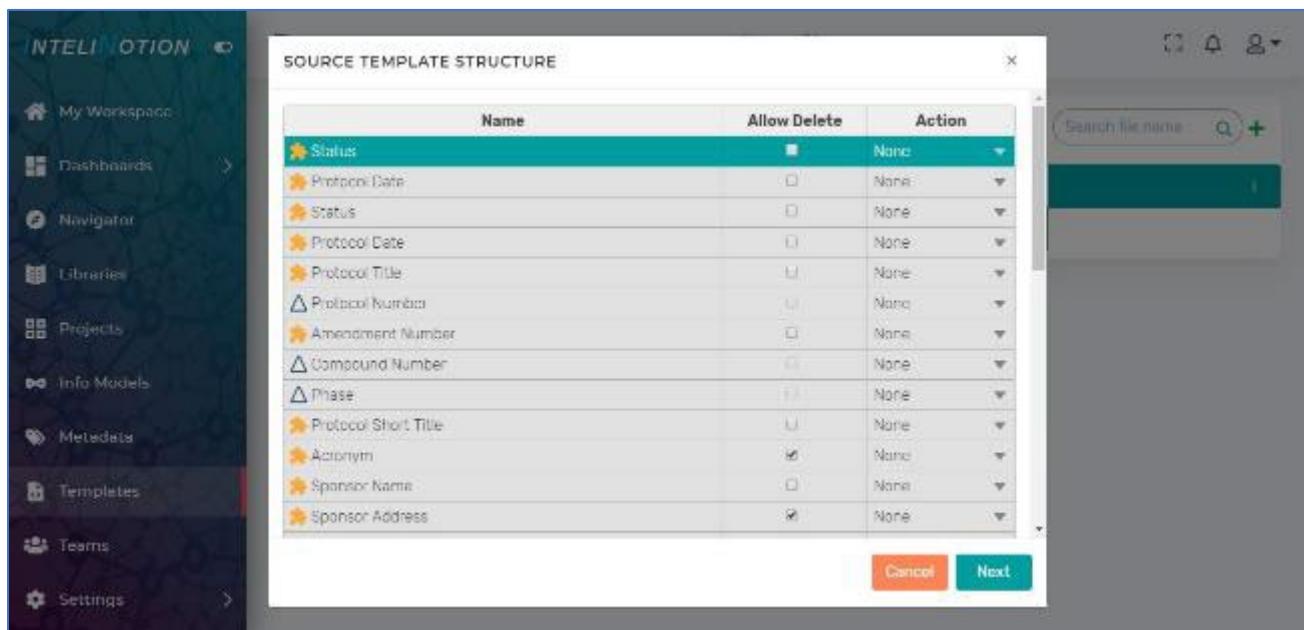
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4. Under **More**, click **Create Variant**.



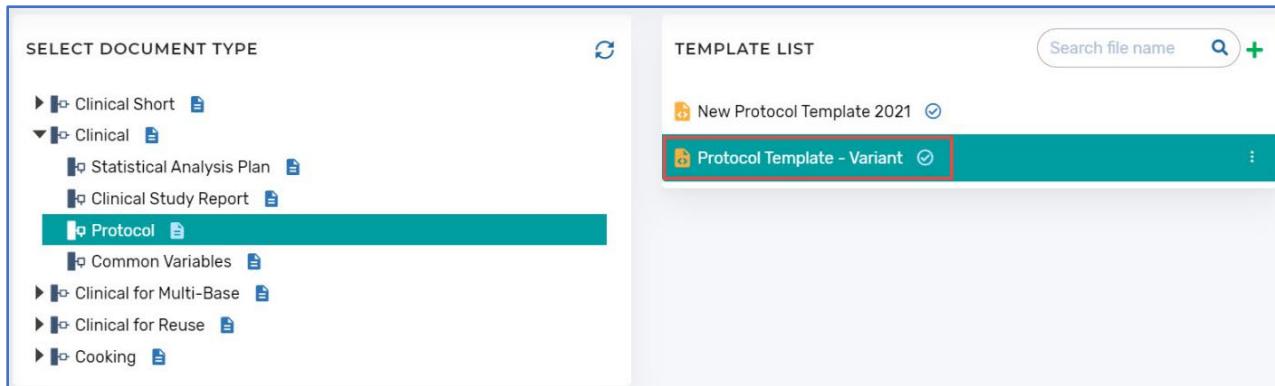
5. A **Source Template Structure** pop-up window will open, wherein appropriate delete policy changes and/or actions (eg, remove) can be taken on the existing elements in the source template.



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6. Follow the steps outlined above. After the template variant creation has been completed, the new template will appear in the template list.



The screenshot shows the software's user interface. On the left, a 'SELECT DOCUMENT TYPE' panel lists various document categories with their icons: Clinical Short, Clinical, Statistical Analysis Plan, Clinical Study Report, Protocol (which is selected and highlighted in blue), Common Variables, Clinical for Multi-Base, Clinical for Reuse, and Cooking. On the right, a 'TEMPLATE LIST' panel shows a list of templates. At the top is 'New Protocol Template 2021'. Below it is 'Protocol Template - Variant', which is highlighted with a red border. A search bar at the top of the list panel contains 'Search file name' with a magnifying glass icon and a '+' icon.

4.3 PUBLISHING A FLAT TEMPLATE

This functionality allows the user to publish a 'flat' template rendition of the current/latest version of a template that includes the related element-level instructional text, common instructional text, and/or auto-inserted library components, populated into the relevant areas of the template itself with the following conditions:

The validation rules used to determine which auto-inserted library component will be inserted into the flat template, as well as which instructional text instances (element and/or common) will be inserted are based on the selected business object class property(ies).

- If there are multiple matches found for the library components, only one will be included in the rendition.
- For instructional text that has a 'match with property' set for a property, the match will be between the instructional text instance and the flat template's property values.
- The flat template rendition formatting will be as follows:
 - Instructional text will use the same functionality of export instructional text contained in the *Word* file.
 - Base component content will retain the same formatting/style as the source base component.
 - AI library component content will retain the same formatting/style as the source library component.
 - Base component and/or library component(s) will retain any embedded content controls (eg, variable, content restriction), if applicable.

Note: To publish a flat template, the user must have at least C-R-U permissions on all the relevant business object classes included in the published flat template.

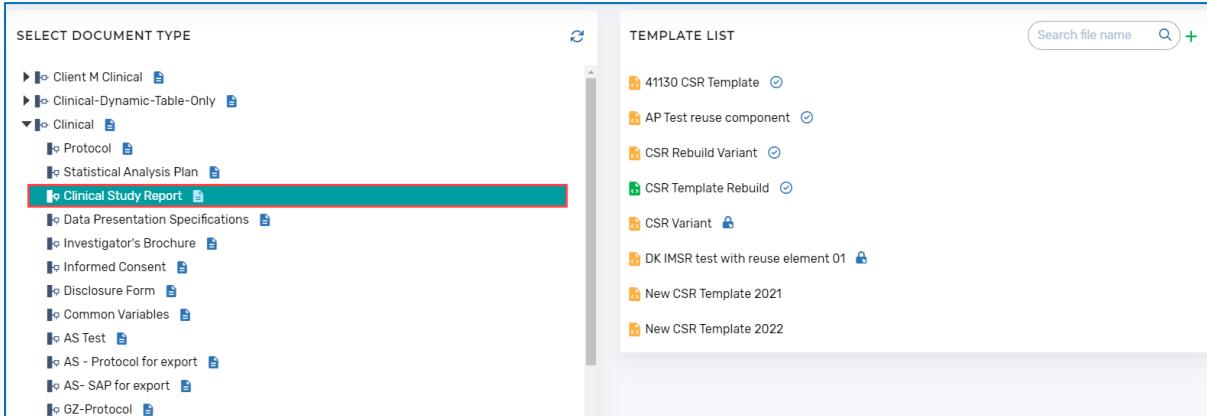
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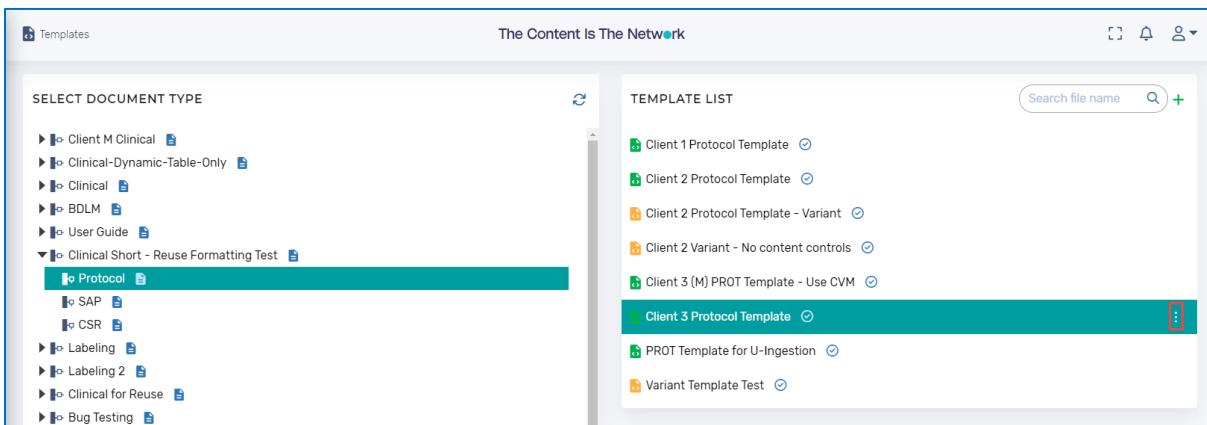
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Follow the steps listed below to publish a flat template.

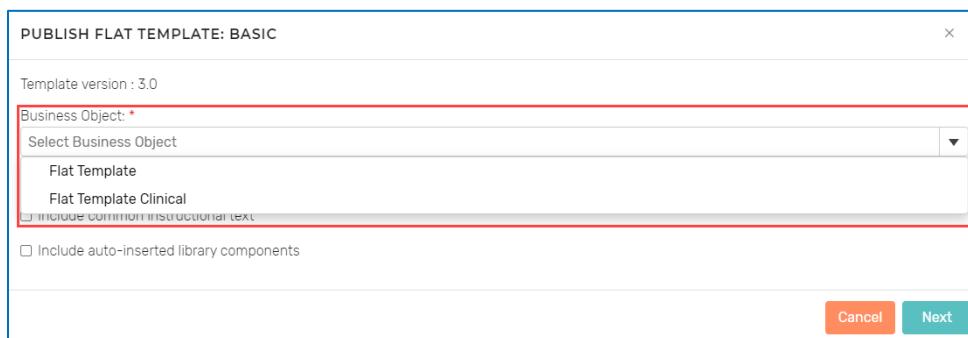
1. In the *InteliNotion Web Console* navigator, click on **Templates**.
2. On the **Templates** page, navigate to the applicable document type and click on it. The Template list for that business object will display.



3. Click on the ellipses next to the desired template and choose **Publish Flat Template**.



4. The **Publish Flat Template: Basic** form will display. Choose the type of flat template from the drop-down menu.



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5. Check the checkbox beside each element to be included in the flat template and click **Next**.

PUBLISH FLAT TEMPLATE: BASIC

Template version : 3.0

Business Object: *

Flat Template

Include element instructional text
 Include common instructional text
 Include auto-inserted library components

Cancel **Next**

6. Enter a name for the flat template in the **Name** field.

PUBLISH FLAT TEMPLATE: PROPERTIES

Name: *

Test Flat Template Publication

State: *

Draft

Cancel **Previous** **Save**

- **IF Flat Template Clinical** is chosen, fill in the optional **Document Type** and **Therapeutic Area** fields, and click **Save**.

PUBLISH FLAT TEMPLATE: PROPERTIES

Name: *

Test Connector 6-23

State: *

Draft

Document Type:

Select Document Type

Therapeutic Area:

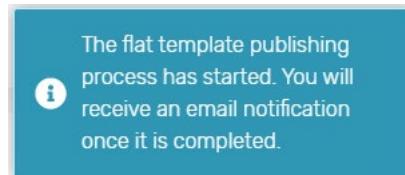
Select Therapeutic Area

Cancel **Previous** **Save**

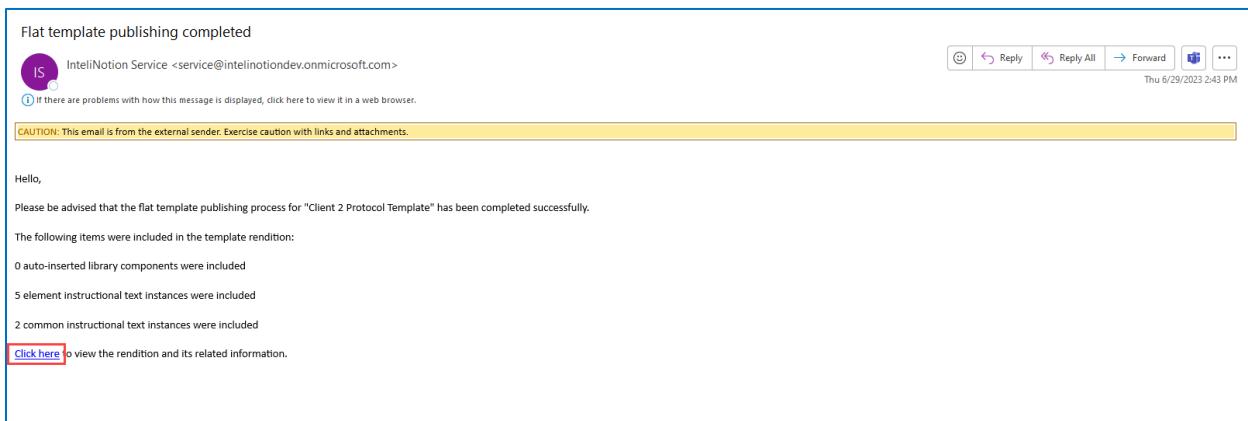
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7. A pop-up message informing the user that the flat publication process has started will display.

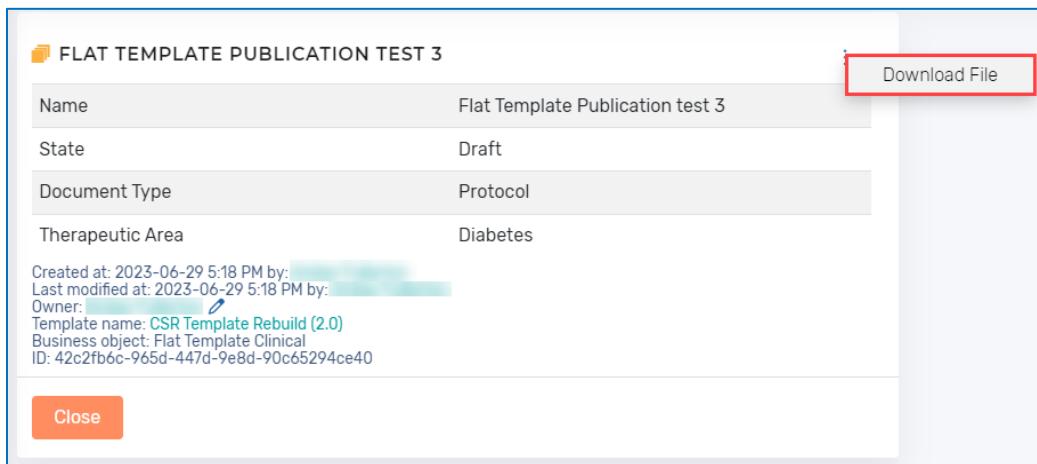


8. The user will receive an email message informing them once the publication process is complete.
9. Click the link contained in the email to view a summary of the rendition.



The email subject is "Flat template publishing completed". The body of the email includes a message from "InteliNotion Service <service@intelinotiondev.onmicrosoft.com>" stating: "The flat template publishing process has started. You will receive an email notification once it is completed." It also contains a "CAUTION: This email is from the external sender. Exercise caution with links and attachments." message. The email ends with standard Outlook controls and a timestamp "Thu 6/29/2023 2:43 PM".

10. If desired, download a copy of the flat template by clicking on the ellipses and choosing **Download File**.



The screenshot shows a modal dialog titled "FLAT TEMPLATE PUBLICATION TEST 3". It displays the following information:

Name	Flat Template Publication test 3
State	Draft
Document Type	Protocol
Therapeutic Area	Diabetes

Below the table, there is a "Download File" button highlighted with a red box. At the bottom left is a "Close" button.

Details at the bottom of the modal:
Created at: 2023-06-29 5:18 PM by: [redacted]
Last modified at: 2023-06-29 5:18 PM by: [redacted]
Owner: [redacted]
Template name: CSR Template Rebuild (2.0)
Business object: Flat Template Clinical
ID: 42c2fb6c-965d-447d-9e8d-90c65294ce40

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5. CREATING A LIBRARY

Within *InteliNotion*, libraries are used to either:

- Manage and govern pre-specified library components, that can either be selected for reuse during authoring or automatically reused during document generation.
- Present a filtered view or list of any objects in the system.

There are 2 types of libraries available in the system:

- **Managed Library** - This option is applicable for **component** business objects **only**.
 - Allows an authorized user to create a library (ie, dedicated container or area within the system) and specify other library owners.
 - Allows an authorized user to update library components (ie enable or disable) for any library regardless of ownership.
 - All users will have read-only access for library components that are in an approved state.
 - Default metadata/properties, including reuse policy for the components, can be set at the library level.
 - These library components can be configured for user- and/or auto-insertion into a document.
- **Non-managed Library** - This option is for all business objects (eg, components, documents, studies, etc.).
 - Allows any user to create a filtered view of prespecified objects in the system, with the help of a Base Query.
 - It is not possible to add components to a non-managed library because its function is to present a view of selected objects already added to the system, and not act as a container for new ones.

Note: Once a library is created and saved, it is not possible to change a non-managed library into a managed one, or vice versa.

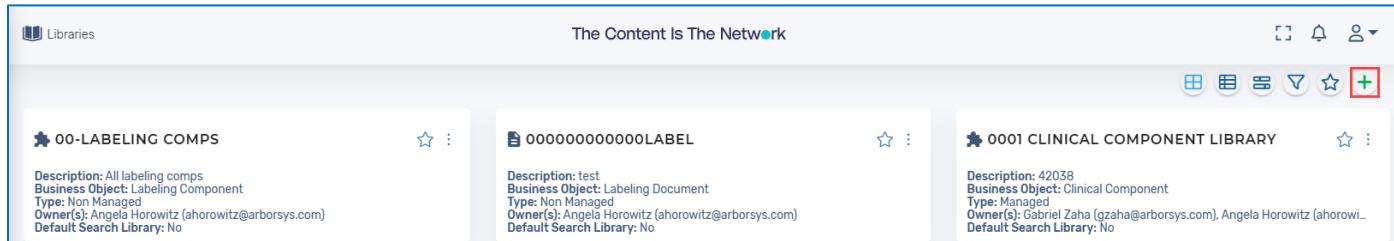
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5.1 CREATING A MANAGED LIBRARY

1. Click on the **add icon**  to add a new library.



The Content Is The Network

Libraries

00-LABELING COMPS

Description: All labeling comps
Business Object: Labeling Component
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No

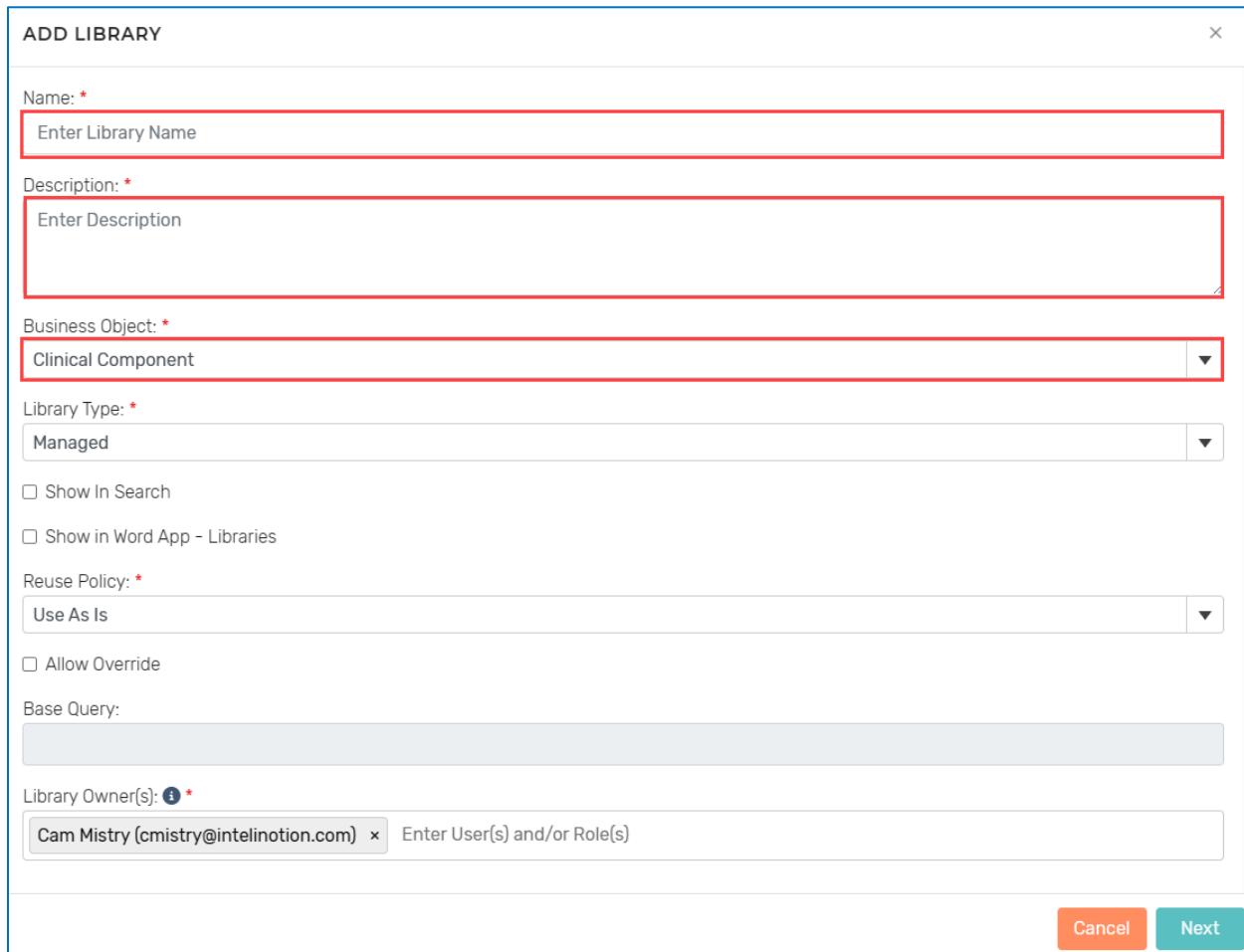
000000000000LABEL

Description: test
Business Object: Labeling Document
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No

0001 CLINICAL COMPONENT LIBRARY

Description: 42038
Business Object: Clinical Component
Type: Managed
Owner(s): Gabriel Zaha (gzaha@arborsys.com), Angela Horowitz (ahorowi...
Default Search Library: No

2. Enter the **Name** and **Description**, and then select **Component** or any of its subtypes (eg, Clinical Component) as the **Business Object** for the library.



ADD LIBRARY

Name: *

Enter Library Name

Description: *

Enter Description

Business Object: *

Clinical Component

Library Type: *

Managed

Show In Search

Show in Word App - Libraries

Reuse Policy: *

Use As Is

Allow Override

Base Query:

Library Owner(s):  *

Cam Mistry (cmistry@intelinotion.com)  Enter User(s) and/or Role(s)

Cancel Next

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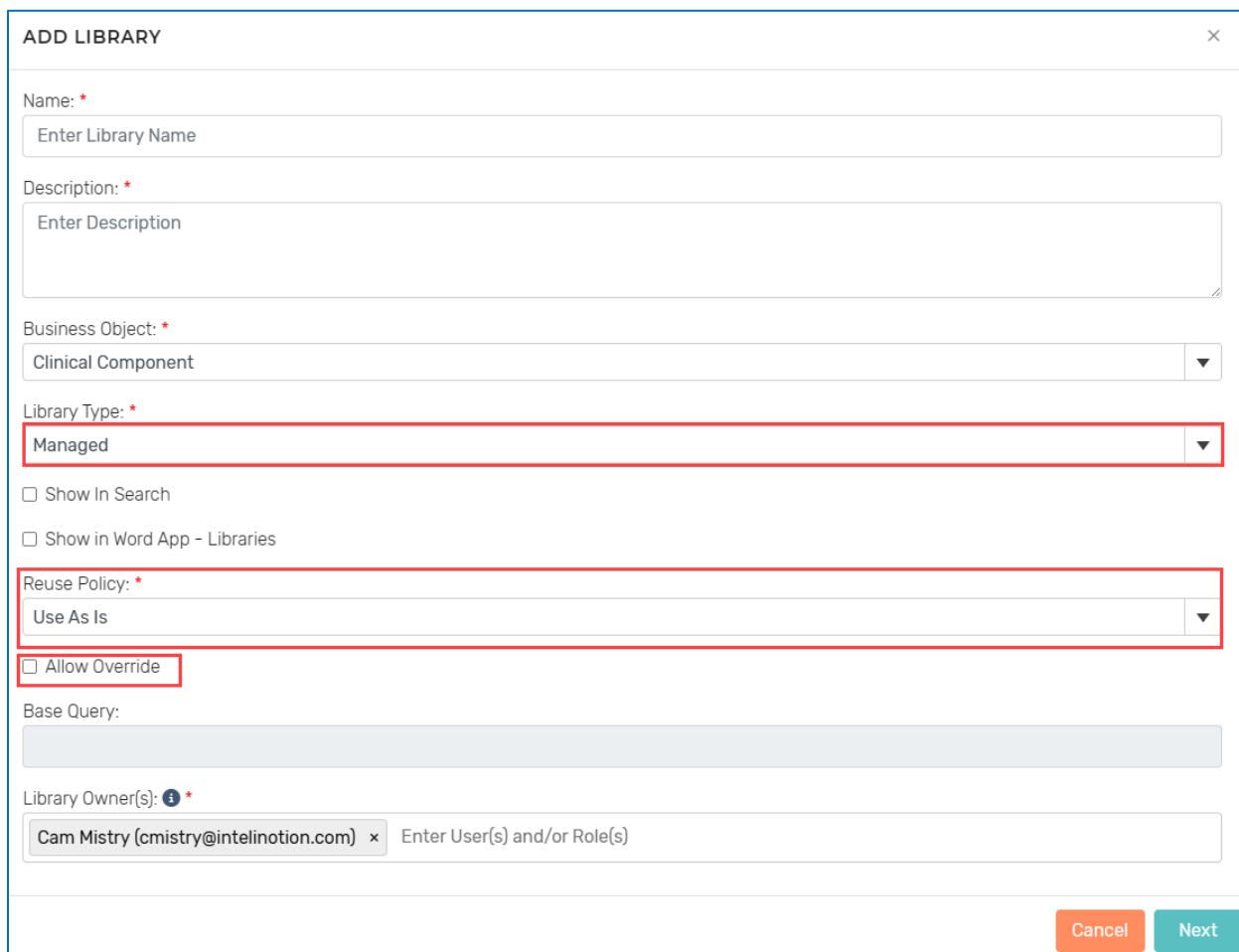
3. Choose **Managed** from the drop-down menu and select the **Reuse Policy** for all components added to the library.

Note: For Reuse Policy, select:

- **Use As Is** if modification of the library component is not allowed.
- **Repurpose** if modification of the library component is permitted, with a relationship maintained back to the source/parent.

5.1.1 Use As Is with Allow Override

1. If **Use As Is** option is chosen, the check box to choose to **Allow Override** will display. This option allows user to override the reuse policy from **Use As Is** to **Repurpose** as components are inserted into a document.



The screenshot shows the 'ADD LIBRARY' dialog box. It includes fields for Name, Description, Business Object, Library Type (set to Managed), Reuse Policy (set to Use As Is), and Allow Override checkbox. The 'Allow Override' checkbox is highlighted with a red border.

- If the library currently has **Repurpose** policy setup and it can be changed to **Use As Is**, the **Allow Override** checkbox will be displayed on the screen and will be unchecked by default.

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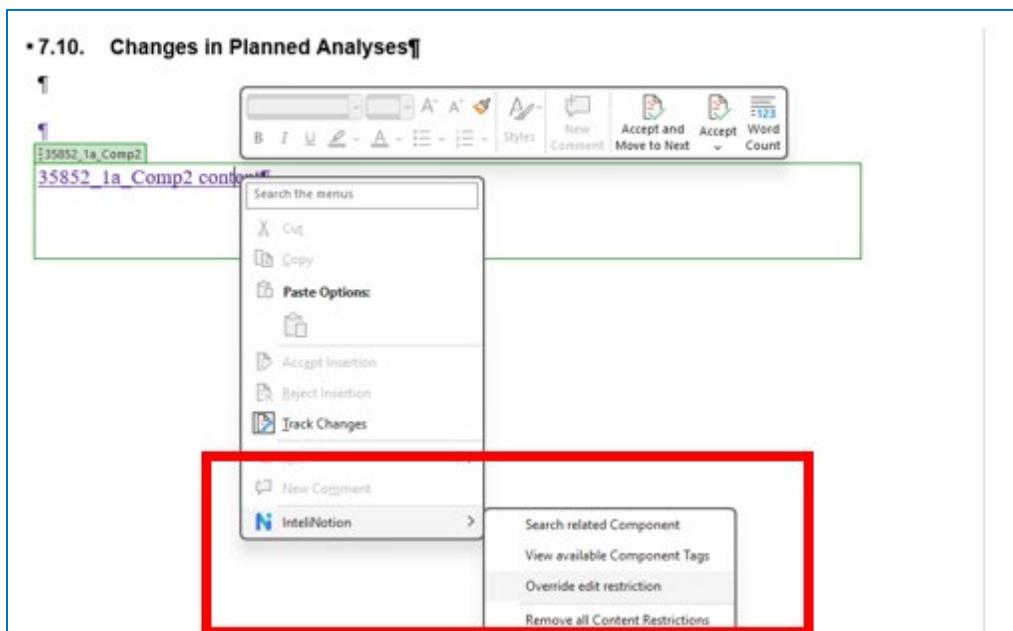
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- The components added to any document via *Word App-Libraries* after changing the library reuse policy to **Use As Is** will be **As-Is** reused into the document.
- If the **Allow Override** checkbox is checked, a user with appropriate override permission will have the option to override edit restriction for the inserted component.
- If the **Allow Override** checkbox is not checked then a user with appropriate override permission will not see the option to override edit restriction for the inserted component.

Note: Components that are already reused in any of the documents when the policy was Use As Is will continue to be As-Is reused and NOT have their reuse policy change. The components that are already reused in any of the documents when the policy was Repurpose will continue to be Repurpose reused and NOT have their reuse policy change.

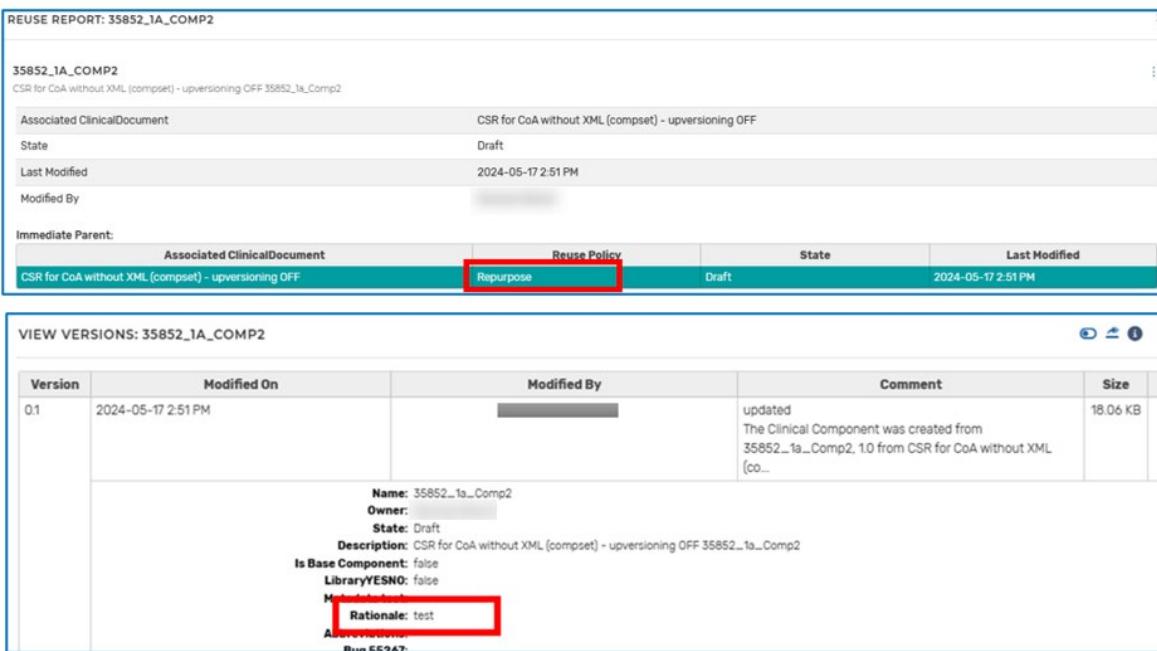
2. The user can right click in the IN Word App to verify the Use As Is component added to the document is not editable, but can override the edit restriction



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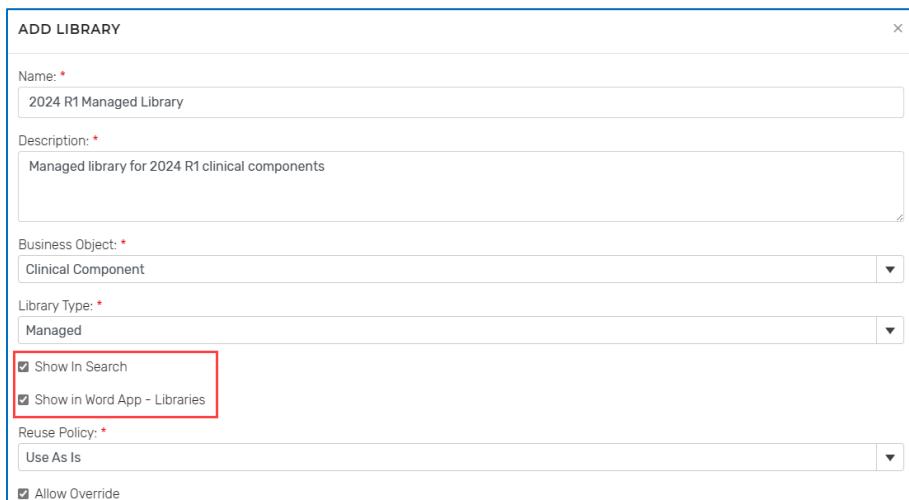
3. The Reuse Report for the component will display a 'Repurpose' reuse policy and the version history will contain the override rationale added by the user.



The screenshot shows two pages from the InteliNotion interface. The top page is titled 'REUSE REPORT: 35852_1A_COMP2' and displays component details: Associated ClinicalDocument (CSR for CoA without XML (compset) - upversioning OFF), State (Draft), Last Modified (2024-05-17 2:51 PM), and Modified By (redacted). The 'Immediate Parent' section shows 'Associated ClinicalDocument' (CSR for CoA without XML (compset) - upversioning OFF) with a 'Reuse Policy' of 'Repurpose' (highlighted with a red box). The bottom page is titled 'VIEW VERSIONS: 35852_1A_COMP2' and lists a single version (0.1) with details: Modified On (2024-05-17 2:51 PM), Modified By (redacted), Comment (updated: The Clinical Component was created from 35852_1a...Comp2, 1.0 from CSR for CoA without XML (co...)), and Size (16.0 KB). Below the table, component metadata is shown: Name: 35852_1a...Comp2, Owner: (redacted), State: Draft, Description: CSR for CoA without XML (compset) - upversioning OFF 35852_1a...Comp2, Is Base Component: false, LibraryYESNO: false, History: (redacted), and Rationale: test (highlighted with a red box). A 'Run E52A7' link is also present.

5.1.2 Show in Word App and Show in Search

1. Check the **Show in Word App – Libraries** box if the library is intended to appear in the list of available libraries in the **Libraries** section of the *InteliNotion Word App*. Also, check the **Show in Search** checkbox for the library to appear as an available filter for a user to select from when performing a search (see details on how to perform a search in the **InteliNotion User Guide Module 5**).

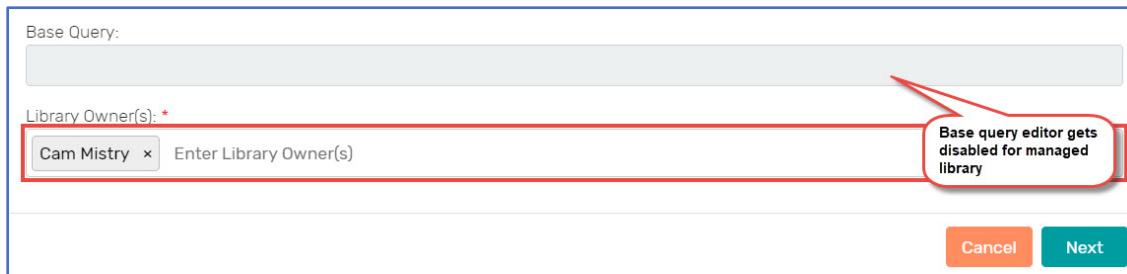


The screenshot shows the 'ADD LIBRARY' dialog box. It includes fields for Name (2024 R1 Managed Library), Description (Managed library for 2024 R1 clinical components), Business Object (Clinical Component), Library Type (Managed), and Reuse Policy (Use As Is). At the bottom, there are two checkboxes: 'Show In Search' (highlighted with a red box) and 'Show in Word App - Libraries' (also highlighted with a red box).

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2. Add other library owners, if needed, and click **Next**.

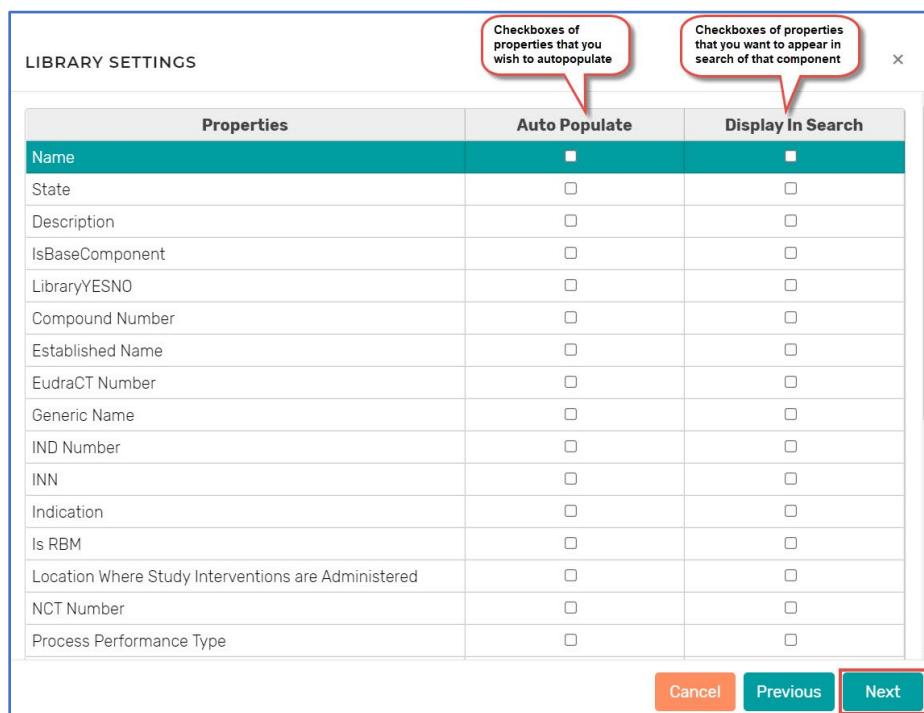


Base Query:

Library Owner(s): * Enter Library Owner(s)

Cancel **Next**

3. In the next window, select Library Settings by checking off the desired properties in the Auto Populate or Display in Search column.

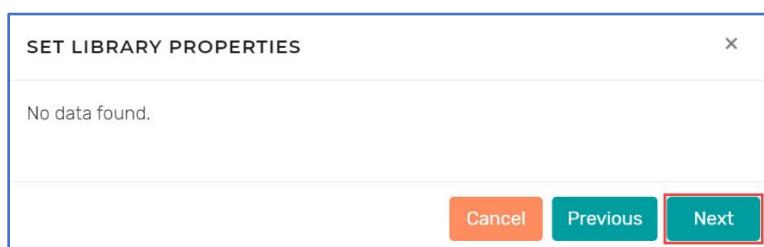


LIBRARY SETTINGS

Properties	Auto Populate	Display In Search
Name	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
State	<input type="checkbox"/>	<input type="checkbox"/>
Description	<input type="checkbox"/>	<input type="checkbox"/>
IsBaseComponent	<input type="checkbox"/>	<input type="checkbox"/>
LibraryYESNO	<input type="checkbox"/>	<input type="checkbox"/>
Compound Number	<input type="checkbox"/>	<input type="checkbox"/>
Established Name	<input type="checkbox"/>	<input type="checkbox"/>
EudraCT Number	<input type="checkbox"/>	<input type="checkbox"/>
Generic Name	<input type="checkbox"/>	<input type="checkbox"/>
IND Number	<input type="checkbox"/>	<input type="checkbox"/>
INN	<input type="checkbox"/>	<input type="checkbox"/>
Indication	<input type="checkbox"/>	<input type="checkbox"/>
Is RBM	<input type="checkbox"/>	<input type="checkbox"/>
Location Where Study Interventions are Administered	<input type="checkbox"/>	<input type="checkbox"/>
NCT Number	<input type="checkbox"/>	<input type="checkbox"/>
Process Performance Type	<input type="checkbox"/>	<input type="checkbox"/>

Cancel **Previous** **Next**

4. If no library properties have been set, the following message appears. Click **Next** to set auto-populate or show properties in search.



SET LIBRARY PROPERTIES

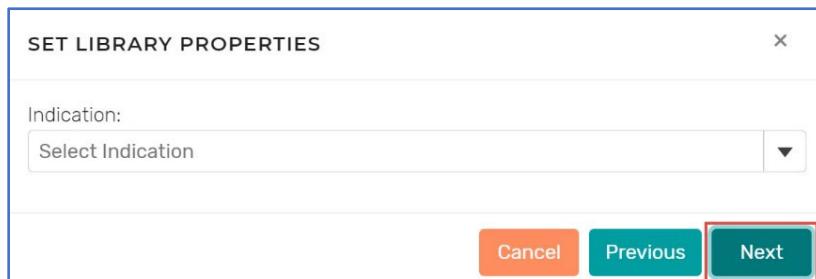
No data found.

Cancel **Previous** **Next**

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5. If the library property(ies) has been set, the user will choose the applicable item from the dropdown menu that appears for that property.

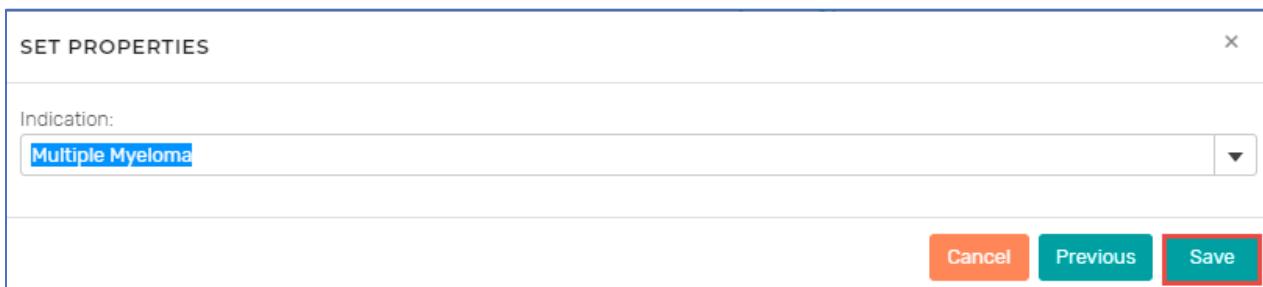


6. If applicable, click the checkboxes for any properties that are to be auto populated for all components added to the library, as well any properties to be displayed when a component from the library is displayed in searched results, and click **Next**.

Notes:

- **Display in Search** checkbox is only applicable when using the *Word* app.
- If specific properties are needed to assist with library component management, be sure to first add the relevant subcategory and value as outlined in [Section 2](#).

7. Select the specific values for the properties checked/selected in the previous step for auto-population and click **Save**.



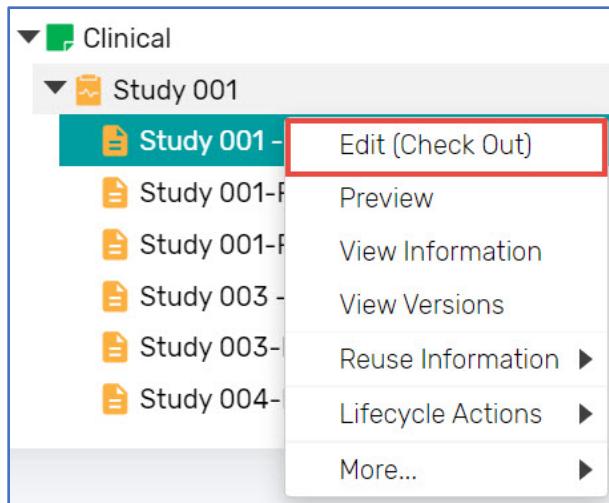
8. Once the library is created, it will appear on the **Libraries** page of the *Web Console*.



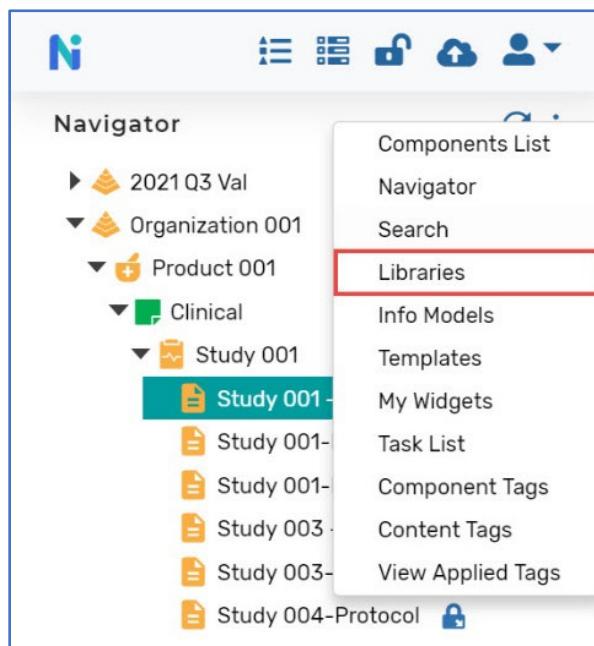
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9. **Edit (Check Out)** a document with the matching property.



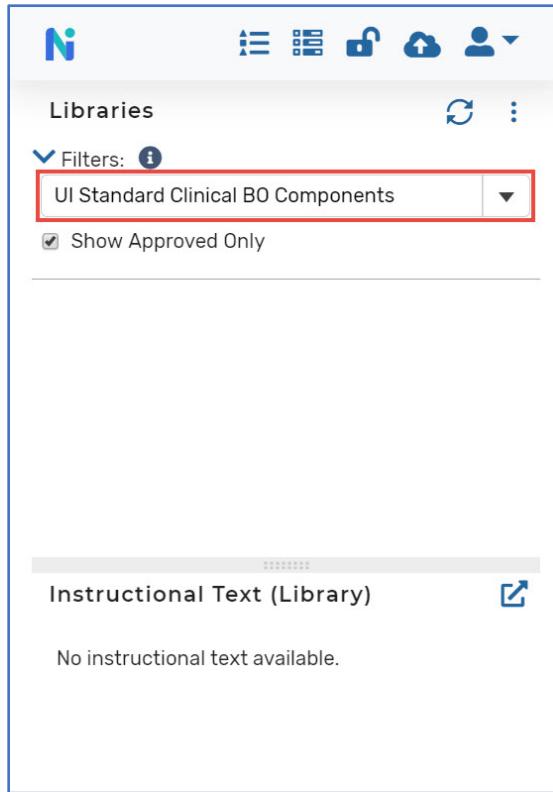
10. Click on the **vertical ellipsis** ⋮ and select **Libraries**.



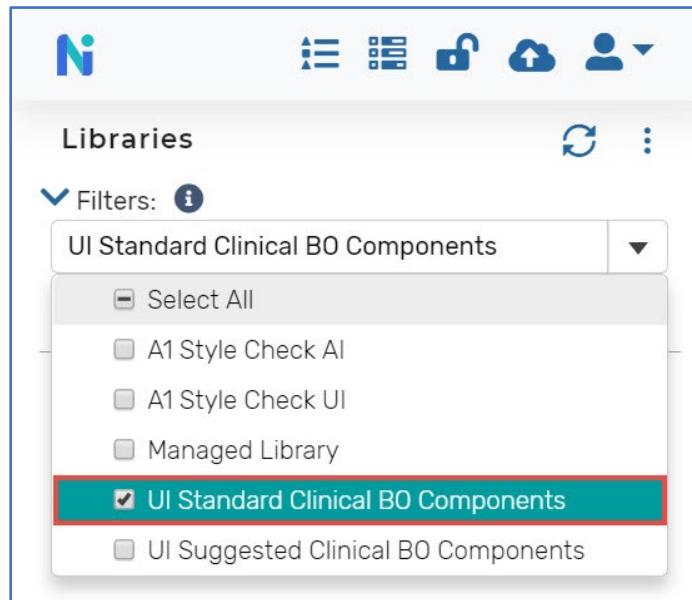
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11. The library will auto-populate for the user.



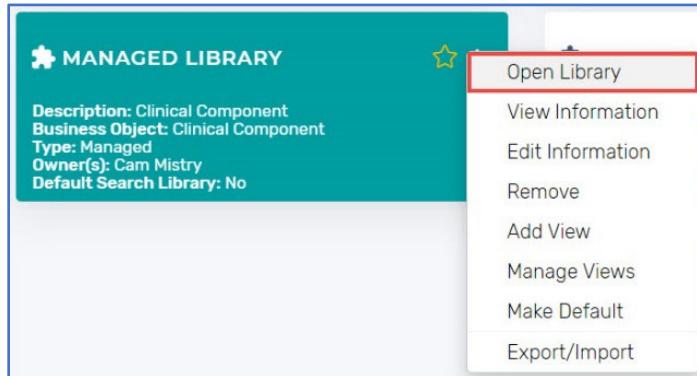
12. The user can choose additional libraries by clicking on the drop-down menu.



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13. Double-click on the library OR click on the **vertical ellipsis** ⋮ beside the library name and click **Open Library** to open the library.



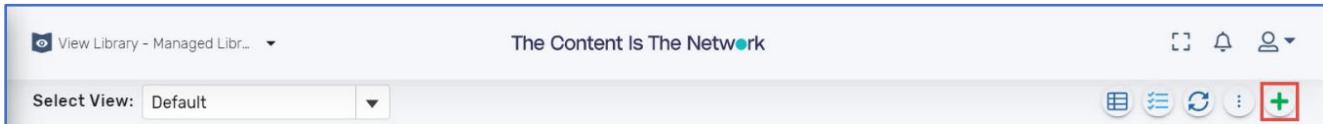
- The initial default view of a new managed library will contain no components.

A screenshot of the InteliNotion web console showing a library view. The title bar says "View Library - Managed Libr...". The main area shows a table header with columns: Name*, Modified On*, Modified By*, and State*. The toolbar at the top includes icons for search, refresh, and a plus sign for adding new items.

Note: See Section 7 for instructions on how to add components to a library.

5.2 CREATING A NON-MANAGED LIBRARY (PRESPECIFIED VIEW)

- Click the **Libraries** option in the left-hand navigation pane of the *Web Console*.
- Click on the **add icon**  to add a new library.

A screenshot of the InteliNotion web console showing a library view. The title bar says "View Library - Managed Libr...". The main area shows a table header with columns: Name*, Modified On*, Modified By*, and State*. The toolbar at the top includes icons for search, refresh, and a plus sign for adding new items. The plus sign icon is highlighted with a red box.

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3. Enter the **Name** and **Description** and select the appropriate **Business Object** for the library (eg, Component, Document). Check the **Show in Search** checkbox for the library to appear as an available filter for a user to select from when performing a search (see details on how to perform a search in the **InteliNotion User Guide Module 5**).

ADD LIBRARY

Name: *	2024 R1 Guide Library
Description: *	This is a non-managed library to get screen shots for the guides
Business Object: *	Clinical Component
Library Type: *	Non Managed
Child Business Object(s)	Select Child Business Object(s)
Components to Include: ⓘ *	All Components Except Managed
<input type="checkbox"/> Show In Search	
Base Query:	
Library Owner(s): ⓘ *	Cam Mistry (cmistry@intelinotion.com) <input type="button" value="x"/> Enter User(s) and/or Role(s)
<input type="button" value="Cancel"/> <input type="button" value="Save"/>	

4. Depending on which type of **Business Object** selected, the **Child Business Object(s)** drop down will be populated with the applicable business object classes. The user can select all classes, multiple applicable classes, or none. If no child classes are selected, the library will only display the objects for the parent object class.

Business Object: *	Clinical Component
Library Type: *	Non Managed
Child Business Object(s)	Select Child Business Object(s)
<input type="checkbox"/> Select All <input type="checkbox"/> Clinical Component	
<input type="checkbox"/> Show In Search	

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- *If* a component class is selected, an additional drop-down menu, **Components to Include**, will display. Users have the option to choose from the following options:
 - **All Components Except Managed** - This is the default selected value. When this option is selected, the library will include all non-managed components and orphan components the selected Component object class(es). It will not include any managed components.
 - **All Components** - When this option is selected, the library will include all non-managed components, all orphan components, and all managed components from the selected Component object class(es).
 - **Managed Components Only** - When this option is selected, the library will include all managed components only from the selected Component object class(es). It will not include any orphan components or any non-managed components.
 - **Orphaned Components Only** - When this option is selected, the library will include all orphaned components only from the selected Component object class(es). It will not include any managed components or any non-managed components.

Child Business Object(s)

Select Child Business Object(s)

Components to Include: *

All Components Except Managed

All Components

Managed Components Only

Orphaned Components Only

Library Owner(s): *

Cam Mistry (cmistry@intelinotion.com) Enter User(s) and/or Role(s)

Note: Orphan components are not typically included in a library/view. It may be useful to create a specific non-managed library for orphaned components if the identification and/or removal of these types of components is needed.

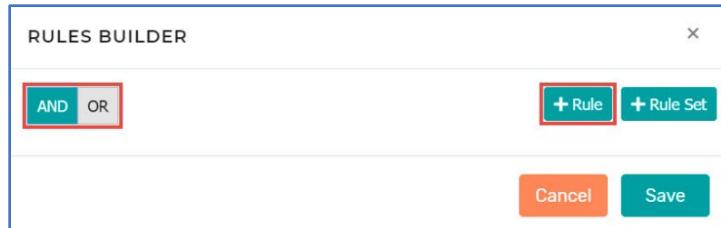
5. If further conditions are desired, create the base query (filter) for the library, as follows:
 - a. Click on the **Edit icon**  to add a base query (filter) for the library.

Base Query:

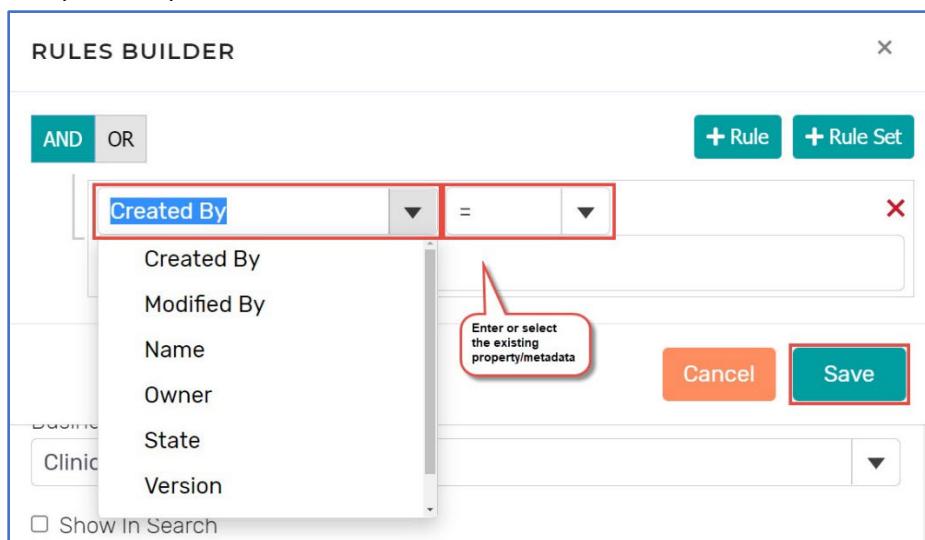
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- b. Select **AND** or **OR** for the type of expression and click **+ Rule**.



- c. Select the relevant **Property** from the list.
 d. Select operator as **=** (equal to) or **!=** (not equal to).
 e. Enter or select an existing value from the dropdown list, based on the selection made in Step 5c.
 f. Repeat Steps 5b-5e, as needed, and click **Save**.



Note: The **+ Rule Set** function can be used if multiple rules need to be grouped together, and then executed either with **(AND)** or alternatively **(OR)** vs another separate rule or ruleset.

- i. *IF* the business object chosen in step 3 was a Document object or one of its child classes, users can include additional rules to populate the non-managed library with document objects in specific states of check out.

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RULES BUILDER

AND OR

Check Out Type	=	Co-authoring with XML	X
		Co-authoring with XML	
		Co-authoring without XML	
		Collaborative Review	
		Single authoring	

Non Managed

Save

ii. Choose the desired checkout state from the drop-down menu.

RULES BUILDER

AND OR

Check Out Type	=	Co-authoring with XML	X
----------------	---	-----------------------	---

Cancel **Save**

iii. Repeat as desired and click **Save**.

RULES BUILDER

AND OR

Check Out Type	=	Co-authoring with XML	X
Check Out Type	=	Collaborative Review	X
Check Out Type	=	Single authoring	X

Cancel **Save**

6. Add other library owners, if needed, and click **Save**.

Library Owner(s): *

Cam Mistry X Enter Library Owner(s)

Enter names of more users as library owners

Cancel **Save**

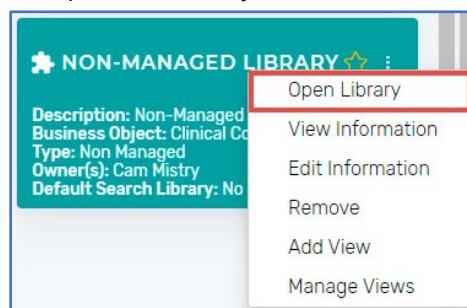
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7. Once the library is created, it will appear on the **Libraries** page of the *Web Console*.



8. Double-click on the library or click on the **vertical ellipsis** button beside the library name and click **Open library** to open the library.



9. Once the non-managed library is opened, its default view will display results based on the business object and base query selections, as shown in this example.

The Content Is The Network

Select View: Default

Name*	Modified On*	Modified By*	State*
Abbreviations	2021-11-21 5:45 PM	Cam Mistry	Draft
Abbreviations	2021-11-21 3:08 PM	Cam Mistry	Draft
Abbreviations	2021-11-15 1:11 PM	Cam Mistry	Draft
Abbreviations	2021-11-15 1:11 PM	Cam Mistry	Draft
Abbreviations	2021-11-03 6:10 PM	Cam Mistry	Draft
Abbreviations	2021-11-03 6:00 PM	Cam Mistry	Draft
Abbreviations	2021-11-02 5:41 PM	Cam Mistry	Draft
Abbreviations	2021-10-19 5:35 PM	Cam Mistry	Draft
AE Collection Period	2021-10-15 4:18 PM	Cam Mistry	Draft
AE Collection Period	2021-10-15 4:18 PM	Cam Mistry	Draft

Page Size: 10 items | 1 2 3 4 5 > >> 1 - 10 of 692

Notes:

- Components in a non-managed library cannot be exported or imported.
- Editing of non-managed library components is enabled via its related source document's Component Status Report.

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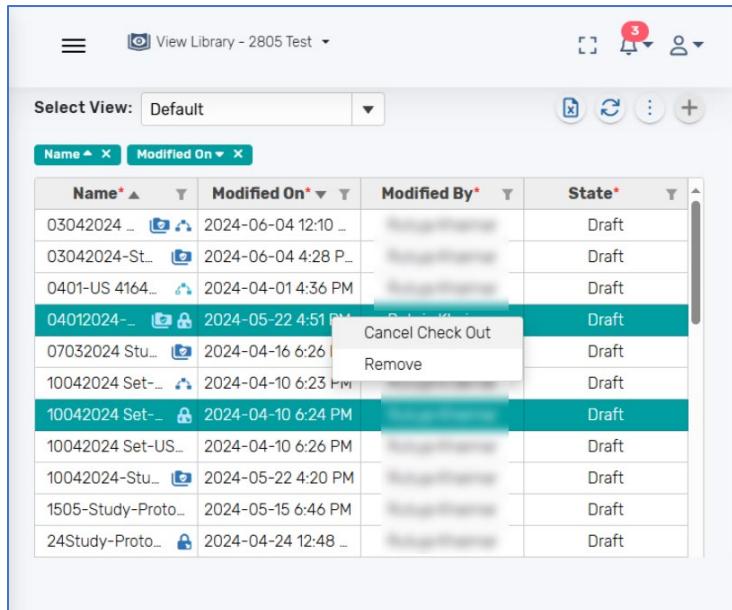
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5.2.1 Additional Functionality for Non-Managed Libraries

Once a non-managed library for any Document business object class has been created, the user can take certain actions for multiple documents at once using the library's datasheet view as listed below, based on the applicable document state.

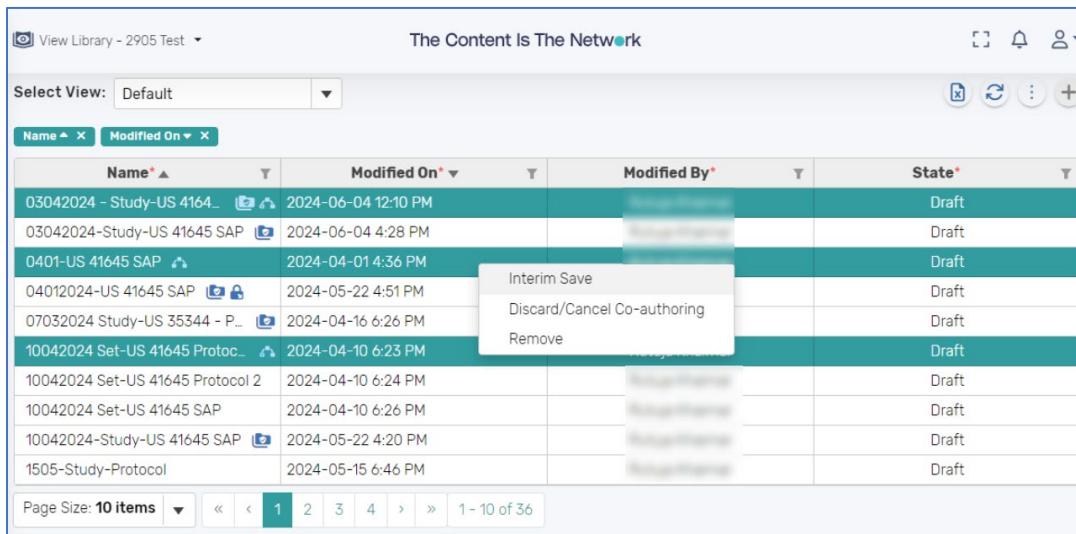
1. Checked-out documents in single authoring can have check out canceled or the document can be removed:



The screenshot shows a library datasheet titled "View Library - 2805 Test". The table has columns: Name*, Modified On*, Modified By*, and State*. A context menu is open over a row for a document checked out on 2024-05-22 at 4:51 PM. The menu options are "Cancel Check Out" and "Remove".

Name*	Modified On*	Modified By*	State*
03042024 ...	2024-06-04 12:10 ...	[redacted]	Draft
03042024-St... [redacted]	2024-06-04 4:28 P... [redacted]	[redacted]	Draft
0401-US 4164... [redacted]	2024-04-01 4:36 PM [redacted]	[redacted]	Draft
04012024- ... [redacted]	2024-05-22 4:51 PM [redacted]	[redacted]	Draft
07032024 Stu... [redacted]	2024-04-16 6:26 ... [redacted]	[redacted]	Draft
10042024 Set-... [redacted]	2024-04-10 6:23 PM [redacted]	[redacted]	Draft
10042024 Set-... [redacted]	2024-04-10 6:24 PM [redacted]	[redacted]	Draft
10042024 Set-US... [redacted]	2024-04-10 6:26 PM [redacted]	[redacted]	Draft
10042024-Stu... [redacted]	2024-05-22 4:20 PM [redacted]	[redacted]	Draft
1505-Study-Proto... [redacted]	2024-05-15 6:46 PM [redacted]	[redacted]	Draft
24Study-Proto... [redacted]	2024-04-24 12:48 ... [redacted]	[redacted]	Draft

2. Documents in co-authoring can have co-authoring discarded/canceled, an interim save performed, or the document can be removed:



The screenshot shows a library datasheet titled "View Library - 2905 Test". The table has columns: Name*, Modified On*, Modified By*, and State*. A context menu is open over a row for a document in co-authoring on 2024-05-22 at 4:51 PM. The menu options are "Interim Save", "Discard/Cancel Co-authoring", and "Remove".

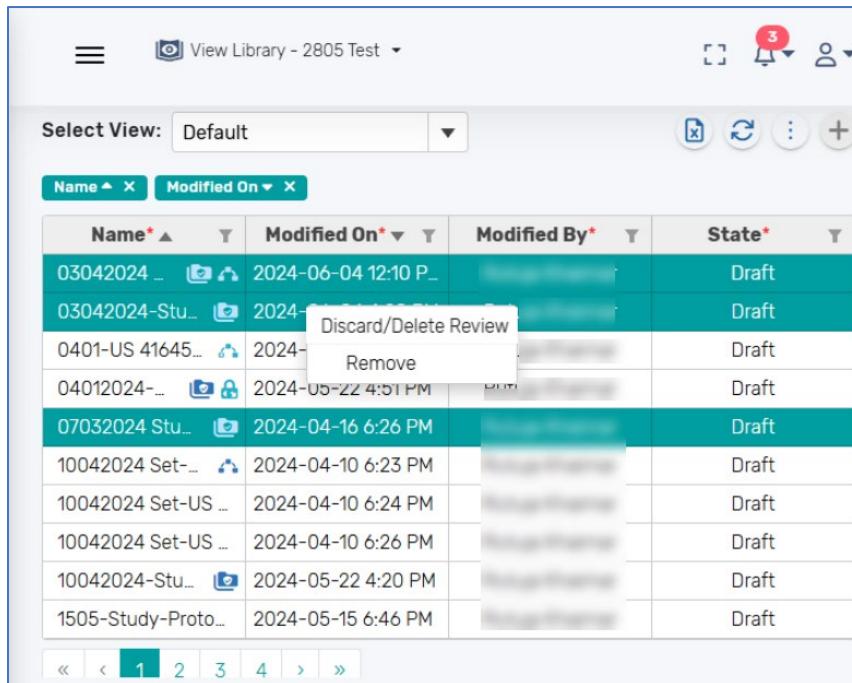
Name*	Modified On*	Modified By*	State*
03042024 - Study-US 4164... [redacted]	2024-06-04 12:10 PM [redacted]	[redacted]	Draft
03042024-Study-US 41645 SAP [redacted]	2024-06-04 4:28 PM [redacted]	[redacted]	Draft
0401-US 41645 SAP [redacted]	2024-04-01 4:36 PM [redacted]	[redacted]	Draft
04012024-US 41645 SAP [redacted]	2024-05-22 4:51 PM [redacted]	[redacted]	Draft
07032024 Study-US 35344 - P... [redacted]	2024-04-16 6:26 PM [redacted]	[redacted]	Draft
10042024 Set-US 41645 Protocol ... [redacted]	2024-04-10 6:23 PM [redacted]	[redacted]	Draft
10042024 Set-US 41645 Protocol 2	2024-04-10 6:24 PM [redacted]	[redacted]	Draft
10042024 Set-US 41645 SAP	2024-04-10 6:26 PM [redacted]	[redacted]	Draft
10042024-Study-US 41645 SAP [redacted]	2024-05-22 4:20 PM [redacted]	[redacted]	Draft
1505-Study-Protocol	2024-05-15 6:46 PM [redacted]	[redacted]	Draft

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3. Documents in collaborative review can have the review discarded/deleted or the document removed:



Name*	Modified On*	Modified By*	State*
03042024 ...	2024-06-04 12:10 P...		Draft
03042024-Stu...	2024-	Discard/Delete Review	Draft
0401-US 41645...	2024-	Remove	Draft
04012024-...	2024-05-22 4:51 PM		Draft
07032024 Stu...	2024-04-16 6:26 PM		Draft
10042024 Set-...	2024-04-10 6:23 PM		Draft
10042024 Set-US ...	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

Notes:

- Cancel, Discard, or Delete actions are not permitted if documents are selected with mixed statuses (ie, check out in single authoring and co-authoring). A user without C-R-U-D-O or relevant override permissions is not permitted to cancel checkout of another person's document. For detailed instructions on canceling checkout, interim save, or cancelling collaborative review see **InteliNotion User Guide Modules 5 & 9**.
- Users can only take the Cancel, Discard, or Delete actions accorded by the specific level of access configured. Eg, user cannot cancel checkout of another person's document if they do not have C-R-U-D-O access along with relevant override permission.

5.3 DEFINING (MANAGED) LIBRARY AUTO SELECTION RULE(S)

This functionality allows multiple managed library auto-selection rules to be set using one or more business object properties with AND/OR operators. Based on matches between the rule set and authored document, relevant managed libraries are preselected and displayed in Word App. When a user editing a document in either single or co-authoring switches the *InteliNotion Word App* to the Libraries view, 1 or more libraries will be preselected based on pre-specified auto selection rules that match properties between the relevant managed library and the open

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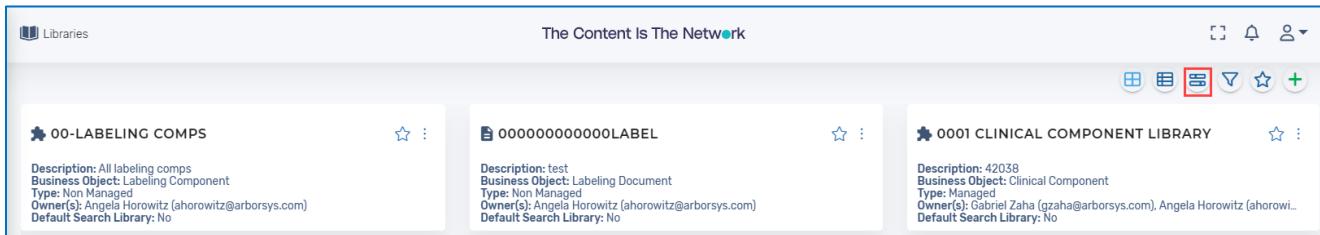
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document. This will occur given the document has at least 1 property that meets the condition(s) of a rule or rule set specified for the relevant managed library or libraries.

This is not a mandatory step in creating managed libraries and is only needed if a user wants to associate specific libraries with conditions occurring in certain documents that meet a pre-selected set of rules. See the steps listed below to associate a managed library with auto selection rules.

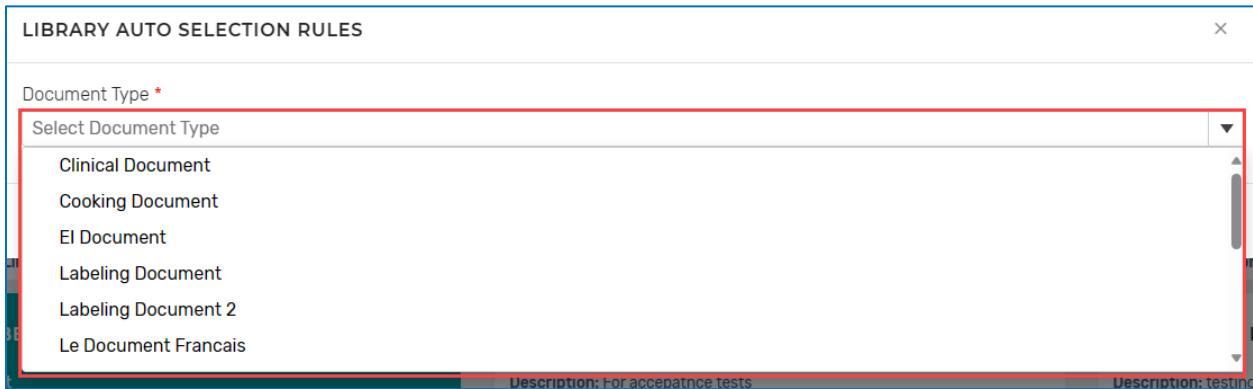
1. Click the **Libraries** option in the left-hand navigation pane of the *Web Console*.
2. Click the **Library auto-selection rule icon**  in the Libraries page of the *Web Console*.



The screenshot shows the 'Libraries' page in the Intelinotion Web Console. It displays three managed libraries:

- 00-LABELING COMPS**:
Description: All labeling comps
Business Object: Labeling Component
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No
- 000000000000LABEL**:
Description: test
Business Object: Labeling Document
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No
- 0001 CLINICAL COMPONENT LIBRARY**:
Description: 42038
Business Object: Clinical Component
Type: Managed
Owner(s): Gabriel Zaha (gzaha@arborsys.com), Angela Horowitz (ahorow...
Default Search Library: No

3. The **Library Auto Selection Rules** window will display. Select the applicable document types from the **Document Type** drop-down menu.



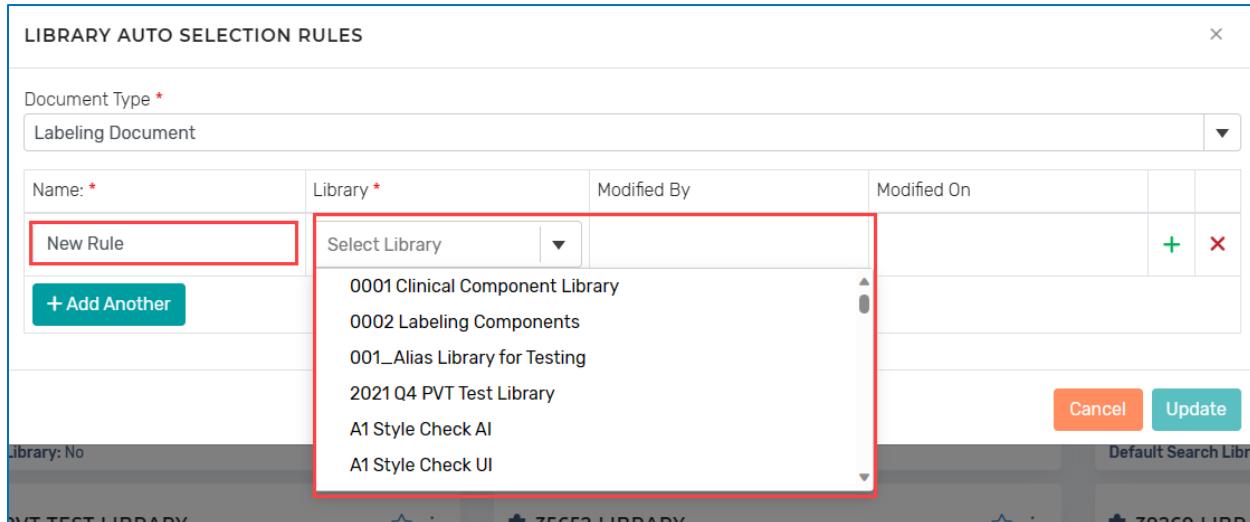
The screenshot shows the 'LIBRARY AUTO SELECTION RULES' dialog box. The 'Document Type *' field is highlighted with a red border. A dropdown menu is open, listing several document types:

- Clinical Document
- Cooking Document
- EI Document
- Labeling Document
- Labeling Document 2
- Le Document Francais

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4. The library auto selection rules builder will display. Enter the desired name for the new rule and choose the applicable library from the drop-down menu.



LIBRARY AUTO SELECTION RULES

Document Type *

New Rule

+ Add Another

Name: * Library * Modified By Modified On

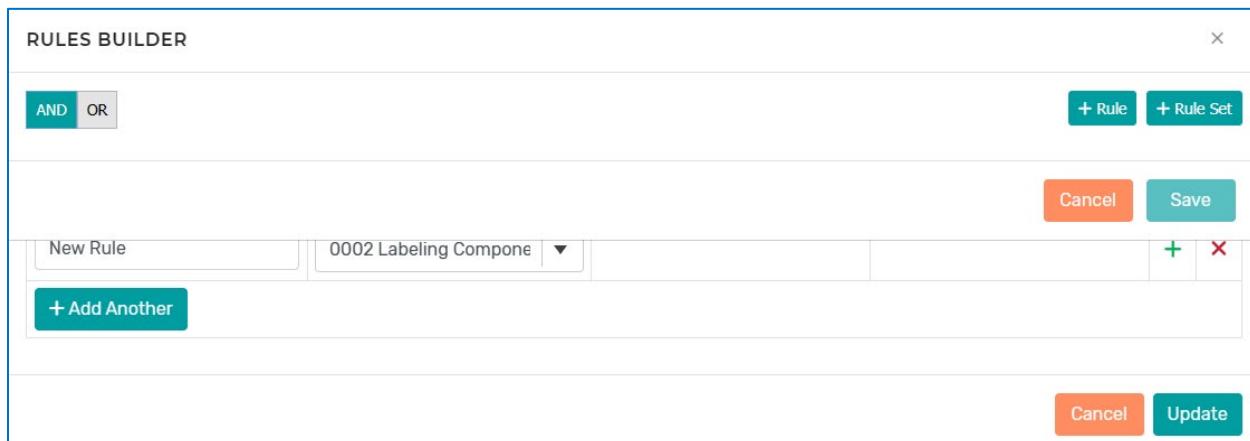
Select Library

0001 Clinical Component Library
0002 Labeling Components
001_Alias Library for Testing
2021 Q4 PVT Test Library
A1 Style Check AI
A1 Style Check UI

Cancel Update Default Search Library

Note: The following steps are optional. It is possible to associate a document type with a library without further conditions or rules. If that is the desired configuration, skip to step 10.

5. Click the green + icon to add a rule condition. The rules builder will display.



RULES BUILDER

AND OR

+ Rule + Rule Set

New Rule 0002 Labeling Components

+ Add Another

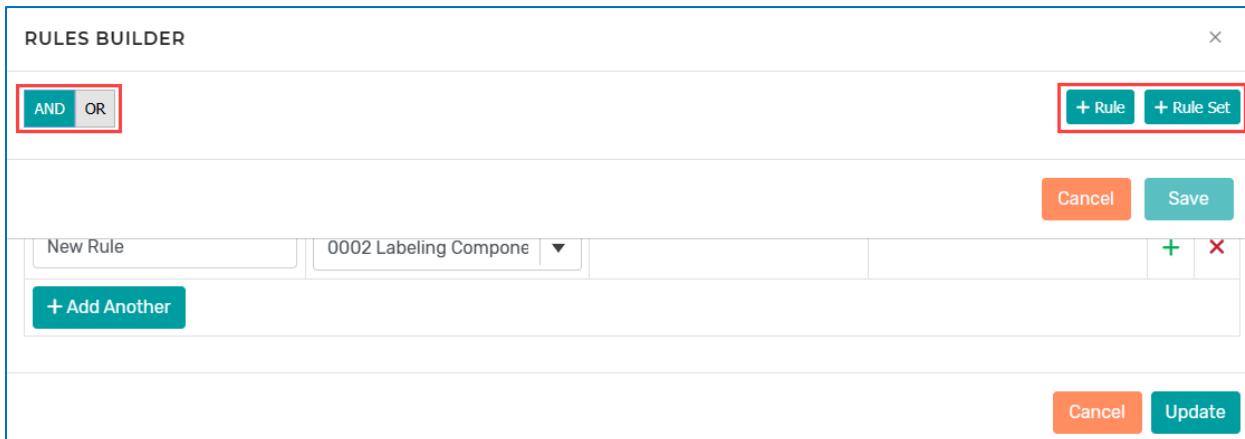
Cancel Save

Cancel Update

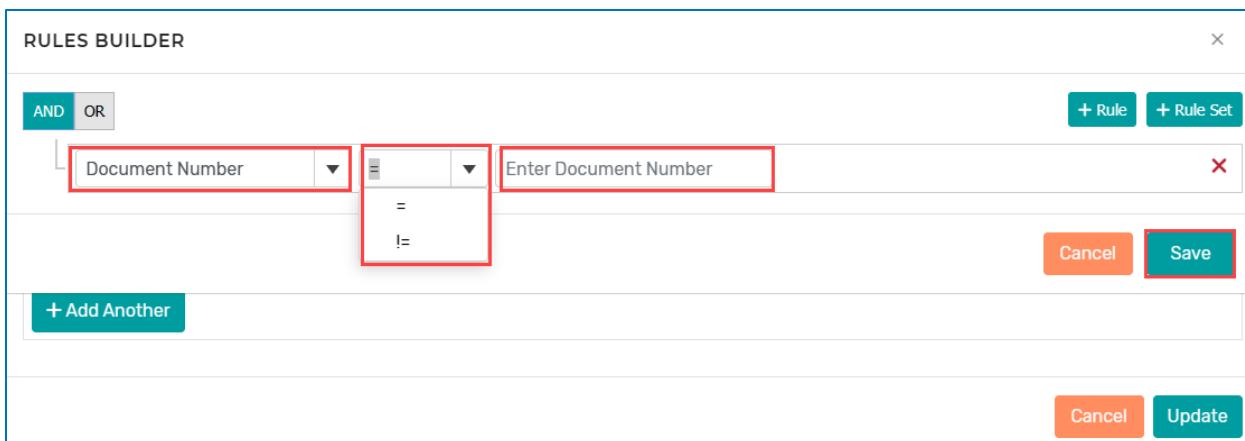
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6. The **AND** condition is selected by default. If desired, switch the condition to **OR**, and click on the **+ Rule** button to add conditions to the library auto selection being configured.



7. Choose the parameters for the rule from the drop-down menus and fill in fields. Depending on the conditions selected, the configurations of these fields will change. If an operator (eg, 'In' or 'Contains') is not supported for a given property, it will not be available in the drop-down for selection within the Rules Builder window (see examples below).



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RULES BUILDER

AND OR

Compound Number	not in	WON-5539	X
Therapeutic Area	in	3 values selected	X

=
!=
in
not in

Cancel Save

No rule	2021 Q4 PVT Test Library	2023-10-27 7:04 AM	+ X
Comp Not TA OR 2	AAID UI AS IS LIBRARY	2023-10-27 7:04 AM	edit X
My Name Here	CSR UI Use As Is Library	2023-10-27 7:04 AM	edit X

+ Add Another

Cancel Update

RULES BUILDER

AND OR

Compound Number	not in	WON-5539	X
Therapeutic Area	in	3 values selected	X

Select All
 Comma, value, added
 Diabetes
 Established Products
 Immunology
 Infectious Diseases
 Inflammation

Cancel Save

No rule	2021 Q4 PVT Test Library	AM + X
Comp Not TA OR 2	AAID UI AS IS LIBRARY	AM edit X
My Name Here	CSR UI Use As Is Library	AM edit X

+ Add Another

Cancel Update

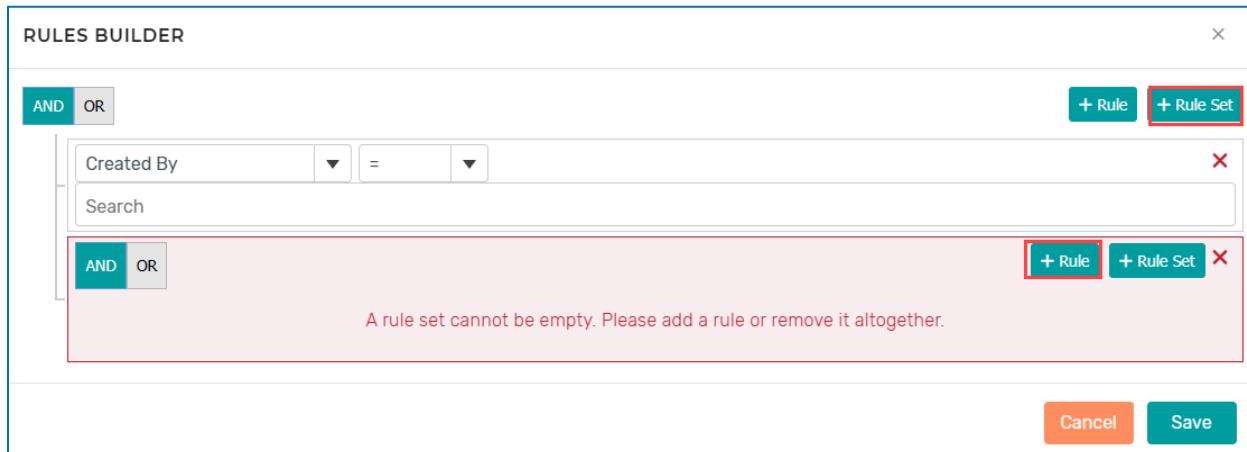
Note: If the document's property allows for multiple values, the rule must use 'In'; otherwise, if the document's property has multiple values selected, the library match will

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not work. If the document's property does not allow for multiple values, then rule can use '=' OR 'In' (recommendation is to use '=').

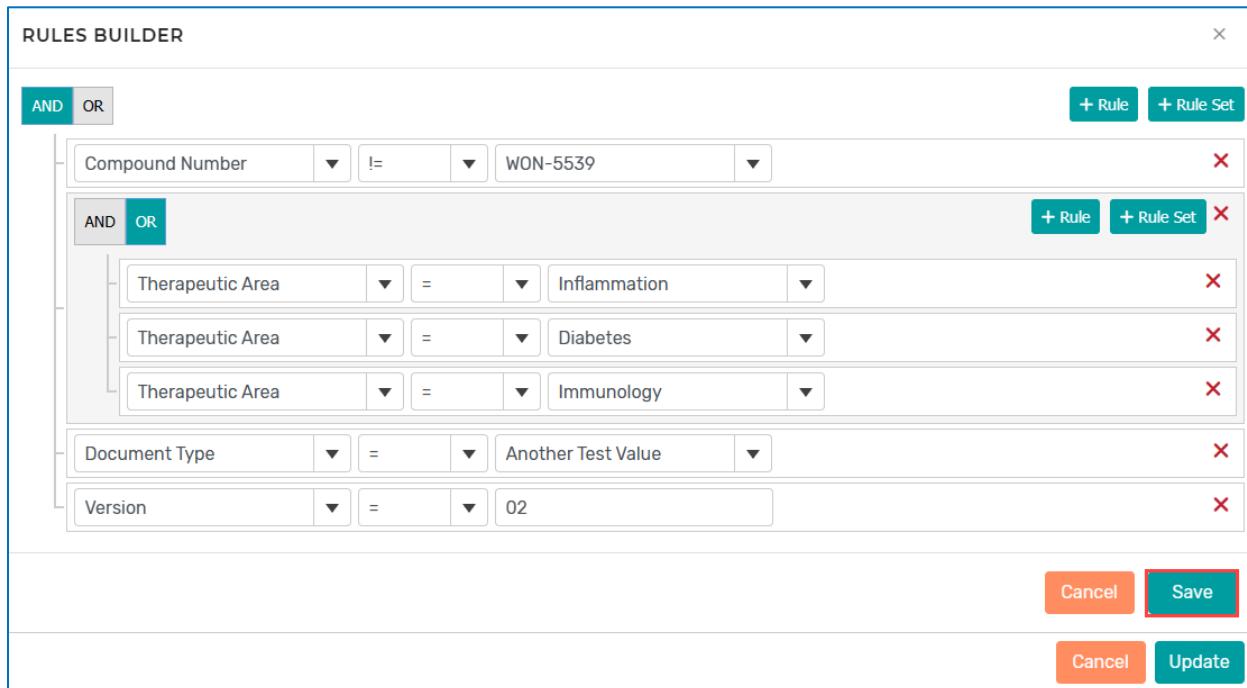
- To add a rule set, click the **+Rule Set** button, and click the **+Rule** button to add rule to the rule set.



The screenshot shows the 'RULES BUILDER' window. At the top, there are 'AND' and 'OR' buttons. Below them is a search bar for 'Created By'. To the right of the search bar are '+ Rule' and '+ Rule Set' buttons, with '+ Rule Set' highlighted with a red border. A large red box surrounds the main rule set area, which contains another 'AND' or 'OR' button and a message: 'A rule set cannot be empty. Please add a rule or remove it altogether.' At the bottom are 'Cancel' and 'Save' buttons.

Note: This can be done as an addendum to a rule, or as its own rule set without any other overarching conditions.

- Once all the conditions have been added to the rule and/or rule set, click **Save**.



The screenshot shows the 'RULES BUILDER' window with a completed rule set. It includes conditions for 'Compound Number' (!= WON-5539), 'Therapeutic Area' (Inflammation, Diabetes, Immunology), 'Document Type' (Another Test Value), and 'Version' (02). The '+ Rule' and '+ Rule Set' buttons are visible at the top right. The 'Save' button is highlighted with a red border. At the bottom are 'Cancel' and 'Update' buttons.

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10. The configured rules will display in the Library Auto Selection Rules window. Click **Update**.

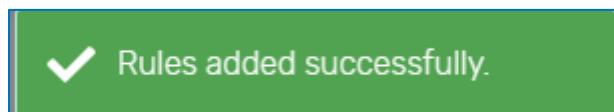
LIBRARY AUTO SELECTION RULES

Name: *	Library *	Modified By	Modified On	
Oncology Library	Oncology Library	[Redacted]	2023-10-27 7:04 AM	
Comp Not TA OR	A1 Style Check AI	[Redacted]	2023-10-27 7:04 AM	
No rule	2021 Q4 PVT Test Library	[Redacted]	2023-10-27 7:04 AM	
Comp Not TA OR 2	AAID UI AS IS LIBRARY	[Redacted]	2023-10-27 7:04 AM	
My Name Here	CSR UI Use As Is Library	[Redacted]	2023-10-27 7:04 AM	

[+ Add Another](#)

Cancel
Update

11. A pop-up informing the user that the rule(s) was created successfully will display.



12. Repeat steps 1-10 as necessary until all desired auto selection rules have been configured.

Note: A library can only be associated with one auto selection rule at a time, though multiple conditions can be placed upon that rule. If it is listed for another rule, an error will display. To add additional conditions to a library already associated with an auto selection rule, follow the steps listed above.

LIBRARY AUTO SELECTION RULES

Name: *	Library *	Modified By	Modified On	
2023 R3 New Rule	2023 R3 New Library	[Redacted]	2023-11-07 11:04 PM	
Guides Rule	2023 R3 New Library	[Redacted]		

[+ Add Another](#)

Cancel
Update

The library is already used in another rule. Please select another library and try again.

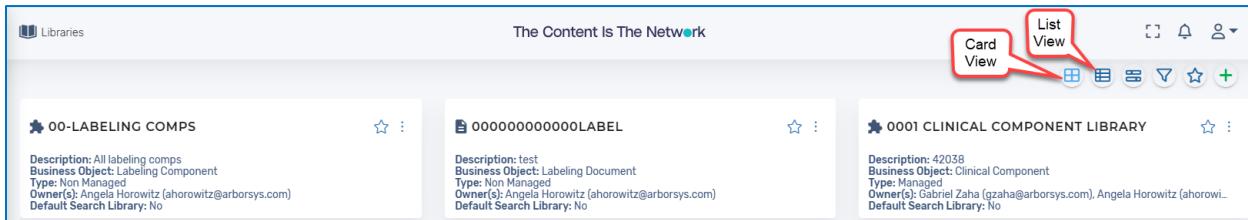
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5.4 MANAGING LIBRARIES

Available libraries can be viewed in either **Card view** or **List view**. Click the appropriate icon as shown below to change views, as appropriate.



The Content Is The Network

Card View

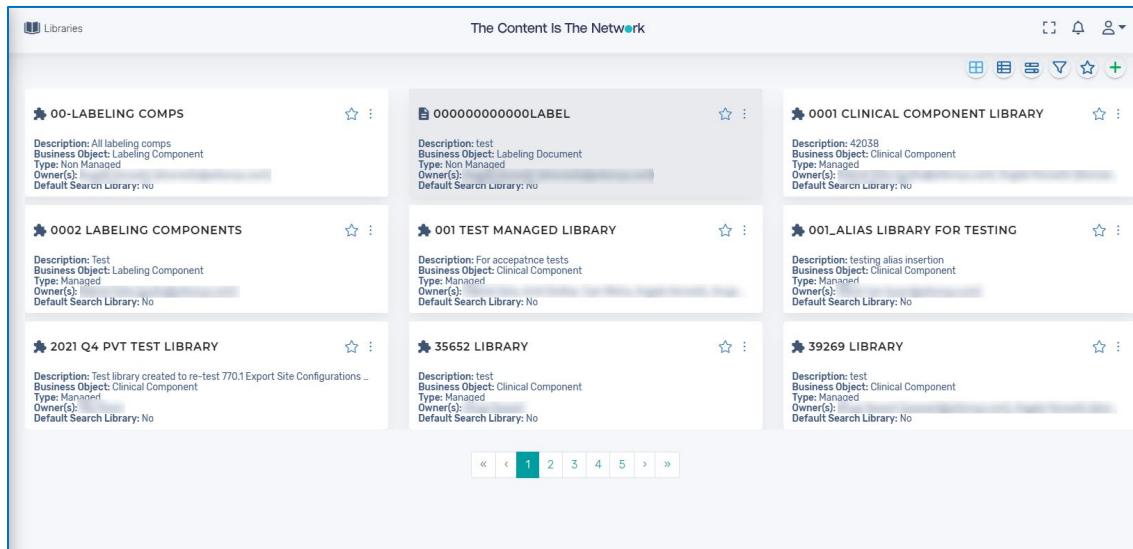
List View

00-LABELING COMPS
Description: All labeling comps
Business Object: Labeling Component
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No

000000000000LABEL
Description: test
Business Object: Labeling Document
Type: Non Managed
Owner(s): Angela Horowitz (ahorowitz@arborsys.com)
Default Search Library: No

0001 CLINICAL COMPONENT LIBRARY
Description: 42038
Business Object: Clinical Component
Type: Managed
Owner(s): Gabriel Zaha (gzaha@arborsys.com), Angela Horowitz (ahorowi...
Default Search Library: No

Card View



The Content Is The Network

00-LABELING COMPS
Description: All labeling comps
Business Object: Labeling Component
Type: Non Managed
Owner(s):
Default Search Library: no

000000000000LABEL
Description: test
Business Object: Labeling Document
Type: Non Managed
Owner(s):
Default Search Library: no

0001 CLINICAL COMPONENT LIBRARY
Description: 42038
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: no

0002 LABELING COMPONENTS
Description: Test
Business Object: Labeling Component
Type: Managed
Owner(s):
Default Search Library: No

001 TEST MANAGED LIBRARY
Description: For acceptance tests
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

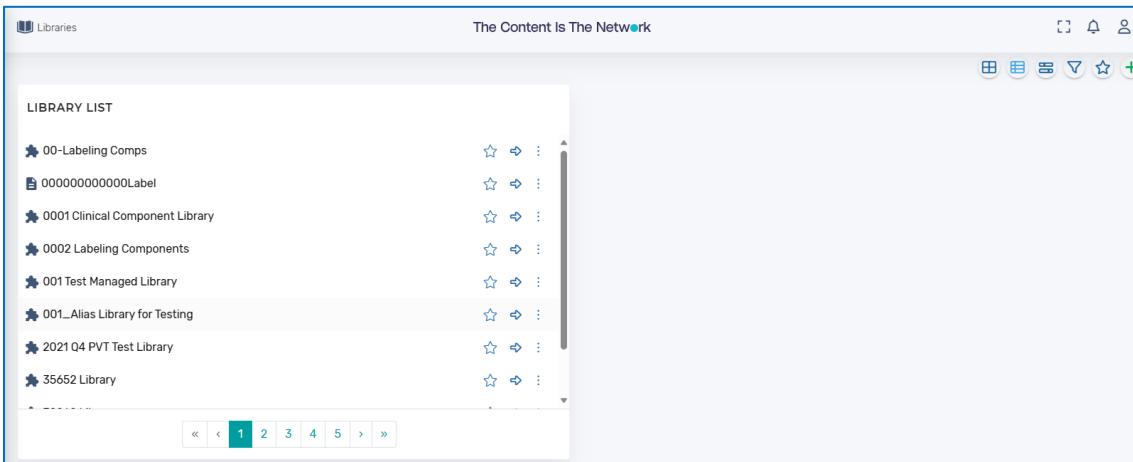
001 ALIAS LIBRARY FOR TESTING
Description: testing alias insertion
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

2021 Q4 PVT TEST LIBRARY
Description: Test library created to re-test 770.1 Export Site Configurations –
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

35652 LIBRARY
Description: test
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

39269 LIBRARY
Description: test
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

List View



The Content Is The Network

LIBRARY LIST

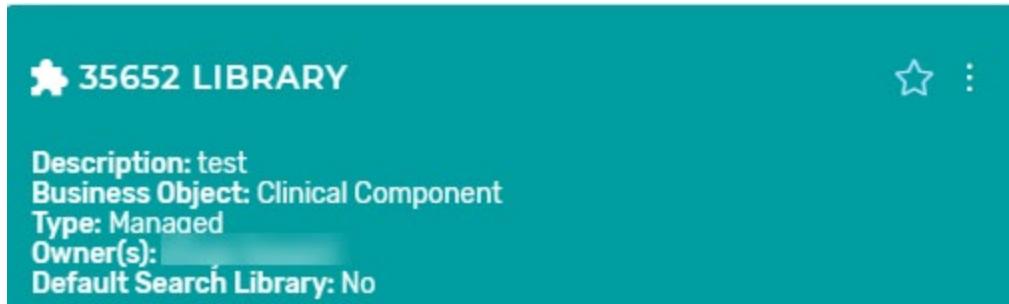
- 00-Labeling Comps**
- 000000000000Label**
- 0001 Clinical Component Library**
- 0002 Labeling Components**
- 001 Test Managed Library**
- 001_Alias Library for Testing**
- 2021 Q4 PVT Test Library**
- 35652 Library**

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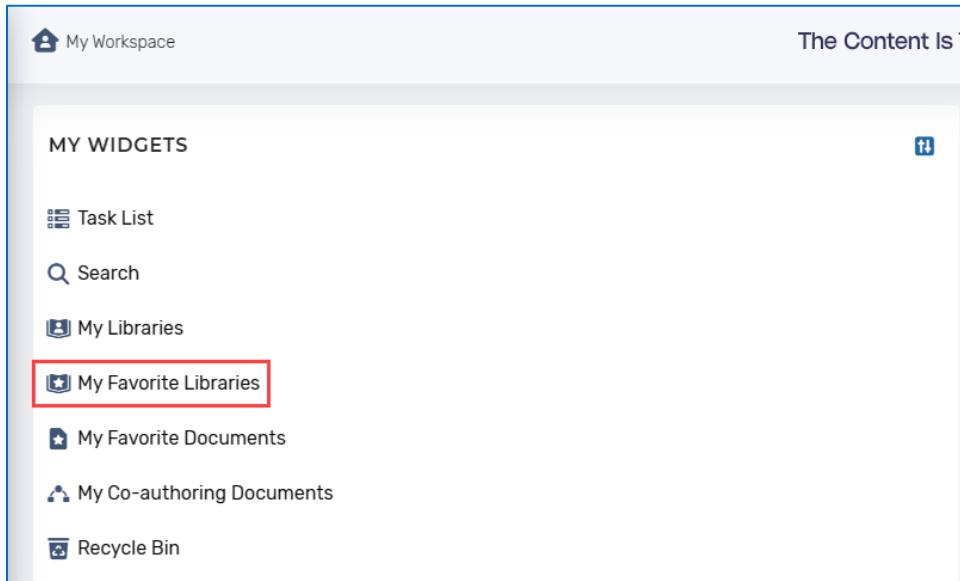
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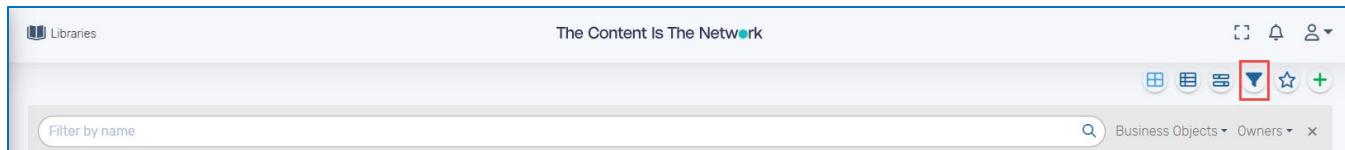
A library can also be favorited by clicking the **star icon** . To quickly view favorite libraries **only**, click the **star icon**  at the top-right hand corner.



A user's favorite libraries will also be available in **My Widgets** under **My Favorite Libraries**.



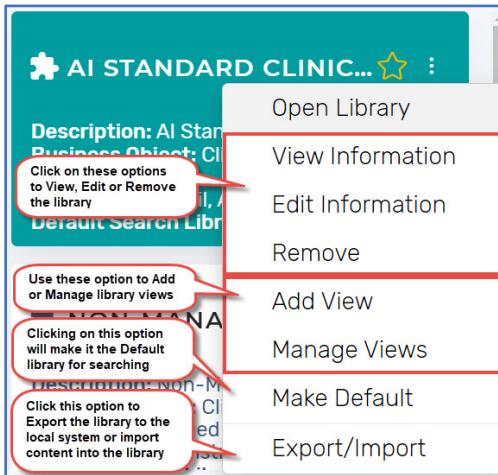
Also, libraries can be filtered by clicking on the **Filter icon**  by providing the partial library name and/or business object and/or library owners.



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To perform an action on any library, click on the **vertical ellipsis** : button beside the library name to select the appropriate action.



To update the library's information (eg, Owner, Auto-populated properties), select **Edit Information** and make changes as required.

Note: If/when managed library auto-populated properties are updated, these changes will not impact existing components already included within the library but will **only** pertain to newly added or imported components.

To update a library's reuse policy from **Repurpose** to **Use As Is** with **Allow Override** checked (see [Section 5.1](#)), users must be aware that the following conditions apply:

- The components added to any document via *Word App-Libraries* after changing the library reuse policy will be repurpose reused into the document.
- The components that are already reused in any of the documents when the policy was **Use As Is** will continue to be As-Is reused and NOT have their reuse policy change.
- If the library currently has **Repurpose** policy setup and it can be changed to **Use As Is**, the **Allow Override** checkbox will be displayed on the screen and will be unchecked by default.
- The components added to any document via *Word App-Libraries* after changing the library reuse policy to **Use As Is** will be As-Is reused into the document.
- If the **Allow Override** checkbox is checked, a user with appropriate override permission will have the option to override edit restriction for the inserted component.
- If the **Allow Override** checkbox is not checked then a user with appropriate override permission will not see the option to override edit restriction for the inserted component.
- The components that are already reused in any of the documents when the policy was **Repurpose** will continue to be Repurpose reused and NOT have their reuse policy change.

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- In the document, the user is able to verify that the component added to the document is not editable at first but can override the edit restriction for the component from the InteliNotion right click menu option.
- The Reuse Report for the component and will have a 'Repurpose' reuse policy and the version history will contain the override.

To remove a library, select **Remove**. For a managed library, both the library itself and its components will be removed, unless one of the components is currently as-is reused in a document (in this case, the user will be notified).

Note: A library cannot be restored from Recycle Bin. However, the managed library components may be restored but will become orphaned within the system.

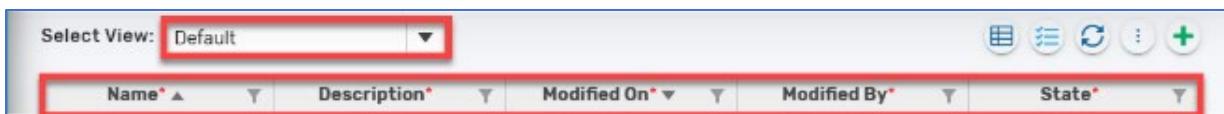
To set a library for a Component object class as the default search library (ie, the library that will be auto selected when a user performs the **Search Related Component** action while editing a document), select **Make Default**. To remove the default setting, select **Remove Default** instead (this option will only display if the library is currently set as the default one).

Note: A library can *only* be made the default search library if it has the Show in Search checkbox checked.

See [Section 5.5](#) for details on how to add and manage library views.

5.5 CREATING A LIBRARY VIEW

A library view can be created for any managed or non-managed library. A view is used to further refine or subset the list of objects (eg, components, documents) displayed in a library. Each library has a **Default** view, which includes all components in the library – for a managed library, this includes all components added; for a non-managed library, this includes any components per the base query rules applied – displayed with their associated properties of **Name**, **Description**, **Modified On**, **Modified By**, and **State**.



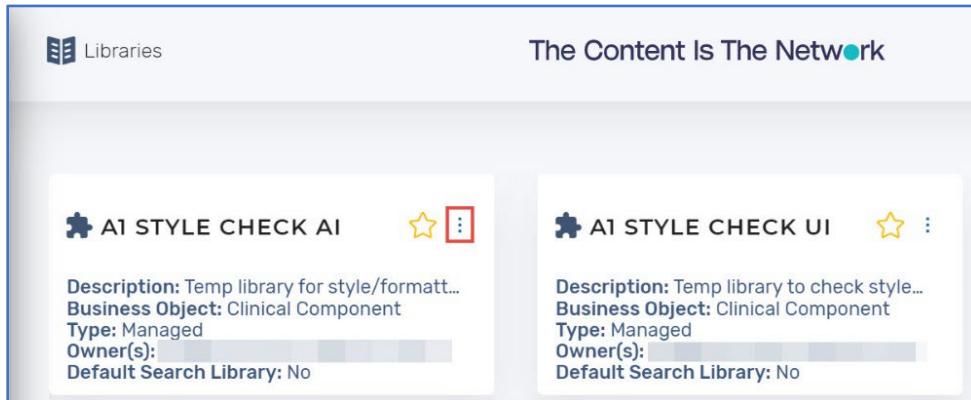
Additional views can be created to further subset the components being displayed. For example, a library that contains all components for a certain document type (eg, protocol) could have different views added to display the components separately by associated therapeutic area (eg, oncology, diabetes, etc.)

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1. A user can view the information for a library component and see the source document by clicking the **vertical ellipsis**  button next to the library name and choosing **View Information**.



The Content Is The Network

A1 STYLE CHECK AI  

Description: Temp library for style/format...
Business Object: Clinical Component
Type: Managed
Owner(s): [redacted]
Default Search Library: No

A1 STYLE CHECK UI  

Description: Temp library to check style...
Business Object: Clinical Component
Type: Managed
Owner(s): [redacted]
Default Search Library: No



AI STANDARD CLINICAL COMPONENTS  

Description: AI Standard Clinical Component
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

NON-MANAGED LIBRARY

Description: Non-Managed Library
Business Object: Clinical Component
Type: Non Managed
Owner(s): Cam Mistry

Open Library

View Information

Edit Information

Remove

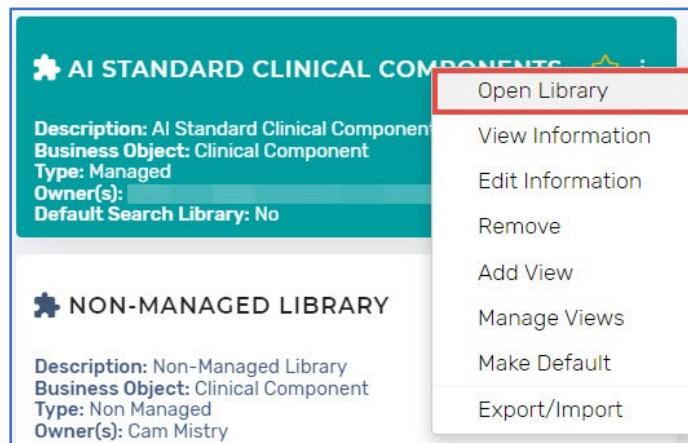
Add View

Manage Views

Make Default

Export/Import

2. Click on the **vertical ellipsis**  button and choose **Open Library**.



AI STANDARD CLINICAL COMPONENTS  

Description: AI Standard Clinical Component
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

NON-MANAGED LIBRARY

Description: Non-Managed Library
Business Object: Clinical Component
Type: Non Managed
Owner(s): Cam Mistry

Open Library

View Information

Edit Information

Remove

Add View

Manage Views

Make Default

Export/Import

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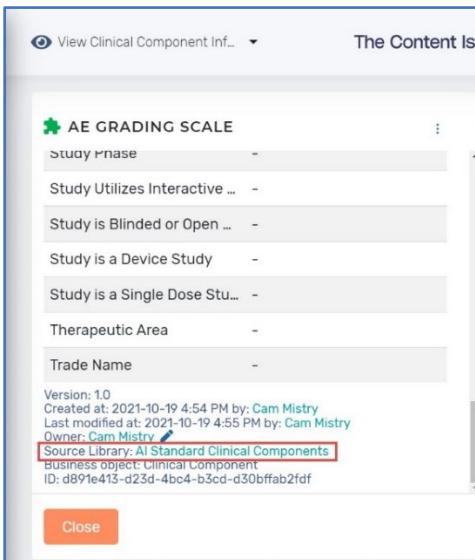
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3. Right-click on an item and choose **View Information**.



Name*	Modified On*	Modified By*	State*
AE Grading Scale	2021-10-19 4:55 PM	Cam Mistry	Approved
AE Grading Scale	4:55 PM	Cam Mistry	Approved
Analyses Adverse Event	4:55 PM	Cam Mistry	Approved
Analyses Adverse Event	4:55 PM	Cam Mistry	Approved
Procedures	4:55 PM	Cam Mistry	Approved
Procedures	4:55 PM	Cam Mistry	Approved

4. The **Clinical Component Information** report will open and the user can scroll down to see the **Source Library**.



AE GRADING SCALE

Study Phase -

Study Utilizes Interactive ... -

Study is Blinded or Open ... -

Study is a Device Study -

Study is a Single Dose Stu... -

Therapeutic Area -

Trade Name -

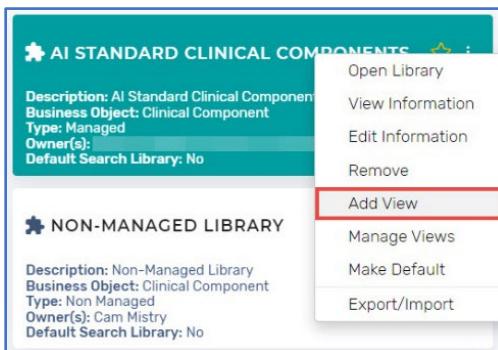
Version: 1.0
Created at: 2021-10-19 4:54 PM by: Cam Mistry
Last modified at: 2021-10-19 4:55 PM by: Cam Mistry
Owner: Cam Mistry

Source Library: **AI Standard Clinical Components**
Business object: Clinical Component
ID: d891e413-d23d-4bc4-b3cd-d30bfffab2fd

Add View

5.5.1 Add New Library View

1. Click on the **vertical ellipsis** : button beside the library name and then click **Add View**.



AI STANDARD CLINICAL COMPONENTS

Description: AI Standard Clinical Components
Business Object: Clinical Component
Type: Managed
Owner(s):
Default Search Library: No

NON-MANAGED LIBRARY

Description: Non-Managed Library
Business Object: Clinical Component
Type: Non Managed
Owner(s): Cam Mistry
Default Search Library: No

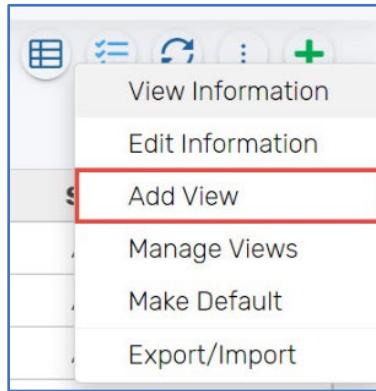
Add View

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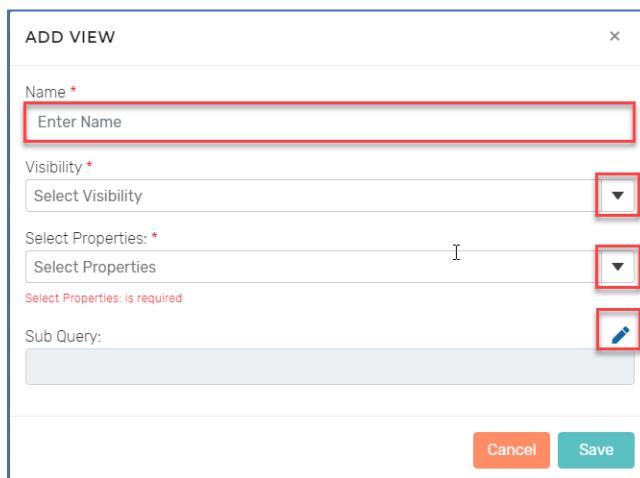
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Note: From within an open library, click on the vertical ellipsis : button at the top-right corner and click **Add View**.



2. Enter a **Name** for the new view and select the **Visibility** for the view (select **Public** if all users should have access to it, and **Private** if only the individual user should have access). Also, select the **Properties** which are to be displayed in the view (eg, the columns to be displayed in the view).

Note: Only users with the appropriate permissions (eg, admins) can create a public view. However, any user can create a private view for any library.



The dialog box contains the following fields:

- Name ***: A text input field with the placeholder "Enter Name".
- Visibility ***: A dropdown menu labeled "Select Visibility".
- Select Properties: ***: A dropdown menu labeled "Select Properties". A note below it says "Select Properties: is required".
- Sub Query:** A text input field with an edit icon.

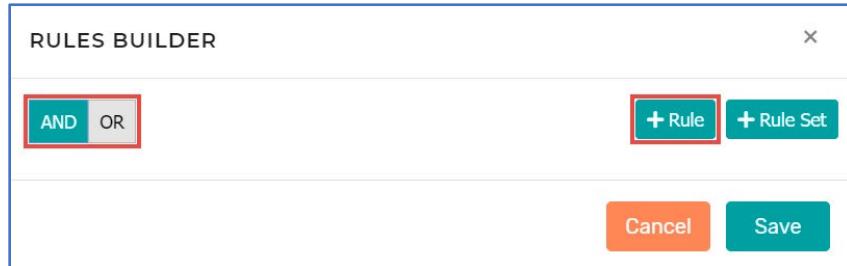
At the bottom are two buttons: "Cancel" and "Save".

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3. Click the **Edit icon** to add a subquery for the view. In the **Rules Builder** form that opens, create an expression for the view, as follows:

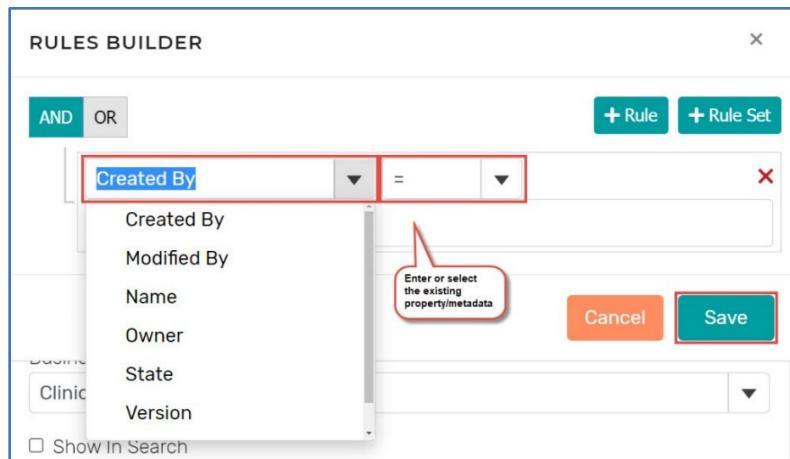
- a. Select **AND** or **OR** for the type of expression and click **+ Rule**.



- b. Select the relevant **Property** from the list.

Note: The listed properties in the **Rules Builder** are managed at the business object level (ie the property must be 'indexable'). If a Property does not appear in the list, contact your admin.

- c. Select operator as **=** (equal to) or **!=** (not equal to).
d. Enter or select an existing value from the dropdown list, based on the selection made in Step 3b.
e. Repeat Steps 3b-3d, as needed, and click **Save**.



The screenshot shows the Rules Builder interface with the following details:
- The title bar says "RULES BUILDER".
- The "AND" button is highlighted with a red border.
- The "Created By" property is selected in the dropdown menu.
- The operator dropdown shows "=".
- A tooltip box with a red border and arrow points to the dropdown menu, containing the text "Enter or select the existing property/metadata".
- The "Save" button is highlighted with a red border.
- Other properties listed in the dropdown include: Modified By, Name, Owner, State, Version, and a checkbox for "Show In Search".

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4. Assign **Column Order** and **Sort Order** for the selected priorities, as appropriate, and click **Save**.

ADD VIEW

Name *	New View
Visibility *	Public
Select Properties: *	5 values selected
Sub Query:	{ "cnd": "and", "rules": [{ "lhs": "CompoundNumber", "op": "=", "type": "Linkset", "displayName": "Compound Number", "rhs": "#10" }] }
Column Order:	Name Modified On Modified By Created By Created On <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> This is the list of properties selected above. Drag and drop to order them as desired. </div>
Sort Order:	Modified On ▲ X Modified By ▲ X <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> Double click on a property listed under column order for it to appear here </div> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> Click on the small direction arrows to sort in ascending or descending order OR Click on the "X" icon to remove property from sort order </div>
Cancel Save	

Notes:

- If a new view was added from within an open library, once the view is saved, the page will refresh immediately and display the components included in the newly added view.
- When a user sorts a library in ascending or descending order, the top of the column will show the sort order.

Select View: New View

Name ▲ X	Modified On ▲ X
Name* ▲	Modified On* ▲
AE Grading Scale	2021-10-19 4:55 PM

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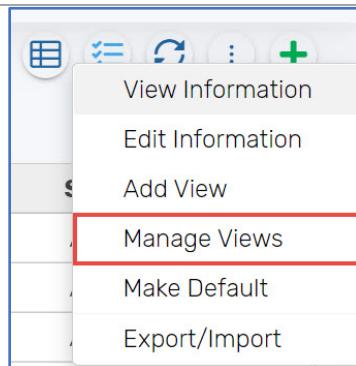
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5.5.1.1 To Update or Delete a Library View

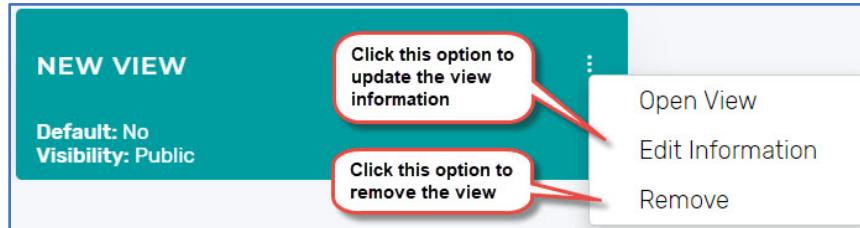
1. Click on the **vertical ellipsis**  button beside the library name and then click **Manage Views**.



Note: From within an open library, click on the **vertical ellipsis**  button at the top-right corner and click **Manage Views**.



2. All views for the library will be displayed. Hover over a view name, click on the **vertical ellipsis**  button beside its name, and select the relevant option shown below, depending on if the view is to be updated/edited or removed.



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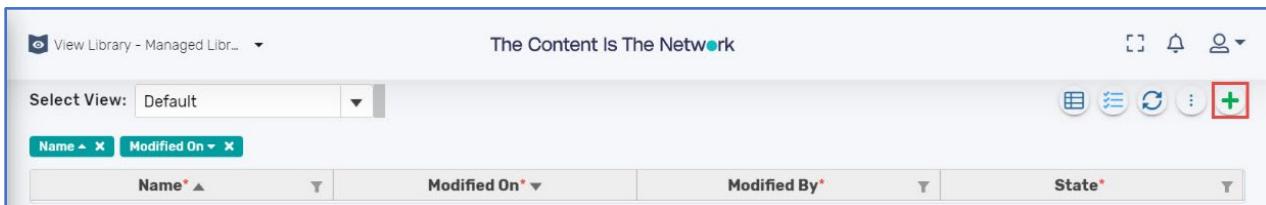
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6. CREATING MANAGED LIBRARY COMPONENTS

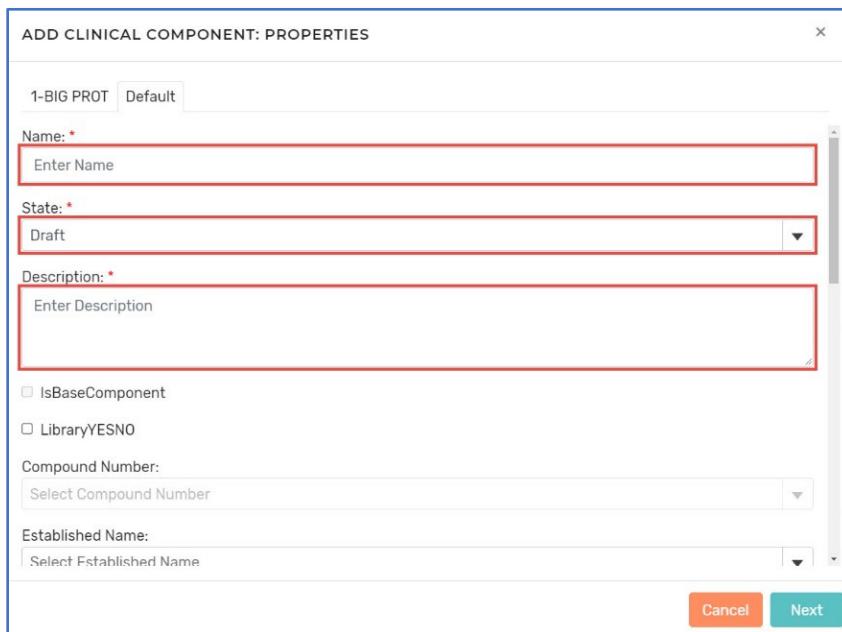
The following functions can be performed by the Library owner and/or an authorized user. Refer to [Section 5.1](#) for details on how to first set up a managed library, so that components may be added to it.

6.1 ADDING A SINGLE COMPONENT TO A LIBRARY

1. From within any view of a managed library **only**, click the **add icon**  at the top-right corner to add a library component.



2. Fill in the **Name** and **Description**, specify lifecycle **State**, select values for relevant properties, and click **Next**. The following special characters are not allowed in the **Name**: ?, <, >, ".

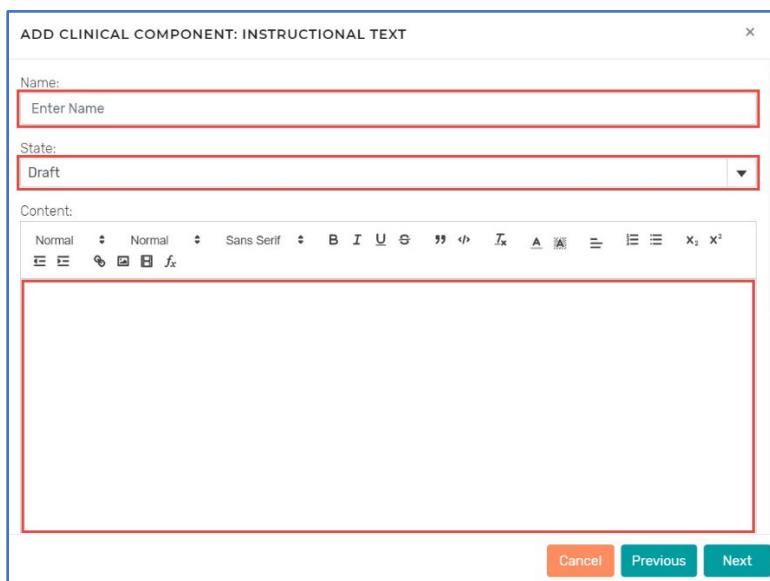
A screenshot of a modal dialog titled 'ADD CLINICAL COMPONENT: PROPERTIES'. It contains fields for 'Name:' (with placeholder 'Enter Name'), 'State:' (set to 'Draft'), and 'Description:' (placeholder 'Enter Description'). There are also checkboxes for 'IsBaseComponent' and 'LibraryYESNO', and dropdowns for 'Compound Number' and 'Established Name'. At the bottom are 'Cancel' and 'Next' buttons.

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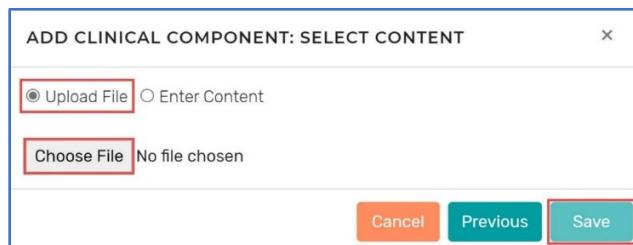
Notes

- The entered **Name** must match the related component/element's name in the document or template **exactly** for the library component to be either auto- and/or user-inserted successfully.
 - The library component must have an appropriate property value assigned, to match against the document's property value, so that it is auto-inserted properly during document generation. The library component may be assigned multiple property values (eg, Phase 1, Phase 1b, Phase 1/2) if it is intended to be used for multiple matches.
3. If needed, add instructional text for the library component by entering a **Name** and selecting a lifecycle **State**. Enter the **Content** for instructional text (may include images, URLs, etc.), and then click **Next**.



The dialog box is titled "ADD CLINICAL COMPONENT: INSTRUCTIONAL TEXT". It contains three main sections: "Name:" with a red border around the input field "Enter Name"; "State:" with a red border around the dropdown menu showing "Draft"; and "Content:" which includes a toolbar with "Normal" and "Sans Serif" buttons, and a rich text editor area with a red border. At the bottom are buttons for "Cancel", "Previous", and "Next".

4. Select content for the library component by either uploading a file (Step 4a) or by entering content (Step 4b).
- Check the **Upload File** button, click **Choose File**, browse to, and select the docx file from the local system that contains the relevant content, click **Open**, and click **Save**.

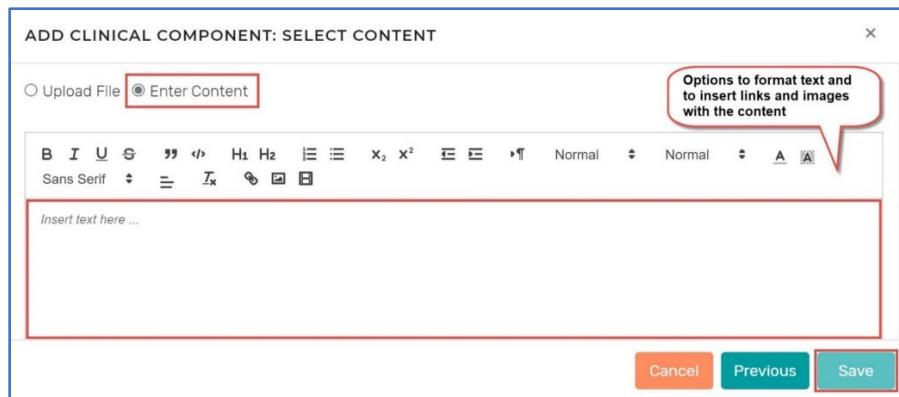


The dialog box is titled "ADD CLINICAL COMPONENT: SELECT CONTENT". It has two radio buttons: "Upload File" (selected) and "Enter Content". Below is a "Choose File" button with the text "No file chosen". At the bottom are buttons for "Cancel", "Previous", and "Save".

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- b. Check the **Enter Content** button, enter content in the text editor box, and click **Save**.



Note: To maintain style consistency when the library component is reused into a document, in some cases, an extra paragraph mark may be needed at the end of the content within the 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 content in the library component.

The newly added component will appear in the library. If the component is not immediately visible, click the **Show all**  display, if needed, to ensure all components regardless of their lifecycle state are displayed. Additionally, a different view (eg, **Default**) may need to be selected, if the component is getting filtered out within the current view.

Note: When a user is editing a managed library component or non-managed library component (via its related **Component Status Report**), the user can see an **Add Content Restriction** action in the *InteliNotion* right-click menu.

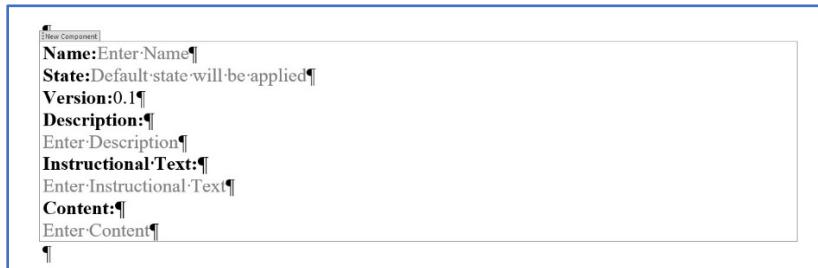
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6.2 ADDING MULTIPLE LIBRARY COMPONENTS AT ONCE USING BULK IMPORT

To add multiple library components at once, a special docx template must be used first to create the library components and then import them into the system. Please request the **Library Bulk Import Template** file from the *InteliNotion* contact, and then follow the steps outlined below.

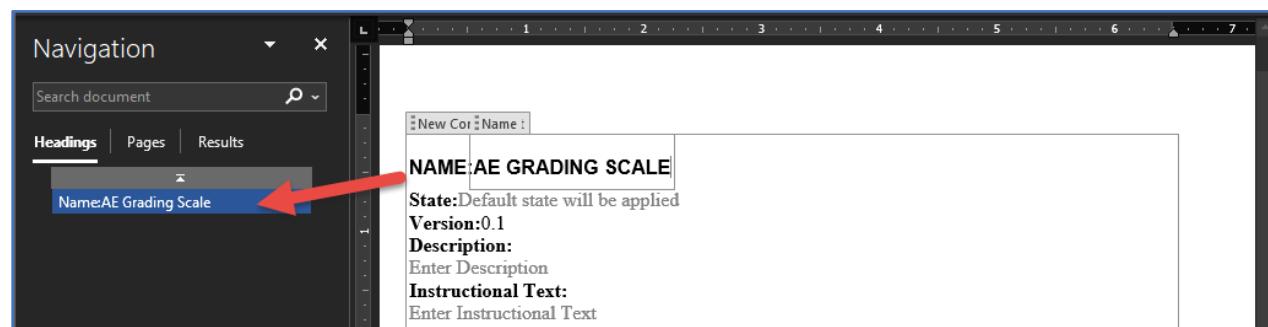
1. Open the **Library Bulk Import Template** file. It will display several content-control boxes within an outer, parent content control box, as shown below.



2. Enter a **Name** for the new component.



For example:



Notes

- The entered **Name** must match the related component/element's name in the document or template exactly for the library component to be either auto- and/or user-inserted successfully.
- That **Name** will be displayed in ALL CAPS within the content control box, but correct capitalization will be displayed in the **Navigation** pane on the left-hand side if turned on.

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3. Omit entering the **State** and **Version**, as they will be automatically created/populated by the system; these sections are locked for editing.

State:Default·state·will·be·applied¶
Version:0.1¶

4. Enter a **Description** for the new component. The **Description** will be displayed to the user when viewing the library component via the *InteliNotion Word App*, so it should be succinct, yet sufficient for easy understanding. This description will assist users in filtering by property when searching for components from managed libraries (see **InteliNotion User Guide, Module 5**).

Description:¶
Enter·Description¶

For example:

Description:¶
CTCAE¶

5. Enter the **Instructional Text** for the new component, if needed. The instructional text will also be displayed when viewing the library component via the *InteliNotion Word App*, to help the user determine if the component is applicable for his/her document and therefore should be used.

Instructional·Text:¶
Enter·Instructional·Text¶

For example:

Instructional·Text:¶
Insert·this·option·for·oncology·studies.¶

6. Add the relevant **Content** for the new component. The content may include formatted text, images, tables, etc.

Content:¶
Enter·Content¶

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For example:

Content:

The investigator will assess the severity for each AE and SAE reported during the study and assign it to 1 of the following CTCAE categories:

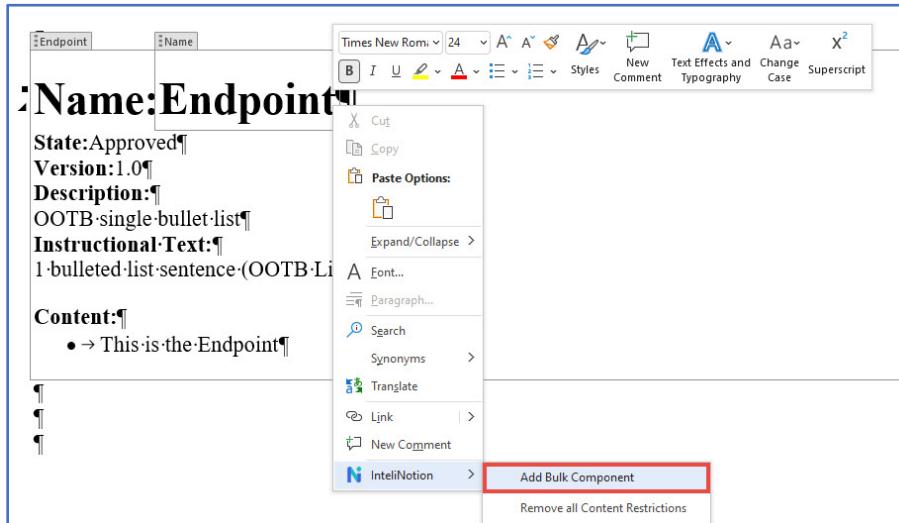
- Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental activities of daily living (ADL)*.
- Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**.
- Grade 4: Life-threatening consequences; urgent intervention indicated.
- Grade 5: Death related to AE.

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

**Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

Note: These properties will be used to filter and sort components when searching at the document level via libraries. The first group displayed will list the indexable optional properties that have been added at the component level. The second group displayed will be the system properties included with all components by default e.g., if the user selects two different libraries and the component classes belonging to these libraries have two common indexable properties between them, then they will only see two properties under the filter section.

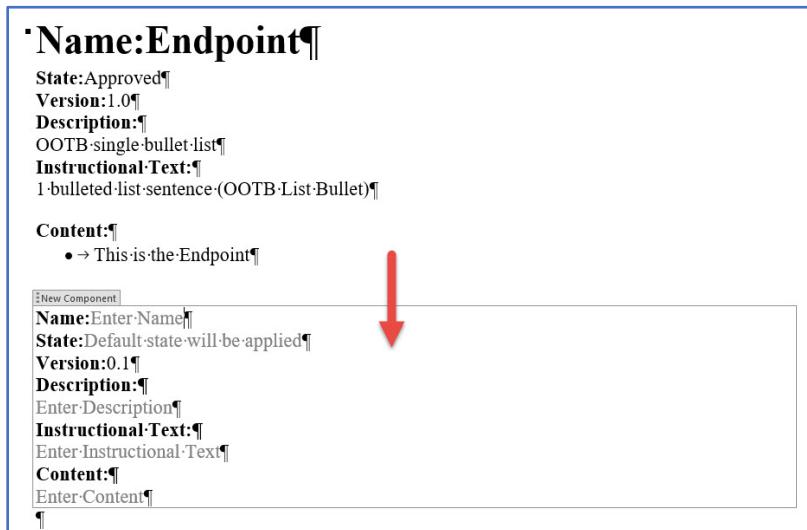
7. To add another component to the file, right-click on the existing outer, parent content control, and under **InteliNotion**, select **Add Bulk Component**.



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8. A new parent content-control box will insert at the bottom. Repeat Steps 2 to 7 above until all components are added to the file, as appropriate.

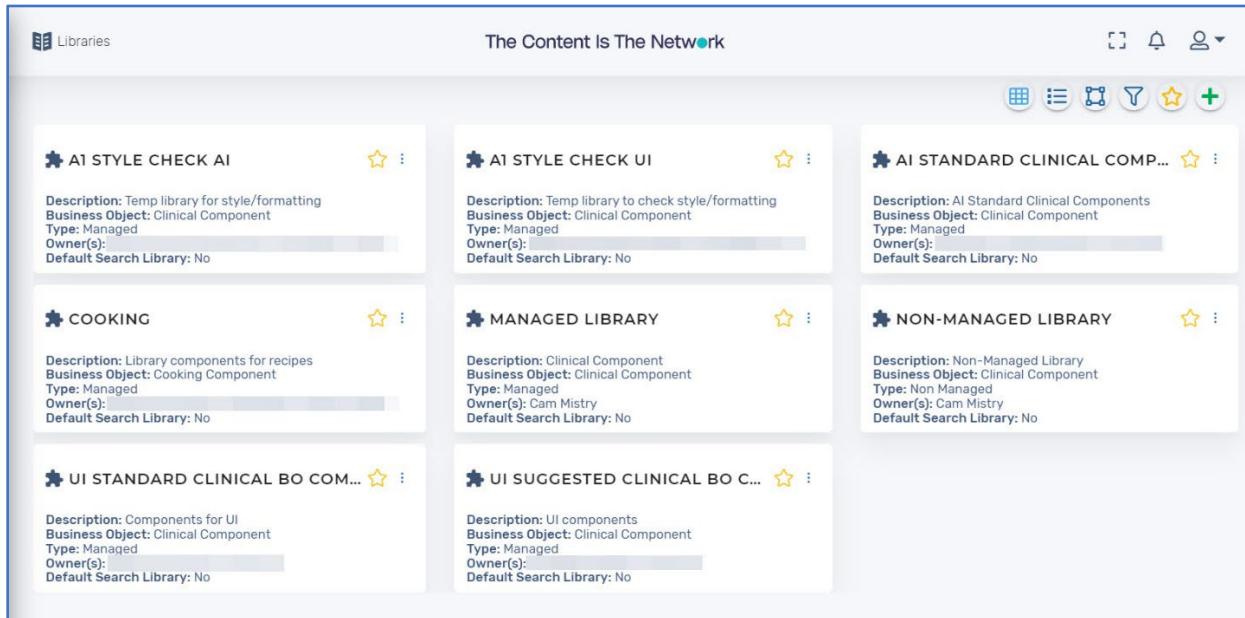


9. When finished **Save** the file locally and close it.



10. Click on the Libraries option in the left-hand navigation pane of the *Web Console*.

11. A grid view of libraries existing in the system (if any) will display.



Library Name	Description	Business Object	Type	Owner(s)	Default Search Library
A1 STYLE CHECK AI	Temp library for style/formatting	Clinical Component	Managed		No
A1 STYLE CHECK UI	Temp library to check style/formatting	Clinical Component	Managed		No
AI STANDARD CLINICAL COMP...	AI Standard Clinical Components	Clinical Component	Managed		No
COOKING	Library components for recipes	Cooking Component	Managed		No
MANAGED LIBRARY	Clinical Component	Clinical Component	Managed	Cam Mistry	No
NON-MANAGED LIBRARY	Non-Managed Library	Clinical Component	Non Managed	Cam Mistry	No
UI STANDARD CLINICAL BO COM...	Components for UI	Clinical Component	Managed		No
UI SUGGESTED CLINICAL BO C...	Ui components	Clinical Component	Managed		No

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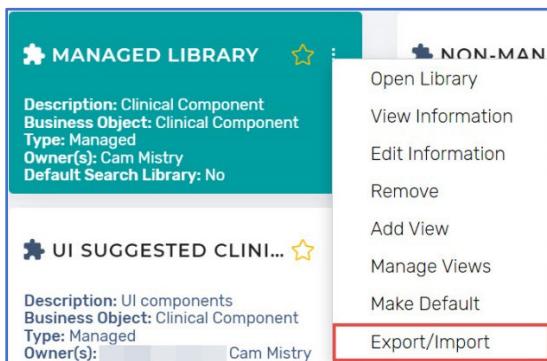
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12. Follow the steps to add a new library, if needed (see [Section 5](#)). Then, to import the bulk library file into it, click on the **vertical ellipsis**  button beside the library name.



Note: **Only** library owners and admin users can add/create components into that library.

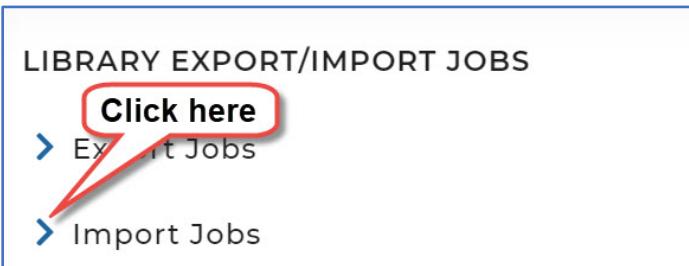
13. A list of options will display. Click on **Export/Import**.



14. The **Export/Import Settings** page will appear on the screen.



15. Expand the **Import Jobs** option.



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16. A tabular list of existing import jobs (if any) will display, along with an option to refresh any open jobs and create a new job.

LIBRARY EXPORT/IMPORT JOBS

> Export Jobs

▼ Import Jobs 

Jobs not available.

17. Click on the **plus sign icon**  to create a new import job.

▼ Import Jobs 

Jobs not available.

18. A **Library Import** form will open.

LIBRARY IMPORT

Name: *

Enter Name

Description:

Enter Description

Import Type: *

CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only
 Batch Word File (formatted content only)

Include Metadata/Property Values Only

File: *

No file chosen

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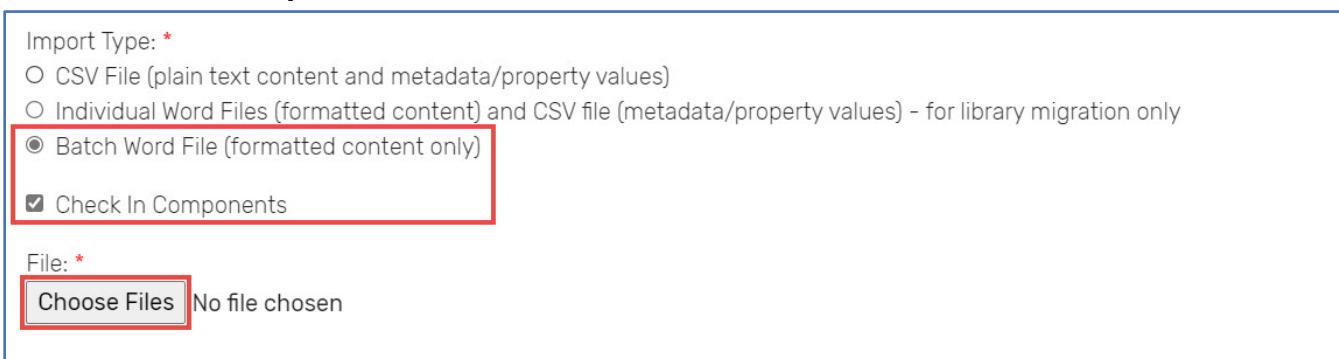
Confidential and proprietary to InteliNotion LLC. This is subject to non-disclosure or confidentiality agreement and must not be shared without prior written consent of InteliNotion LLC.

19. Enter a **Name** and **Description** for the import.



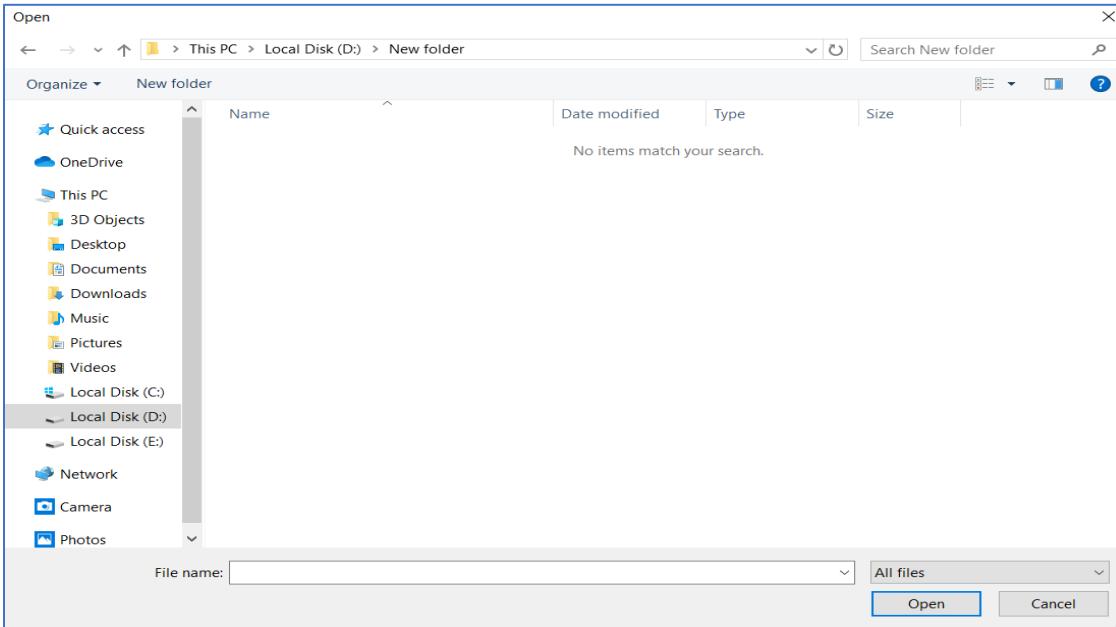
The screenshot shows a 'LIBRARY IMPORT' dialog box. It contains two input fields: 'Name:' with placeholder 'Enter Name' and 'Description:' with placeholder 'Enter Description'. Both fields are highlighted with a red border.

20. Select the Batch Word file (formatted content only) option under **Import Type**, click the **Check In Components** checkbox, and click on **Choose Files**.



The screenshot shows the 'Import Type' section of a configuration screen. It includes three radio button options: 'CSV File (plain text content and metadata/property values)', 'Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only', and 'Batch Word File (formatted content only)', which is selected and highlighted with a red border. Below this is a checked checkbox for 'Check In Components'. Further down is a 'File:' field with a 'Choose Files' button, also highlighted with a red border.

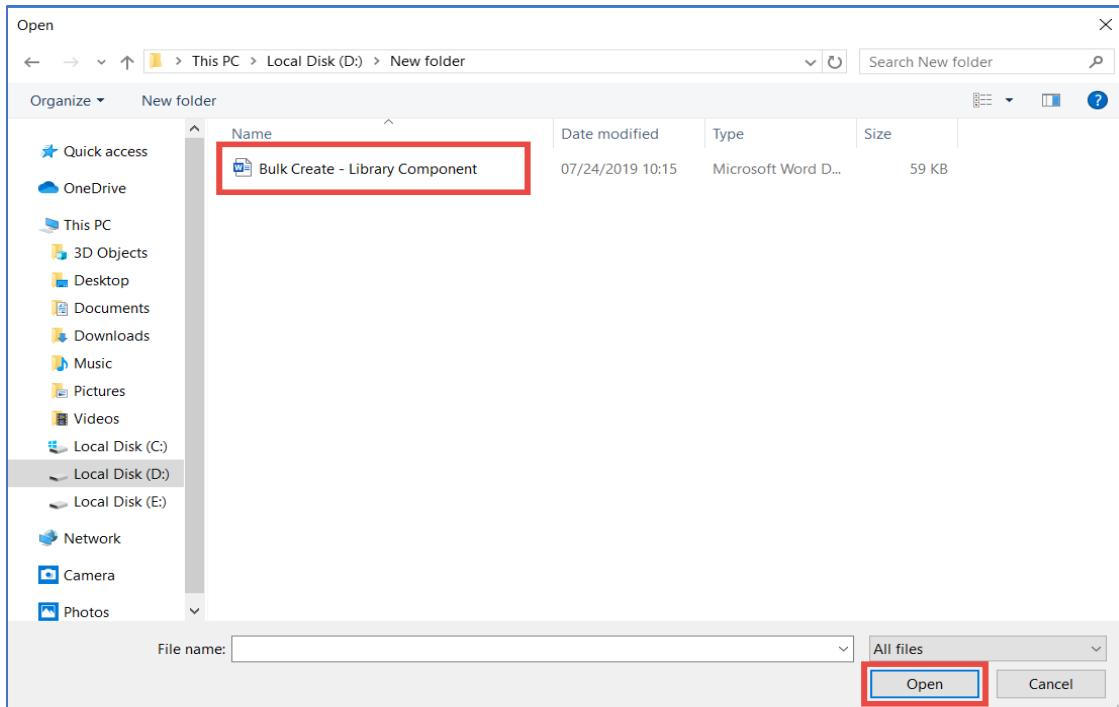
21. An option to browse to and select the file from the local system should appear on the screen.



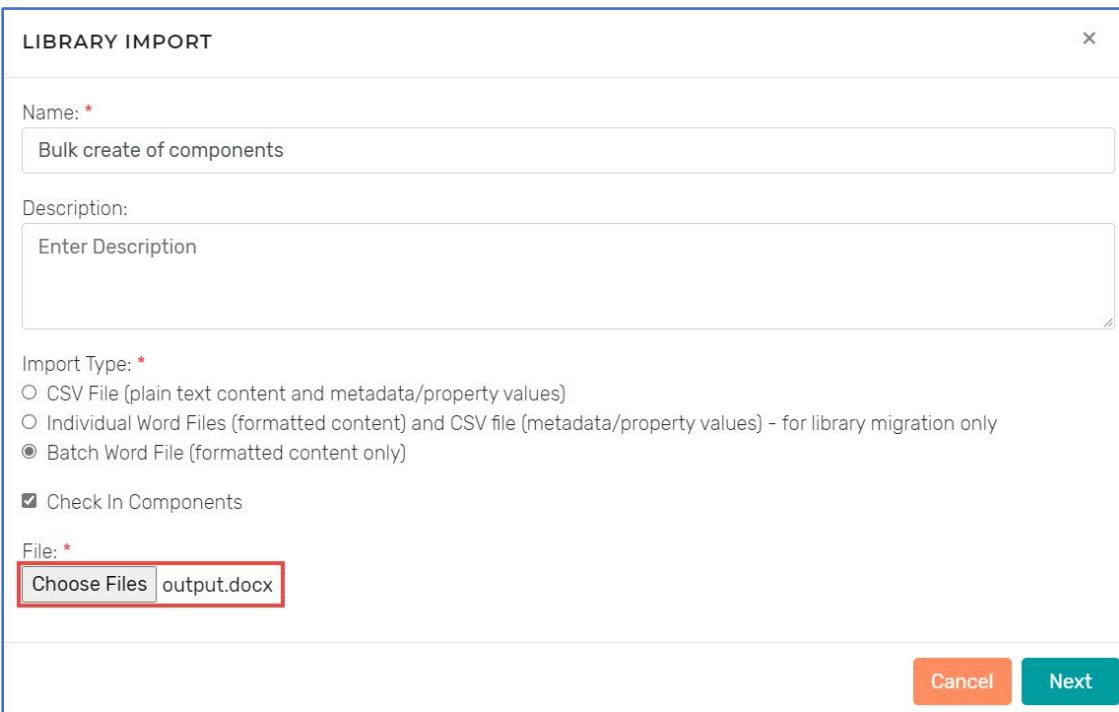
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22. Browse to the location of the previously saved file (Step 9 above), select it, and click **Open**.



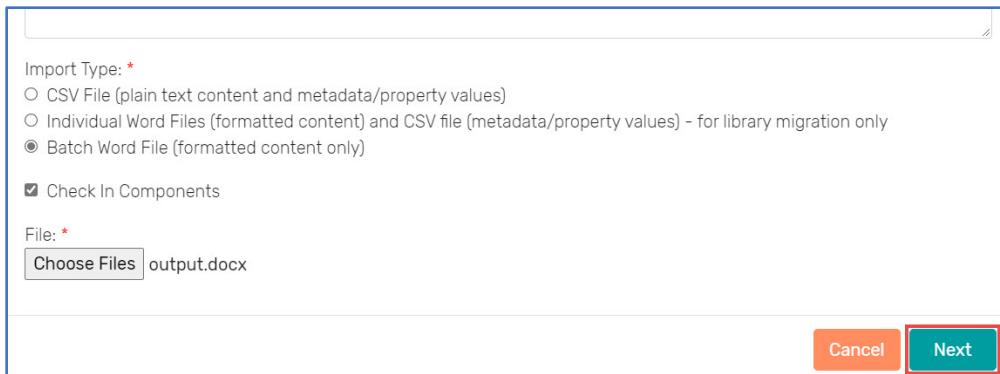
23. The selected file's location will appear in the form.

A screenshot of the 'LIBRARY IMPORT' form. The 'Name:' field contains 'Bulk create of components'. The 'Description:' field has 'Enter Description'. Under 'Import Type:', the 'Batch Word File (formatted content only)' radio button is selected. The 'Check In Components' checkbox is checked. The 'File:' field shows 'output.docx' with a red box around the 'Choose Files' button. At the bottom are 'Cancel' and 'Next' buttons.

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24. Click **Next**.



Import Type: *

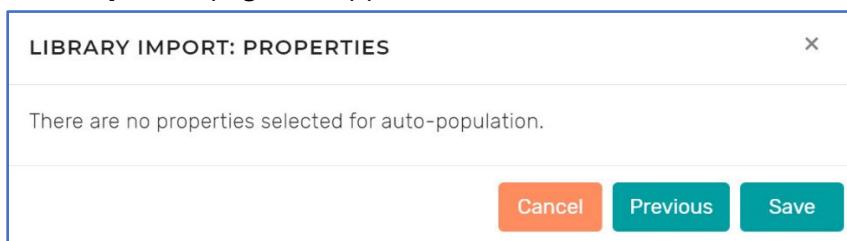
CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) – for library migration only
 Batch Word File (formatted content only)

Check In Components

File: *

output.docx

25. An **Import: Properties** page will appear on the screen.

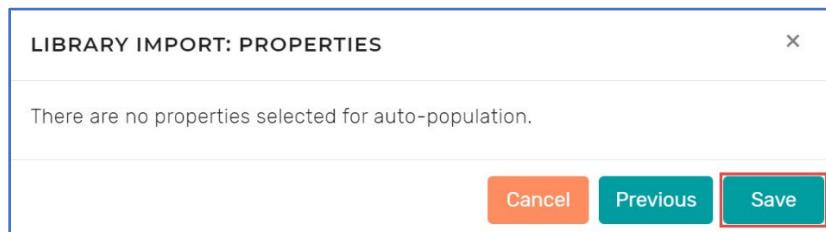


LIBRARY IMPORT: PROPERTIES

There are no properties selected for auto-population.

Note: If any library-level properties are configured to be auto-populated, as per the library's configuration, they will be listed. If none are configured, the following message will be displayed: There are no properties selected for auto-population.

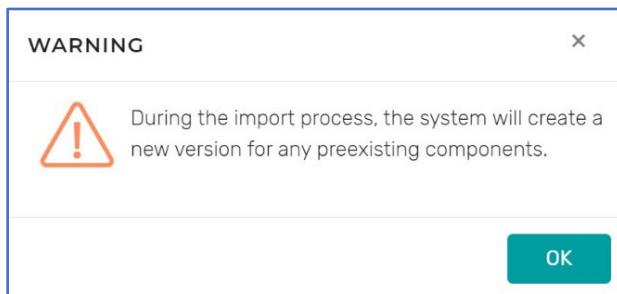
26. Click **Save** to complete the import job.



LIBRARY IMPORT: PROPERTIES

There are no properties selected for auto-population.

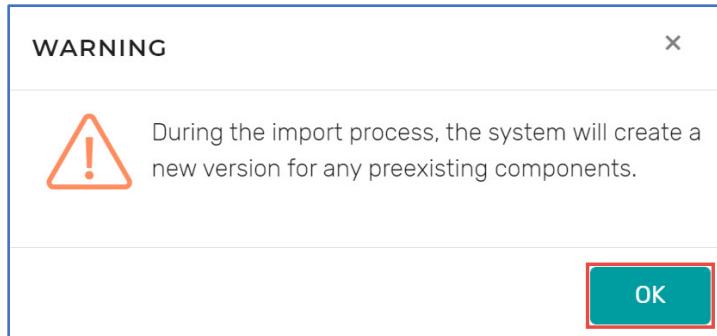
27. A warning message will display on the screen.



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28. Click **OK** to proceed.



29. The new import job will appear in the tabular list with **Status** of **Pending**.

Import Jobs						
Name	Created By	Created On ▾	Description	Status	Reports	Remove
Test	Cam Mistry	2021-11-23 5:03 ...		Pending		

Note: After the import job finishes – its completion time depends on the number of components – the user will receive an email with a subject line that states “Import Library Job Completed,” and an included link to open the list of **Import Jobs**.

30. To update the job’s status, either click the link in the email to open the **Import Jobs** page, or, if the page was left open after saving the job, click the **Refresh icon**, shown below.

Import Jobs						
Name	Created By	Created On ▾	Description	Status	Reports	Remove
Test	Cam Mistry	2021-11-23 5:03 ...		Complete		

31. If the import job was successful, its status will show as **Complete**, where if the import job was not successful, its status will show as **Error**.

Status	Reports	Remove
Complete		

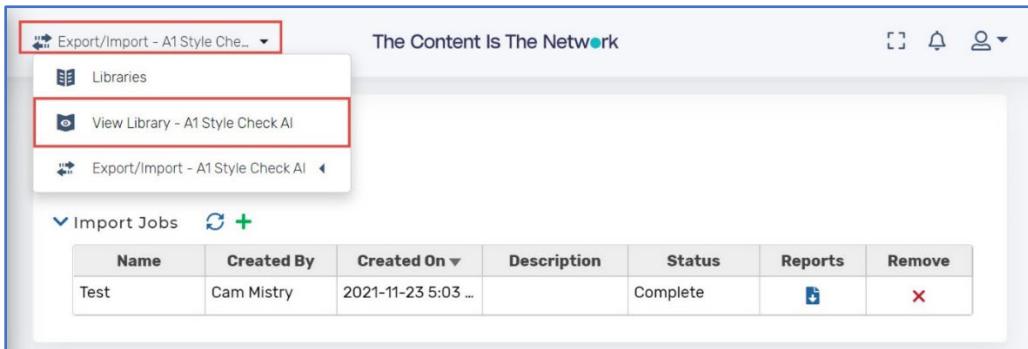
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32. If the job's status is Complete, click the **Download Report icon**  to view/confirm that all components were created as expected.

Note: If the job's status is **Error**, click the **Download Report icon**  to view the errors and make the needed corrections.

33. Switch back to the library view by selecting **View Library** from the dropdown list.



The screenshot shows the InteliNotion interface with a dropdown menu open under 'View Library'. The selected item is 'View Library - A1 Style Check AI', which is highlighted with a red border. Below the dropdown, there is a table titled 'Import Jobs' with one row containing 'Test' as the name, 'Cam Mistry' as the created by, and '2021-11-23 5:03 ...' as the created on date. The status is listed as 'Complete'.

34. Any new or existing library components will be displayed if they are in an approved state.



The screenshot shows the InteliNotion interface with the 'Select View' dropdown set to 'Default'. The 'Approved' button in the toolbar is highlighted with a red border. The toolbar also includes other icons for search, refresh, and add.

Note: The default library setting is **Show approved only**, as indicated by the related button highlighted/activated on the screen.

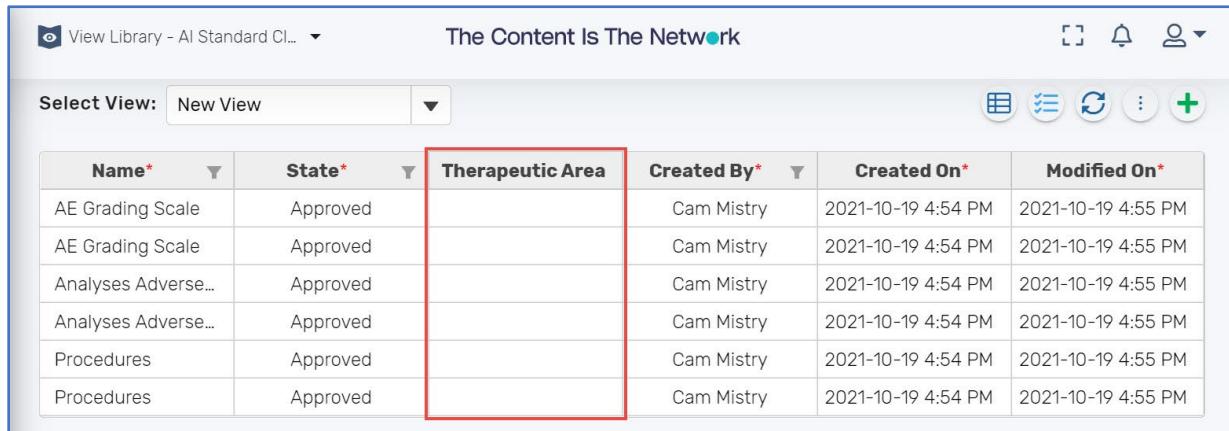
35. Switch the library setting to **Show all** by clicking the related button, to view all the components in their current state. The newly added components will be in a Draft state with version 0.1.



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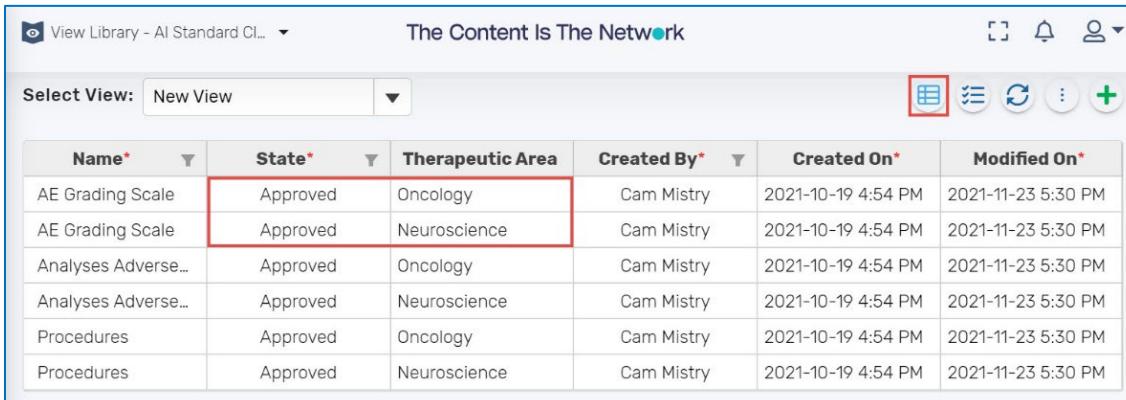
36. Assign properties to the new components, as applicable, and approve the components so they appear in the **Show approved only** for all users to view and access. See [Section 6.3](#) for details on how to update these properties for a single component or multiple components in bulk.



Name*	State*	Therapeutic Area	Created By*	Created On*	Modified On*
AE Grading Scale	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM
AE Grading Scale	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM
Analyses Adverse...	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM
Analyses Adverse...	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM
Procedures	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM
Procedures	Approved		Cam Mistry	2021-10-19 4:54 PM	2021-10-19 4:55 PM

Note: The Default library view can be modified, or a new view created (see [Section 5.5](#)), if needed, to easily view and/or edit the properties of the components in the tabular view.

For example:



Name*	State*	Therapeutic Area	Created By*	Created On*	Modified On*
AE Grading Scale	Approved	Oncology	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM
AE Grading Scale	Approved	Neuroscience	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM
Analyses Adverse...	Approved	Oncology	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM
Analyses Adverse...	Approved	Neuroscience	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM
Procedures	Approved	Oncology	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM
Procedures	Approved	Neuroscience	Cam Mistry	2021-10-19 4:54 PM	2021-11-23 5:30 PM

37. If needed, click on the **Show Approved Only** button shown below to view the most recently approved versions of the components.



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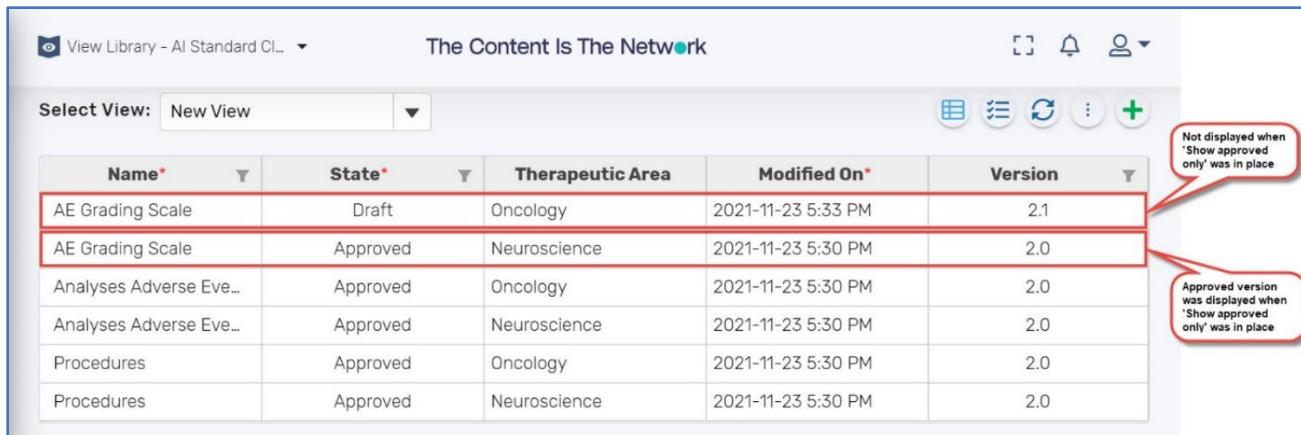
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6.3 ENABLING, UPDATING, AND DELETING LIBRARY COMPONENTS

A managed library component can only be auto- and/or user-inserted into a document if it is in an approved state. Like instructional text, library components may be either manually changed to an approved state or sent through a review and/or approval lifecycle (if configured for the relevant **Component** business object class). If a library component is later updated (eg, changed back to a draft state), the most **recently approved version** of the library component will still be used by the system, either for auto-insertion into the document during its generation or for display in the *InteliNotion Word App* pane for users to view.

If an approved library component that has already been reused into another document is later updated, the user will receive a notification about the modification if/when the document is next opened; subsequently, the user can select any updated version of the library component to use (ie, refresh) into the document. Therefore, it is recommended to always reapprove an updated library component to ensure the newly approved version is available for users to select from and use.

Note: The **Show all**  display must be enabled before a component can be modified or deleted.



The screenshot shows a library component list with columns: Name*, State*, Therapeutic Area, Modified On*, and Version. The rows are as follows:

Name*	State*	Therapeutic Area	Modified On*	Version
AE Grading Scale	Draft	Oncology	2021-11-23 5:33 PM	2.1
AE Grading Scale	Approved	Neuroscience	2021-11-23 5:30 PM	2.0
Analyses Adverse Eve...	Approved	Oncology	2021-11-23 5:30 PM	2.0
Analyses Adverse Eve...	Approved	Neuroscience	2021-11-23 5:30 PM	2.0
Procedures	Approved	Oncology	2021-11-23 5:30 PM	2.0
Procedures	Approved	Neuroscience	2021-11-23 5:30 PM	2.0

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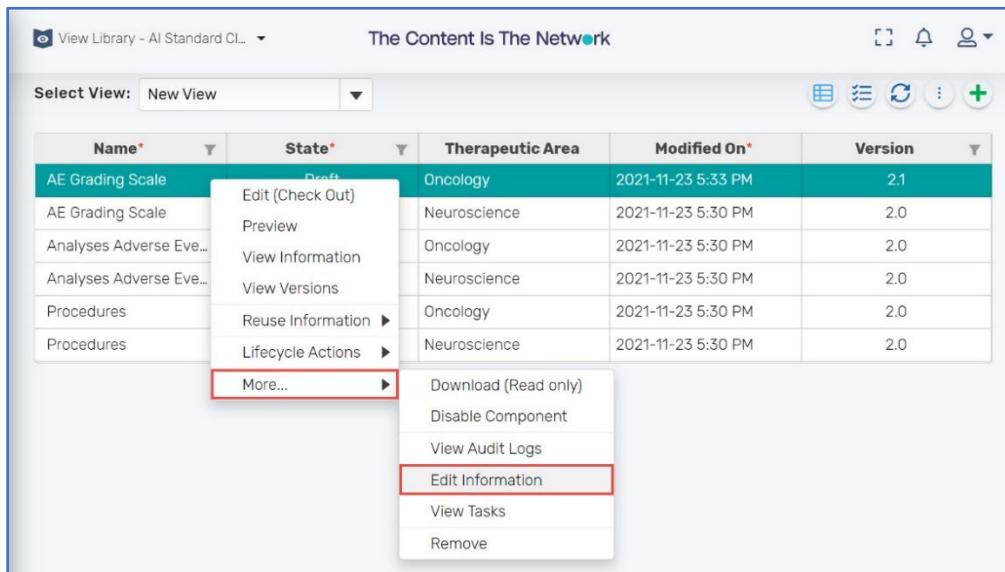
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6.3.1 Library Component's Information (Properties)

To update the information properties of a library component, follow the steps listed in the sections below, as applicable.

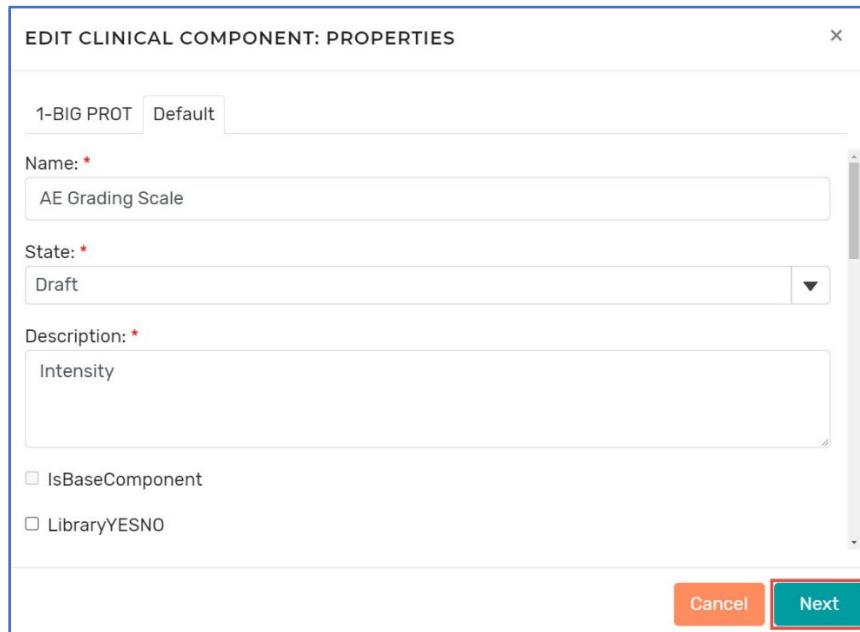
6.3.1.1 Single Component Option 1

- Right-click on a component (in a row) and under **More**, click **Edit Information**.



Name*	State*	Therapeutic Area	Modified On*	Version
AE Grading Scale	Draft	Oncology	2021-11-23 5:33 PM	2.1
AE Grading Scale	Preview	Neuroscience	2021-11-23 5:30 PM	2.0
Analyses Adverse Eve...	View Information	Oncology	2021-11-23 5:30 PM	2.0
Analyses Adverse Eve...	View Versions	Neuroscience	2021-11-23 5:30 PM	2.0
Procedures	Reuse Information ▶	Oncology	2021-11-23 5:30 PM	2.0
Procedures	Lifecycle Actions ▶	Neuroscience	2021-11-23 5:30 PM	2.0

- Make the necessary edits to the component's properties and click **Next**. If necessary, update the instructional text for the component on the next page, and click **Update**.



EDIT CLINICAL COMPONENT: PROPERTIES

1-BIG PROT Default

Name: * AE Grading Scale

State: * Draft

Description: * Intensity

IsBaseComponent

LibraryYESNO

Cancel Next

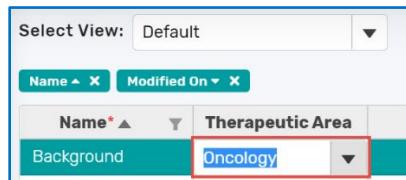
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6.3.1.2 Single Component Option 2

Single-click in a cell to activate it, and then update the value, as applicable.



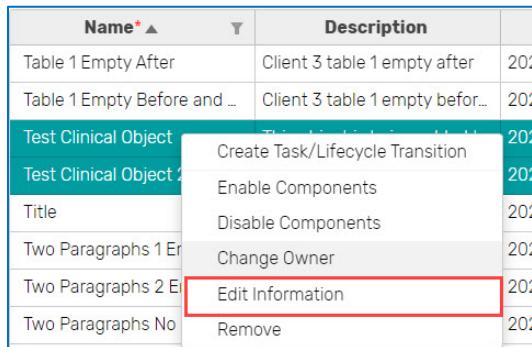
Note: This option can **only** be performed on user-dependent properties displayed in the view.

6.3.1.3 Multiple Components

Select multiple components (rows) by using either **Ctrl + click** or **Shift + click** on the keyboard and follow one of the following sets of steps, as applicable.

Note: To bulk update components, all components must be checked in.

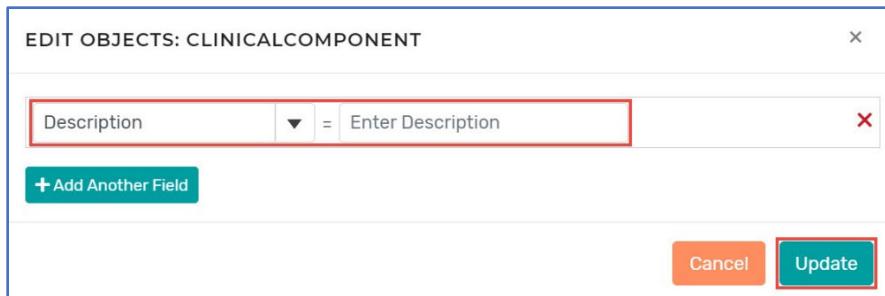
1. Right-click in the highlighted area and click **Edit Information**.



Name*	Description	
Table 1 Empty After	Client 3 table 1 empty after	202
Table 1 Empty Before and ...	Client 3 table 1 empty befor...	202
Test Clinical Object	This is a test clinical object	202
Test Clinical Object 2		202
Title		202
Two Paragraphs 1 Entit...		202
Two Paragraphs 2 Entit...		202
Two Paragraphs No		202

Note: To bulk update components, all components must be checked in.

2. Use the dropdown list to select a property to update for the selected components, enter or select the appropriate value, and then click **Update**. If multiple properties need to be updated, click the **+ Add Another Field** button and make the required selections before clicking **Update**.



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Note: A user can select multiple managed library components and then initiate a lifecycle action task against them as per their related business object's lifecycle.

OR

1. Choose multiple components within the managed library. Right-click on the items and choose **Create Task**.

Name*▲	Description	
Table 1 Empty After	Client 3 table 1 empty after	202
Table 1 Empty Before and ...	Client 3 table 1 empty befor...	202
Test Clinical Object	Create Task/Lifecycle Transition	202
Test Clinical Object 2		202
Title		202
Two Paragraphs 1 Er		202
Two Paragraphs 2 E		202
Two Paragraphs No		202
		202

- If the components are not in the same state, the user will get an error message
 - If the components are in the same state, the user will be able to create the task
2. When the assigned user(s) complete the task, the library component's lifecycle will transition accordingly.

OR

1. Choose multiple components and select **Change Owner**.

Name*▲	Description	
Table 1 Empty After	Client 3 table 1 empty after	202
Table 1 Empty Before and ...	Client 3 table 1 empty befor...	202
Test Clinical Object	Create Task/Lifecycle Transition	202
Test Clinical Object 2		202
Title		202
Two Paragraphs 1 Er		202
Two Paragraphs 2 E		202
Two Paragraphs No		202
		202

2. Enter the name of the new owner in the **User** field.

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3. If an email notification should be sent, check the **Send Notification Checkbox**.
4. Enter a subject and message in the respective fields and click **Send**.

CHANGE OWNER

User: *

Send Notification

Subject: *

Message: *

Cancel **Save**

5. A pop-up informing the user that the owner was updated successfully for the applicable objects will display.

✓ Owner for 2 object(s) updated successfully.

Note: If an object owner cannot be changed, a table listing the object and the reason for failure will display:

FAILED TO UPDATE OWNER OF OBJECT(S)

Object Name	Owner	Reason
Test Clinical Object 2	Cam Mistry	User is already owner of object.
Test Clinical Object	Cam Mistry	User is already owner of object.

Close

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6.3.2 Updating a Library Component's Content

To update the content of a library component, follow the steps listed in the sections below, as applicable.

Notes:

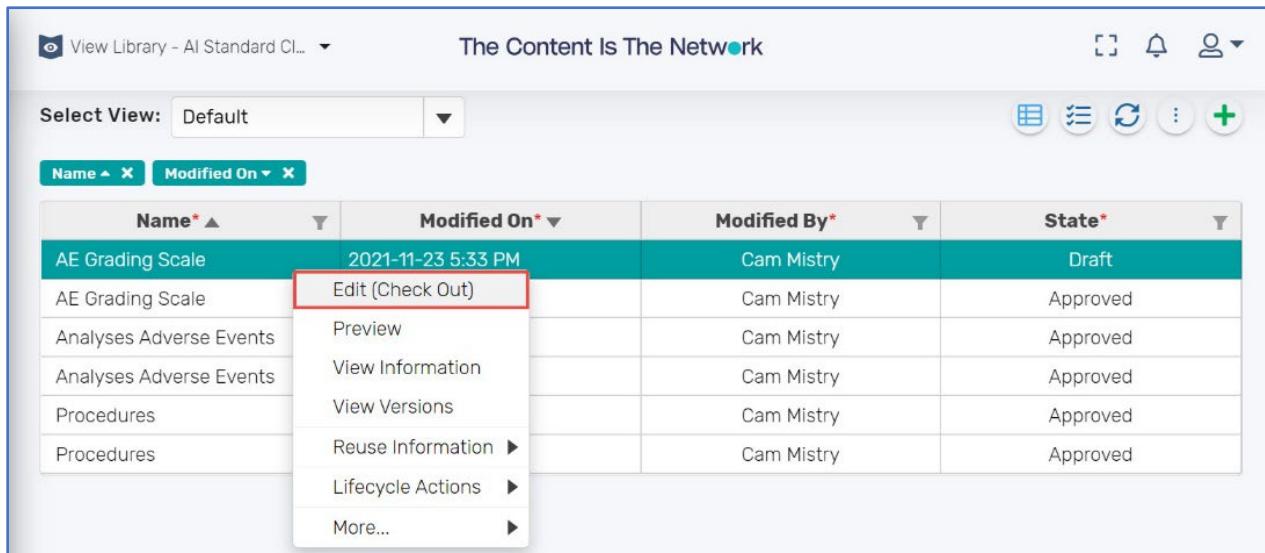
- If Track Changes are left on in a component, the updates version cannot be accepted/refreshed by the user in the document via the Component Status Report.
- A user will be able to view/accept and refresh any newer version of a library component than the one originally reused in the document as long as it is in an "approved" state and is enabled.

6.3.2.1 Single Component

1. Ensure that the **Show all** library setting is enabled.



2. Right-click on a component (in a row) and click **Edit (Check Out)**.



The screenshot shows a library interface with a table of components. The first component, 'AE Grading Scale', has a context menu open over its 'Modified On' field. The menu items are: Edit (Check Out) (highlighted with a red box), Preview, View Information, View Versions, Reuse Information, Lifecycle Actions, and More... The table columns are: Name*, Modified On*, Modified By*, and State*. The data in the table is as follows:

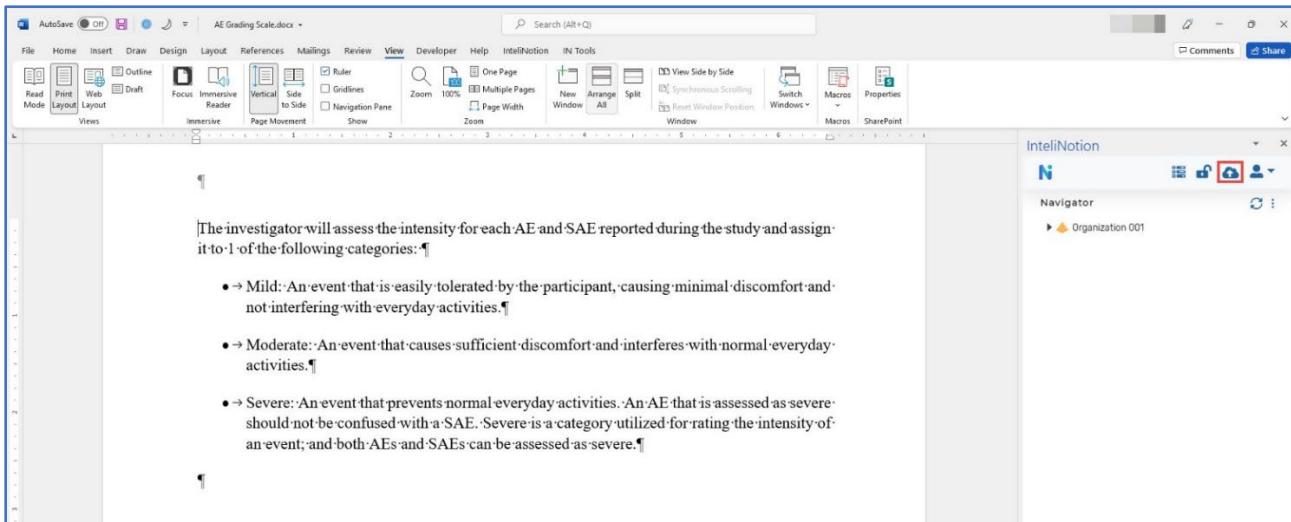
Name*	Modified On*	Modified By*	State*
AE Grading Scale	2021-11-23 5:33 PM	Cam Mistry	Draft
AE Grading Scale		Cam Mistry	Approved
Analyses Adverse Events		Cam Mistry	Approved
Analyses Adverse Events		Cam Mistry	Approved
Procedures		Cam Mistry	Approved
Procedures		Cam Mistry	Approved

Note: Components in a non-managed library should not be edited this way.

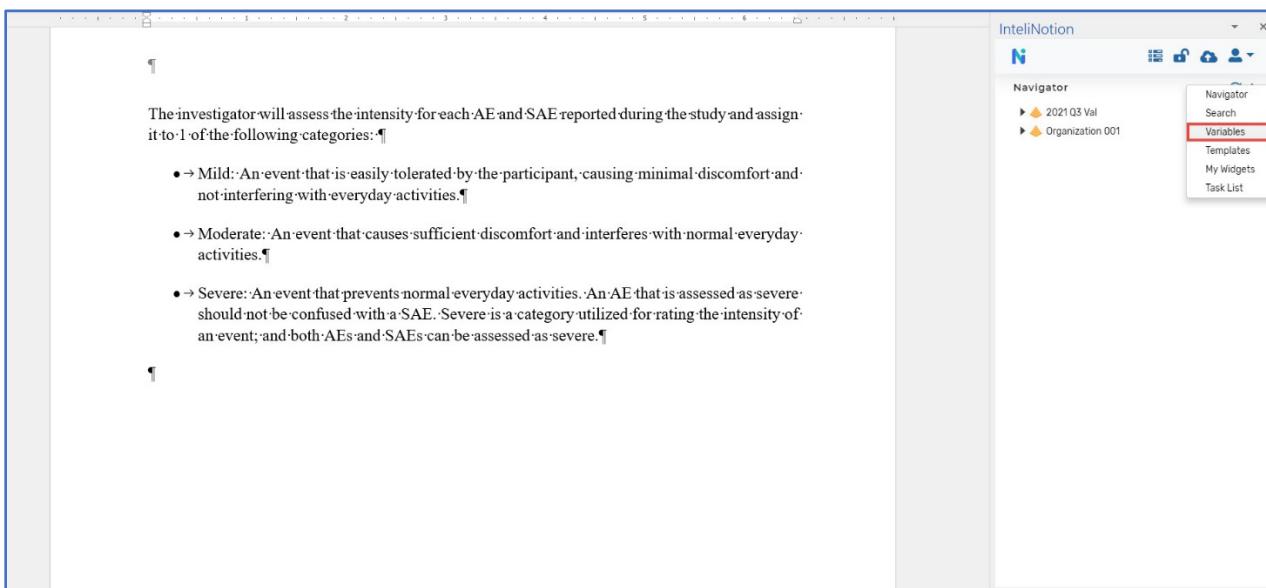
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3. The component will open in *MS Word* and the *InteliNotion Word App* will automatically open. Make necessary edits to the component.



4. If necessary, insert a variable into a library component's content by clicking the **vertical ellipsis**  button menu in the *InteliNotion Word App* and then selecting **Variables**. Select the relevant **Business Object** with a property value to be used for the variable's content and click the arrow next to the property name to insert it into the component (it will insert at the cursor location).

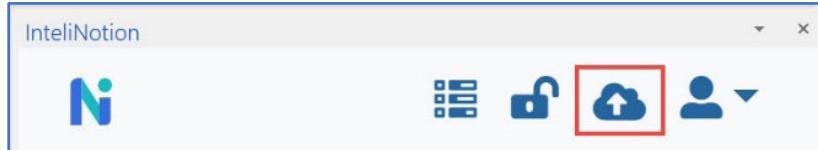


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Note: When editing an individual library component, the user can delete either a single instance or all instances of the selected variable.

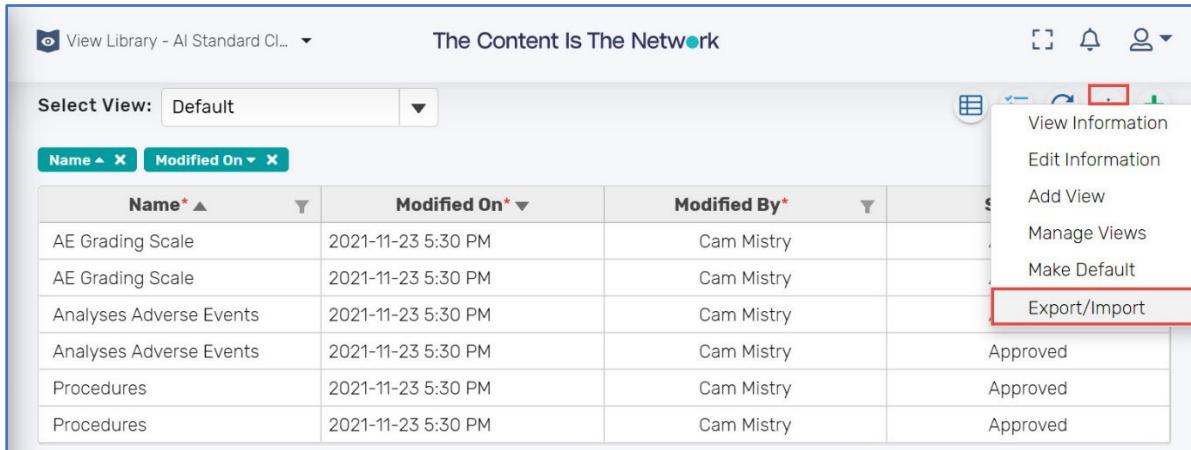
5. Save and check in the component using the icon shown below.



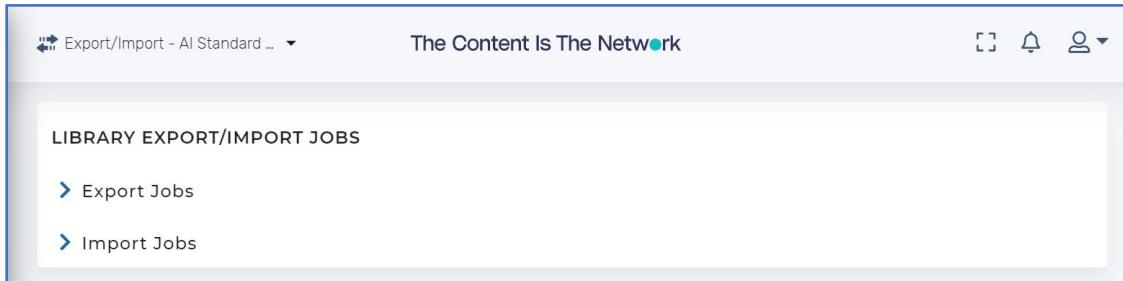
6.4 EXPORT MULTIPLE LIBRARY COMPONENTS IN BULK

To bulk export multiple library components, follow the steps listed below.

1. Click the vertical ellipsis : button at the top-right corner and then select **Export/Import**.

A screenshot of the InteliNotion software interface showing a list of library components. On the right side, a context menu is open over one of the rows. The menu options are: View Information, Edit Information, Add View, Manage Views, Make Default, and Export/Import. The 'Export/Import' option is highlighted with a red box.

2. The **Export/Import Settings** page will appear on the screen.

A screenshot of the 'LIBRARY EXPORT/IMPORT JOBS' page. It shows two main sections: 'Export Jobs' and 'Import Jobs'. Both sections have a small arrow icon followed by the text 'Export Jobs' and 'Import Jobs' respectively.

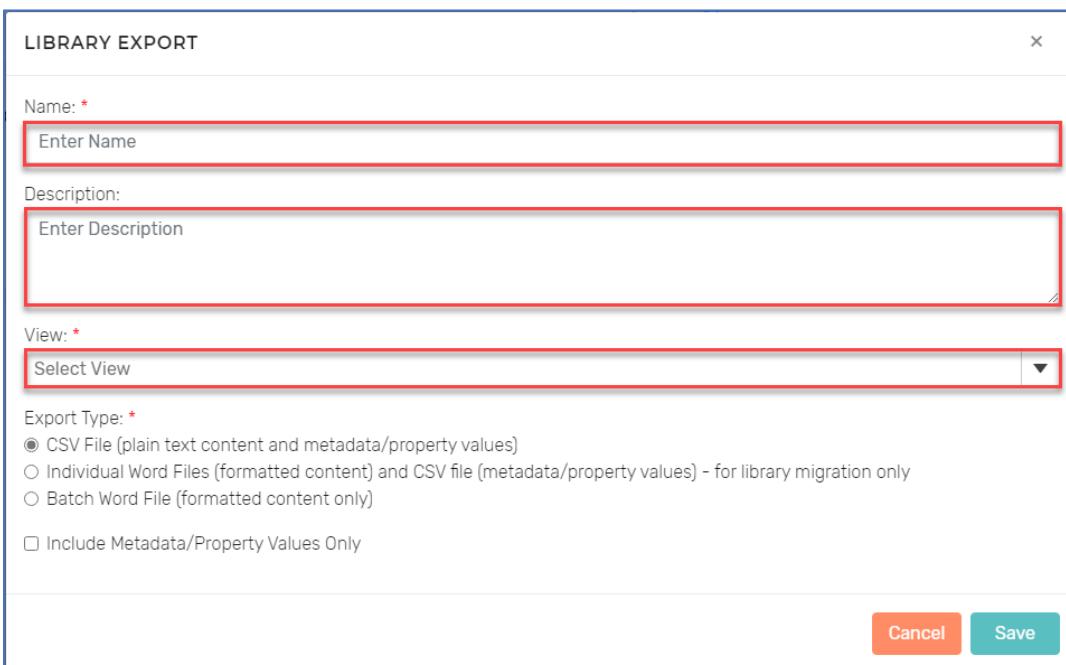
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3. Expand the **Export Jobs** section and click on the **plus sign icon**  to create a new export job.



4. Fill in the required form details such as the **Name** for the export job, a **Description**, and select the **View** to specify which components will be exported.



The screenshot shows the 'LIBRARY EXPORT' dialog box. It contains fields for 'Name' (with placeholder 'Enter Name'), 'Description' (with placeholder 'Enter Description'), and 'View' (with placeholder 'Select View'). Below these are options for 'Export Type': 'CSV File (plain text content and metadata/property values)' (radio button selected), 'Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only' (radio button), 'Batch Word File (formatted content only)' (radio button), and a checkbox for 'Include Metadata/Property Values Only'. At the bottom right are 'Cancel' and 'Save' buttons.

Note: When selecting a view, note that only the properties contained in that view will be included in the exported csv file, when applicable.

5. Select the **Export Type** as appropriate:

- **CSV File** – select this option to export the components' plain text content and/or metadata in a CSV file. This option is best suited for updating the library components' properties **only**. To do this, check the **Metadata/Property Values Only** checkbox.
- **Individual Word Files** – select this option to migrate the library components from 1 site to another. This option should not be used for bulk editing the content of selected library components.

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- **Batch Word File** – select this option to export the components' formatted content in a single docx file. This is the best option for updating the content of existing library components and/or adding new components. It is recommended to click the **Check Out Components** checkbox to ensure other users do not unintentionally edit the components while the user is updating them in the bulk file.

Export Type: *

CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only
 Batch Word File (formatted content only)

Check Out Components

6. Click **Save**.
7. Once the export job has been initiated, it will appear in the **Export Jobs** list with a **Pending** status.

LIBRARY EXPORT/IMPORT JOBS

▼ Export Jobs  

Name	Created By	Created On ▾	Description	Status	Download	Remove
CSV Export	Cam Mistry	2021-11-23 6:48 ...		Pending		

➤ Import Jobs

8. Once the export job completes successfully, its status will change to **Complete**, and in the Download column a **Download file** option will be available.

LIBRARY EXPORT/IMPORT JOBS

▼ Export Jobs  

Name	Created By	Created On ▾	Description	Status	Download	Remove
CSV Export	Cam Mistry	2021-11-23 6:48 ...		Complete		

➤ Import Jobs

Note: If the export job completes with an error, its status will change to **Error**; hover over the **icon** shown below to view the error and take corrective action.

Status		Download
Error		

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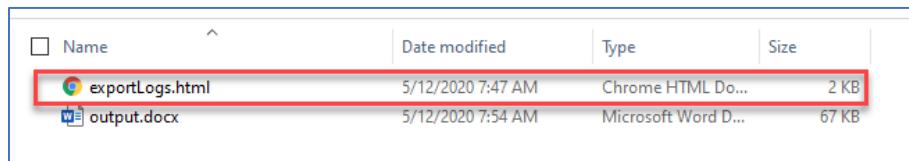
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9. Click **Download file** to download the file locally and open it.

10. The **CSV File** export will download a single .csv file that looks like the example below.

A	B	C	D	E	F	
1	ID	Name	ModifiedC	ModifiedB	State	Content
2	4ac8d98b-	AE Grading Scale	2021-11-2	Cam Mistr	Approved	The investigator will assess
3	d891e413-	AE Grading Scale	2021-11-2	Cam Mistr	Draft	The investigator will assess
4	08f3c567-	Procedures	2021-11-2	Cam Mistr	Approved	For annual visits
5	610fb019-	Procedures	2021-11-2	Cam Mistr	Approved	For annual visits
6	85391631	Analyses Adverse Events	2021-11-2	Cam Mistr	Approved	The verbatim terms entered
7	90712142	Analyses Adverse Events	2021-11-2	Cam Mistr	Approved	The verbatim terms entered

11. The **Batch Word File** export will download a zip file that contains an HTML report of the exported items in HTML format and a docx file with the library components.



12. When the HTML report is opened in a browser, it will display information about the **ID**, **Name**, and **Class** of each exported component, along with the **Status** (of the export action) with the **Reason** for failure (if any).

Exporting component with instructional text using batch word file option

Number of components exported successfully: 8

Number of components failed to export: 0

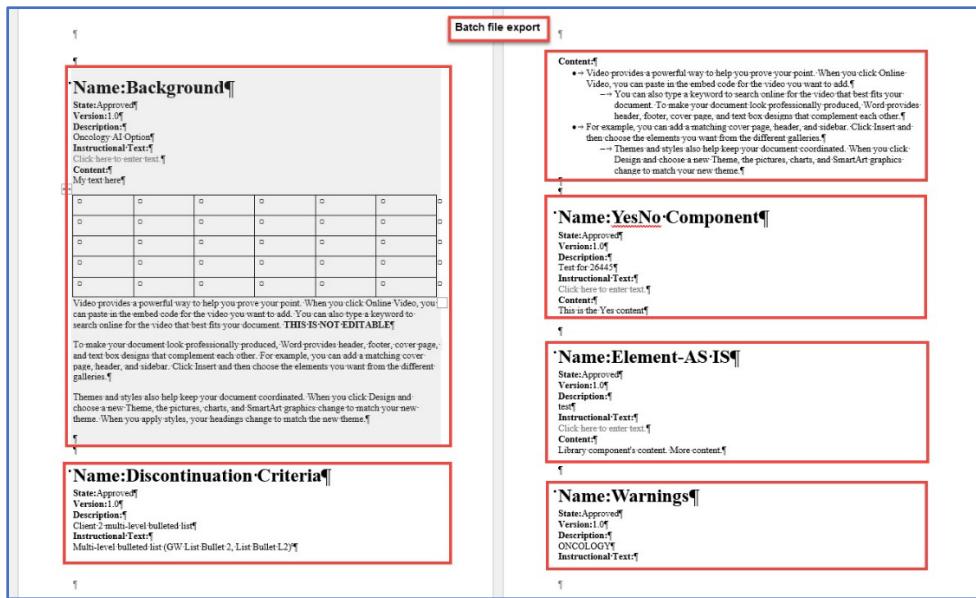
ID	Name	Class	Status	Reason
d4949509-bcb3-4840-a552-b6b1ba4e905b	Procedures	LibraryComponent	Exported Successfully	
c6fedb62-72fc-41b0-8089-f8fd34a4fb15	Analyses Adverse Events	LibraryComponent	Exported Successfully	
cfae8344-c1fc-479c-836e-54d42d13e27a	Procedures	LibraryComponent	Exported Successfully	
1299ea53-2158-4124-a293-83a869ef00d1	Analyses Adverse Events	LibraryComponent	Exported Successfully	
e24f0f5a-afa1-43eb-b5e6-d4c3115c5628	Procedures	LibraryComponent	Exported Successfully	
d1e560fd-4b51-4e54-b4fe-aa2b1983ac86	AE Grading Scale	LibraryComponent	Exported Successfully	
04dd83f7-8fa6-45b9-b998-1457b74e68df	Test Component 2	LibraryComponent	Exported Successfully	
0e11d1a5-bdae-4095-a101-256a741bd329	AE Grading Scale	LibraryComponent	Exported Successfully	

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13. When the docx file is opened, all the components will be listed as shown below.



The screenshot shows a Microsoft Word document with five library components listed:

- Name:Background**: State:Approved, Version:1.0, Description:Oncology All Oncos, Instructional Text:Click here to enter text, Content:My text here! This component contains a 6x6 grid of placeholder text boxes.
- Name:YesNo Component**: State:Approved, Version:1.0, Description:Test for 26445, Instructional Text:Click here to enter text, Content:This is the Yes content!
- Name:Element-AS-IS**: State:Approved, Version:1.0, Description:test, Instructional Text:Click here to enter text, Content:Library component's content. More content!
- Name:Discontinuation-Criteria**: State:Approved, Version:1.0, Description:Closest 2 multi-level bulleted lists!, Instructional Text:Multi-level bulleted list (GW List Bullet 2, List Bullet L2)!, Content:This component contains two nested bulleted lists.
- Name:Warnings**: State:Approved, Version:1.0, Description:ONCOLOGY, Instructional Text:, Content:ONCOLOGY

14. Incorporate any edits to a library component's **Name**, **Description**, **Instructional Text**, and/or **Content**, and then **Save** the updated file locally.

Notes:

- When editing library components in a Batch Word File, there is no guard to prevent the copy/paste of content that is still within an outer content control. Therefore, users must be careful to not inadvertently paste content that is still within a content control; if this happens, the import of the updated file will fail.
- At this stage, it is possible to place content restrictions in the library components that will be preserved during the import process. See the **InteliNotion User Guide Module 5** for details.

15. Return to the Export/Import Settings section in Step 2 above. Expand the **Import Jobs** section and then click the **add icon**  to add a new import job using the updated file saved locally.



LIBRARY EXPORT/IMPORT JOBS

①  Export Jobs ②  

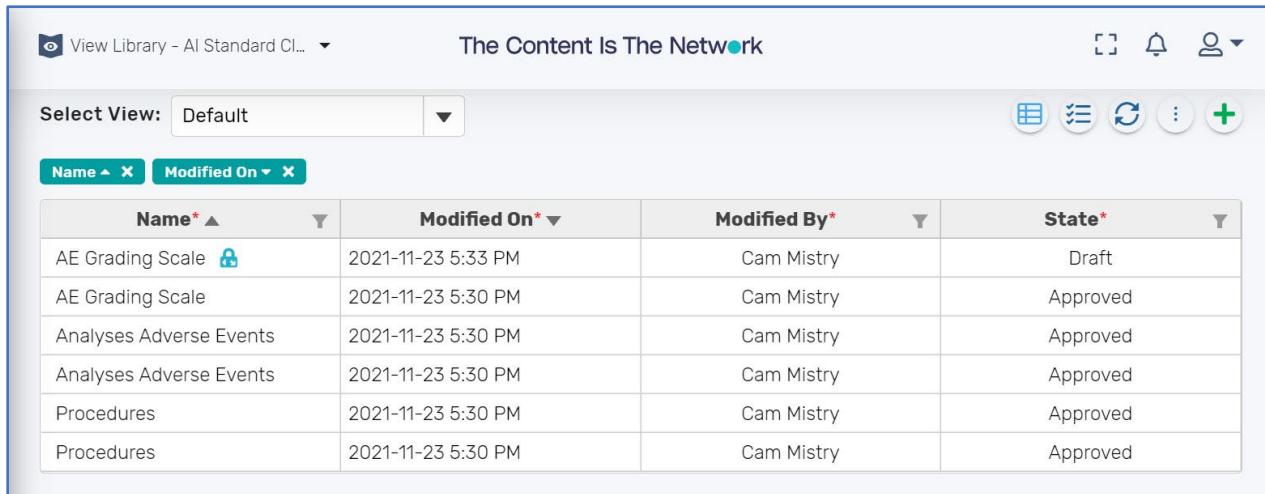
Jobs not available.

> Import Jobs

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16. After the **Import Job** completes, navigate to the library view to see the up-versioned components.



Name*	Modified On*	Modified By*	State*
AE Grading Scale 	2021-11-23 5:33 PM	Cam Mistry	Draft
AE Grading Scale	2021-11-23 5:30 PM	Cam Mistry	Approved
Analyses Adverse Events	2021-11-23 5:30 PM	Cam Mistry	Approved
Analyses Adverse Events	2021-11-23 5:30 PM	Cam Mistry	Approved
Procedures	2021-11-23 5:30 PM	Cam Mistry	Approved
Procedures	2021-11-23 5:30 PM	Cam Mistry	Approved

Notes:

- All components included in the import file will be up-versioned, even if the component was not edited in the local file.
- After a library component is deleted, but left in the Recycle Bin, if it is included in the imported bulk library file, it will be auto-restored and up-versioned after the import completes.
- Unless the default **State** has been set to an approved state in the library's auto-populated properties, all up-versioned components will be in a draft state, and therefore need to be re-approved before they are available for use.

6.4.1 Exporting Multiple Libraries in Bulk

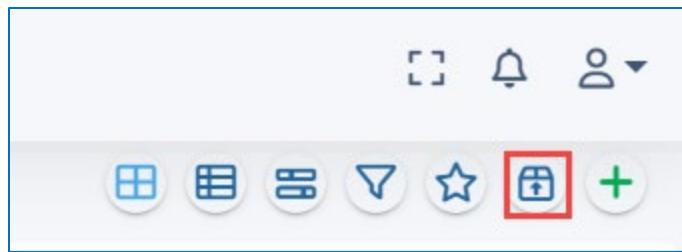
A full control administrator or an authorized user with **Manage Libraries** functional permissions with at least RU permission for relevant component Business Object class(es) can bulk export components in batch word files from multiple managed libraries in which they are configured as owner in single operation. Follow the steps listed below to batch export multiple libraries to a *Word* file.

1. Navigate to the Libraries page and click the **Batch export into Word file** icon.

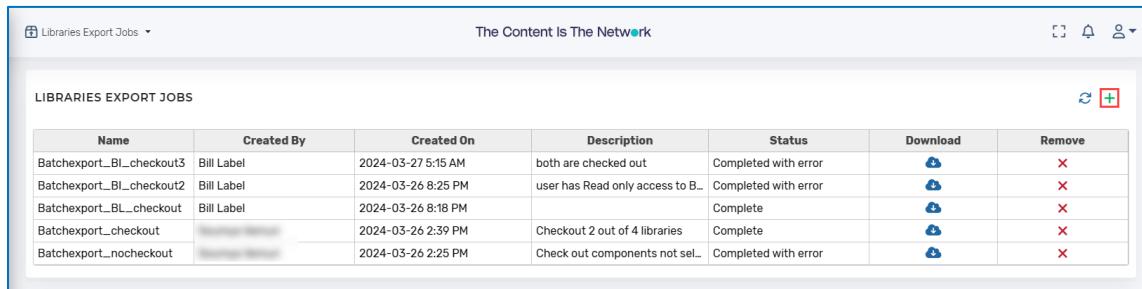
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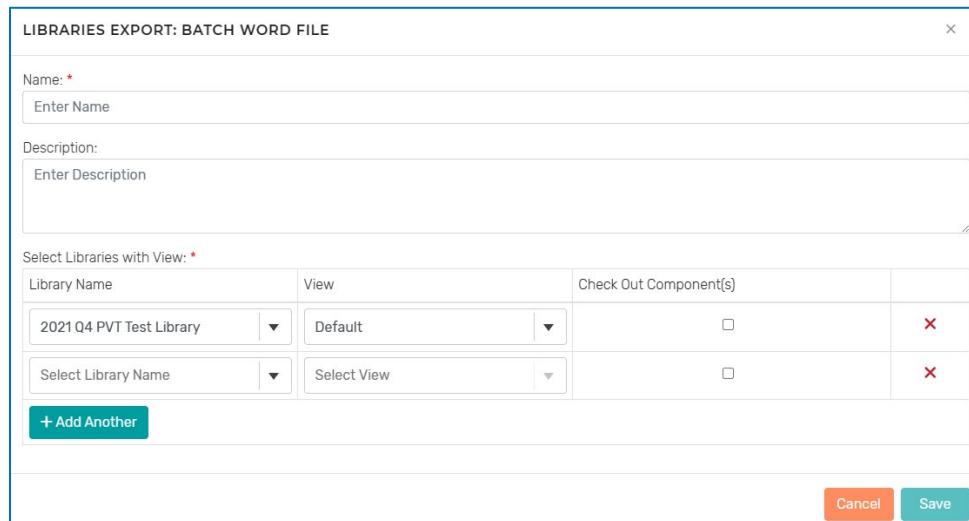


2. The **Libraries Export Jobs** page will display. Click the green plus icon to add a batch export job.



Name	Created By	Created On	Description	Status	Download	Remove
Batchexport_BI_checkout3	Bill Label	2024-03-27 5:15 AM	both are checked out	Completed with error		
Batchexport_BI_checkout2	Bill Label	2024-03-26 8:25 PM	user has Read only access to B...	Completed with error		
Batchexport_BL_checkout	Bill Label	2024-03-26 8:18 PM		Complete		
Batchexport_checkout	[REDACTED]	2024-03-26 2:39 PM	Checkout 2 out of 4 libraries	Complete		
Batchexport_nocheckout	[REDACTED]	2024-03-26 2:25 PM	Check out components not sel...	Completed with error		

3. The **Libraries Export: Batch Word File** pop-up window will display. Enter the name of the export job, and if desired, a description of the job.



LIBRARIES EXPORT: BATCH WORD FILE

Name: *

Description:

Select Libraries with View: *

Library Name	View	Check Out Component(s)
2021 Q4 PVT Test Library	Default	<input type="checkbox"/>
Select Library Name	Select View	<input type="checkbox"/>

+ Add Another

Cancel **Save**

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4. Select the library to be exported from the **Library Name** drop-down menu.

LIBRARIES EXPORT: BATCH WORD FILE

Name: *	Enter Name								
Description:	Enter Description								
Select Libraries with View: *									
Library Name	View	Check Out Component(s)							
Select Library Name	Select View	<input type="checkbox"/>	X						
<table border="1"> <tr> <td>2021 Q4 PVT Test Library</td> <td></td> </tr> <tr> <td>2024 R1 AMR Test Library</td> <td></td> </tr> <tr> <td>2024 R1 TC 34018 AMR</td> <td></td> </tr> </table>				2021 Q4 PVT Test Library		2024 R1 AMR Test Library		2024 R1 TC 34018 AMR	
2021 Q4 PVT Test Library									
2024 R1 AMR Test Library									
2024 R1 TC 34018 AMR									

Cancel Save

5. Select the view to be exported from the **View** drop-down menu and choose whether components will be checked out while the export is being completed.

LIBRARIES EXPORT: BATCH WORD FILE

Name: *	Enter Name										
Description:	Enter Description										
Select Libraries with View: *											
Library Name	View	Check Out Component(s)									
2021 Q4 PVT Test Library	Select View	<input type="checkbox"/>	X								
<table border="1"> <tr> <td>+ Add Another</td> <td>Default</td> <td><input type="checkbox"/></td> <td>X</td> </tr> <tr> <td></td> <td>Disabled View</td> <td><input type="checkbox"/></td> <td>X</td> </tr> </table>				+ Add Another	Default	<input type="checkbox"/>	X		Disabled View	<input type="checkbox"/>	X
+ Add Another	Default	<input type="checkbox"/>	X								
	Disabled View	<input type="checkbox"/>	X								

Cancel Save

Note: Multiple views can be selected for multiple libraries. When selecting the view to be exported, only the data available from that view will be exported.

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6. Click the **Add Another** button to add additional batch export jobs and repeat steps 3-5 until all the desired export jobs have been added. Click **Save**.

LIBRARIES EXPORT: BATCH WORD FILE

Name: *	Guides Export Batch		
Description:	Enter Description		
Select Libraries with View: *			
Library Name	View	Check Out Component(s)	
2021 Q4 PVT Test Library	Disabled View	<input type="checkbox"/>	X
2024 R1 AMR Test Library	Default	<input checked="" type="checkbox"/>	X
+ Add Another			
Cancel Save			

7. The pending export job will display in the **Libraries Export Jobs** table.

LIBRARIES EXPORT JOBS

Name	Created By	Created On	Description	Status	Download	Remove
Guides Export Batch	[REDACTED]	2024-05-08 2:32 PM		Pending		
Batchexport_BI_checkout3	[REDACTED]	2024-03-27 5:15 AM	both are checked out	Completed with error		X
Batchexport_BI_checkout2	[REDACTED]	2024-03-26 8:25 PM	user has Read only access to B...	Completed with error		X
Batchexport_BL_checkout	[REDACTED]	2024-03-26 8:18 PM		Complete		X
Batchexport_checkout	[REDACTED]	2024-03-26 2:39 PM	Checkout 2 out of 4 libraries	Complete		X
Batchexport_nocheckout	[REDACTED]	2024-03-26 2:25 PM	Check out components not sel...	Completed with error		X

8. The user will receive an email informing them of job completion, and detailing any errors contained in the export, if applicable.

Export libraries job completed

IS IntelNotion Service <service@intelinotiondev.onmicrosoft.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.

Hello,

Please be advised that the export libraries job named "Guides Export Batch" has been completed.

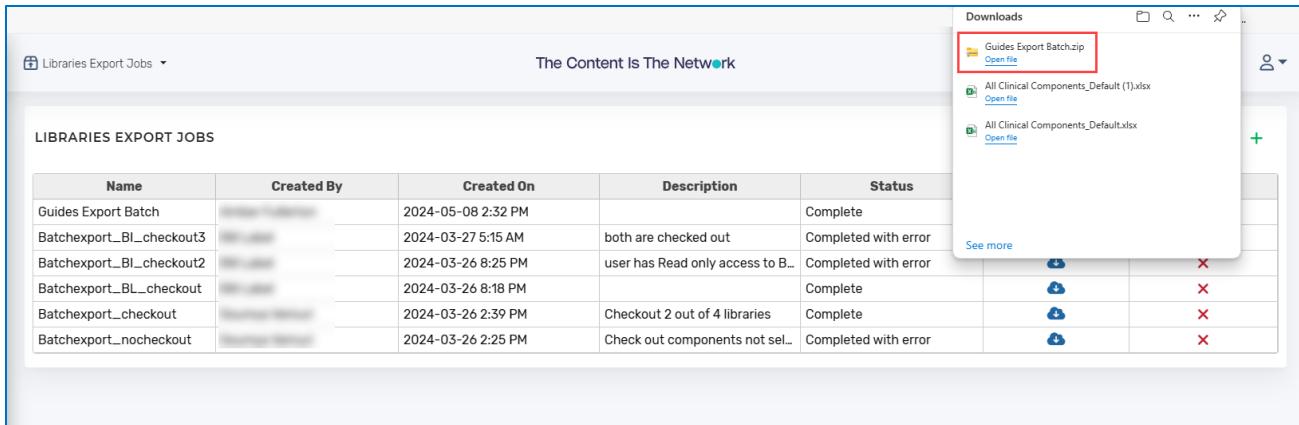
[Click here](#) to view all jobs.

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Note: Read only users who check off the 'Check Out Components' checkbox, the export completes and job status "Completed with Error" with no batch file generated for a relevant component BO class w. If the checkbox is not checked off upon export or if multiple libraries of different BO classes were selected for export, the batch word file will be generated without error and for each BO class, as appropriate.

9. Click the **Download**  icon to receive the export batch zip file.

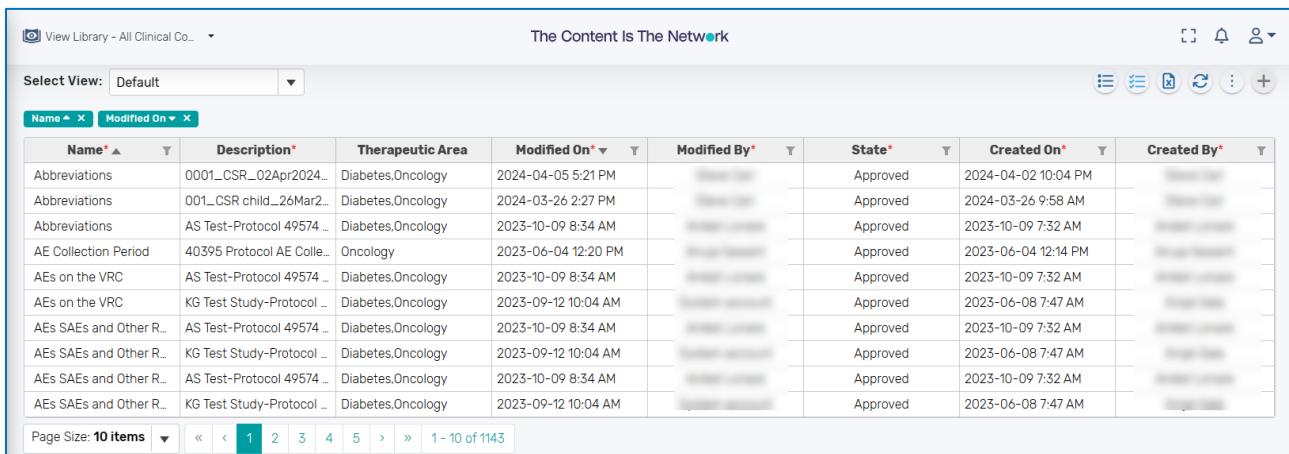


Name	Created By	Created On	Description	Status
Guides Export Batch	[REDACTED]	2024-05-08 2:32 PM		Complete
Batchexport_BL_checkout3	[REDACTED]	2024-03-27 5:15 AM	both are checked out	Completed with error
Batchexport_BL_checkout2	[REDACTED]	2024-03-26 8:25 PM	user has Read only access to B...	Completed with error
Batchexport_BL_checkout	[REDACTED]	2024-03-26 8:18 PM		Complete
Batchexport_checkout	[REDACTED]	2024-03-26 2:39 PM	Checkout 2 out of 4 libraries	Complete
Batchexport_nocheckout	[REDACTED]	2024-03-26 2:25 PM	Checkout components not sel...	Completed with error

6.4.2 Exporting Data in a Non-Managed Library to an Excel File

Data in a non-managed library can be exported from the datasheet view by a full control administrator or a user with the applicable Manage Libraries functional permission for the relevant Business Object class(es). Follow the steps listed below to export non-managed library data to an Excel file.

1. In the InteliNotion Web Console, navigate to the desired non-managed library, and double click to enter the datasheet view.



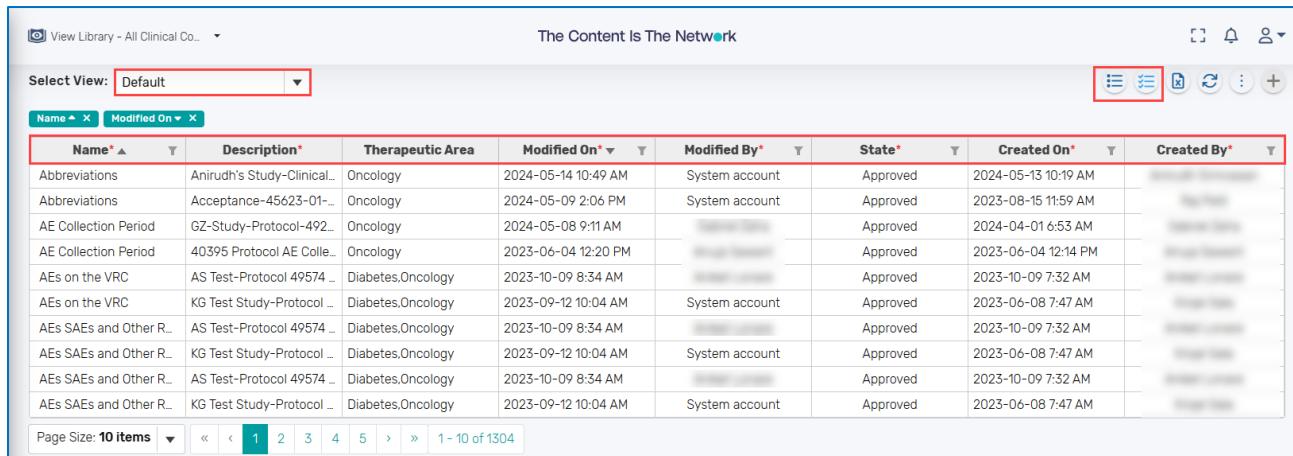
Name*	Description*	Therapeutic Area	Modified On*	Modified By*	State*	Created On*	Created By*
Abbreviations	0001_CSR_02Apr2024...	Diabetes,Oncology	2024-04-05 5:21 PM	[REDACTED]	Approved	2024-04-02 10:04 PM	[REDACTED]
Abbreviations	001_CSR child..._26Mar2...	Diabetes,Oncology	2024-03-26 2:27 PM	[REDACTED]	Approved	2024-03-26 9:58 AM	[REDACTED]
Abbreviations	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM	[REDACTED]	Approved	2023-10-09 7:32 AM	[REDACTED]
AE Collection Period	40395 Protocol AE Colle...	Oncology	2023-06-04 12:20 PM	[REDACTED]	Approved	2023-06-04 12:14 PM	[REDACTED]
AEs on the VRC	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM	[REDACTED]	Approved	2023-10-09 7:32 AM	[REDACTED]
AEs on the VRC	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	[REDACTED]	Approved	2023-06-08 7:47 AM	[REDACTED]
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM	[REDACTED]	Approved	2023-10-09 7:32 AM	[REDACTED]
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	[REDACTED]	Approved	2023-06-08 7:47 AM	[REDACTED]
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM	[REDACTED]	Approved	2023-10-09 7:32 AM	[REDACTED]
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	[REDACTED]	Approved	2023-06-08 7:47 AM	[REDACTED]

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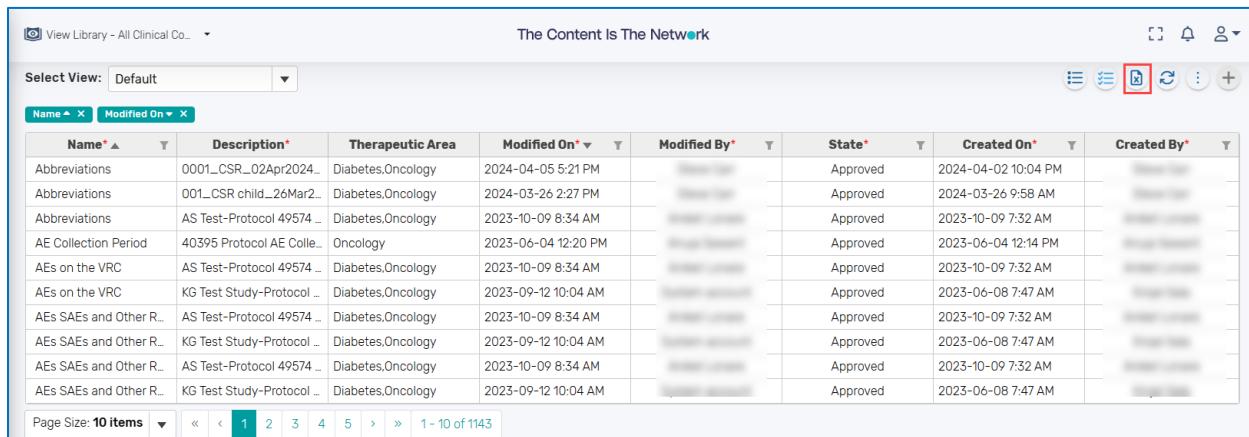
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2. Choose the desired view from the **Select View** drop-down menu along with any desired filters. The user can also select from 'Show Approved Only' and 'Show All' views.



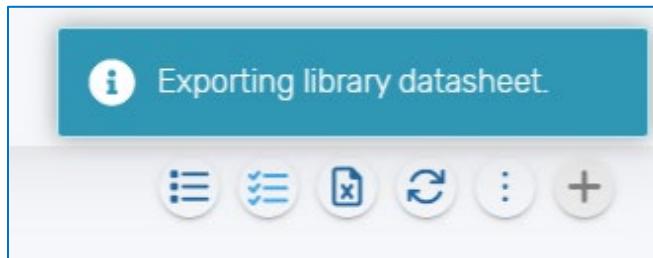
Name*	Description*	Therapeutic Area	Modified On*	Modified By*	State*	Created On*	Created By*
Abbreviations	Anirudh's Study-Clinical...	Oncology	2024-05-14 10:49 AM	System account	Approved	2024-05-13 10:19 AM	
Abbreviations	Acceptance-45623-01...	Oncology	2024-05-09 2:06 PM	System account	Approved	2023-08-15 11:59 AM	
AE Collection Period	GZ-Study-Protocol-492...	Oncology	2024-05-08 9:11 AM		Approved	2024-04-01 6:53 AM	
AE Collection Period	40395 Protocol AE Colle...	Oncology	2023-06-04 12:20 PM		Approved	2023-06-04 12:14 PM	
AEs on the VRC	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs on the VRC	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	System account	Approved	2023-06-08 7:47 AM	
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	System account	Approved	2023-06-08 7:47 AM	
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM	System account	Approved	2023-06-08 7:47 AM	

3. Click the Export library's datasheet view as xlsx file icon.



Name*	Description*	Therapeutic Area	Modified On*	Modified By*	State*	Created On*	Created By*
Abbreviations	0001_CSR_02Apr2024...	Diabetes,Oncology	2024-04-05 5:21 PM		Approved	2024-04-02 10:04 PM	
Abbreviations	001_CSR child_26Mar2...	Diabetes,Oncology	2024-03-26 2:27 PM		Approved	2024-03-26 9:58 AM	
Abbreviations	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AE Collection Period	40395 Protocol AE Colle...	Oncology	2023-06-04 12:20 PM		Approved	2023-06-04 12:14 PM	
AEs on the VRC	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs on the VRC	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM		Approved	2023-06-08 7:47 AM	
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM		Approved	2023-06-08 7:47 AM	
AEs SAEs and Other R...	AS Test-Protocol 49574 ...	Diabetes,Oncology	2023-10-09 8:34 AM		Approved	2023-10-09 7:32 AM	
AEs SAEs and Other R...	KG Test Study-Protocol ...	Diabetes,Oncology	2023-09-12 10:04 AM		Approved	2023-06-08 7:47 AM	

4. A progress window will display to inform the user that the data is being exported.



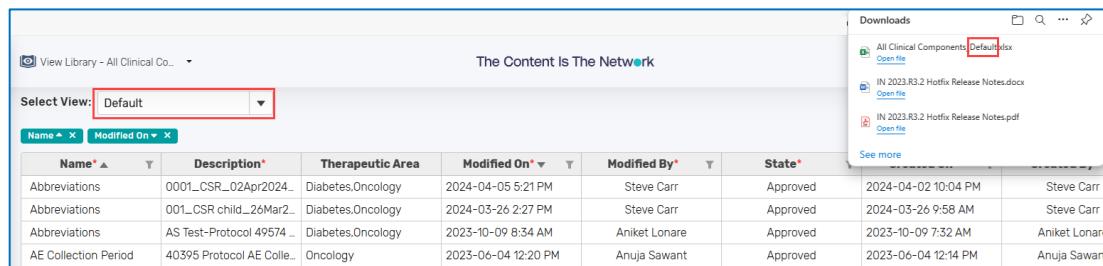
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5. The exported data will appear in the download window.

Notes:

- When exporting data from a non-managed library, the system will only export the data selected via the view and any filters applied at the time of export.

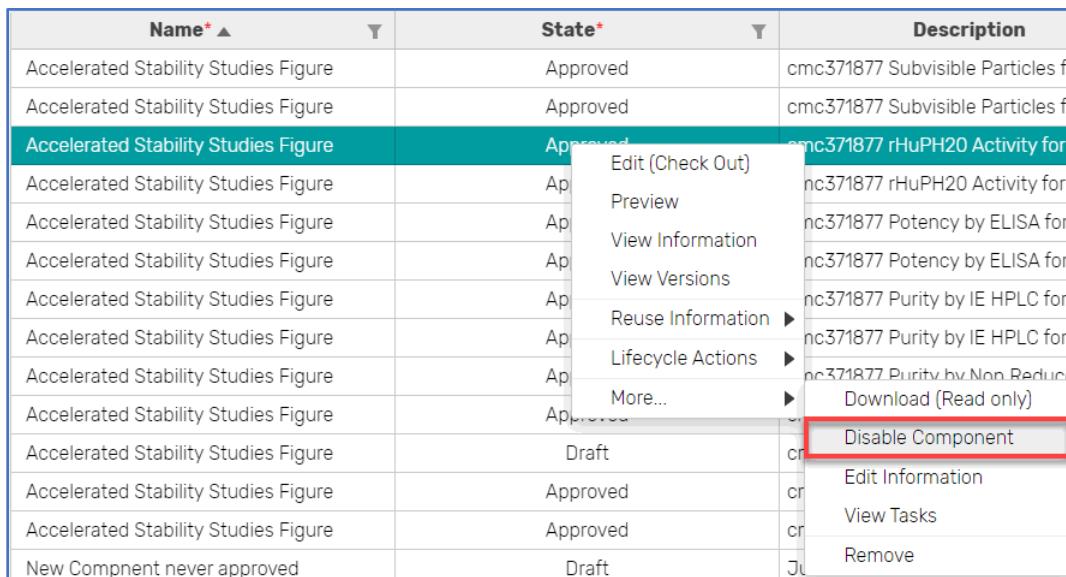


The screenshot shows a table of clinical components with columns for Name, Description, Therapeutic Area, Modified On, Modified By, and State. A dropdown menu 'Select View' is open, showing 'Default' as the selected option. To the right, a 'Downloads' window is open, listing three files: 'All Clinical Components Default.xlsx', 'IN 2023.R3.2 Hotfix Release Notes.docx', and 'IN 2023.R3.2 Hotfix Release Notes.pdf'. Each file has an 'Open file' link below it.

- If the chosen data configuration for export is more than the system limit of 10,000 rows, a warning message will display and the user will be prompted to change the export configuration to comply with system requirements.

6.5 DISABLING/ENABLING LIBRARY COMPONENTS

Library component can be Disabled/Enabled through the right click menu; this menu will be available for library owners only.



The screenshot shows a table of components with columns for Name, State, and Description. A context menu is open over a row for 'Accelerated Stability Studies Figure'. The menu options include: Edit (Check Out), Preview, View Information, View Versions, Reuse Information, Lifecycle Actions, More..., Download (Read only), Disable Component, Edit Information, View Tasks, and Remove. The 'Disable Component' option is highlighted with a red box.

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A Disabled component will have an indicator next to its name:

Name*	
Accelerated Stability Studies Figure	
Accelerated Stability Studies Figure	
Accelerated Stability Studies Figure	☒
Accelerated Stability Studies Figure	
Accelerated Stability Studies Figure	

A Library Component that has been disabled will not appear as available content to be used in the *Word App* regardless of the lifecycle state (The Library has to be configured with **Show in Word App** option checked).

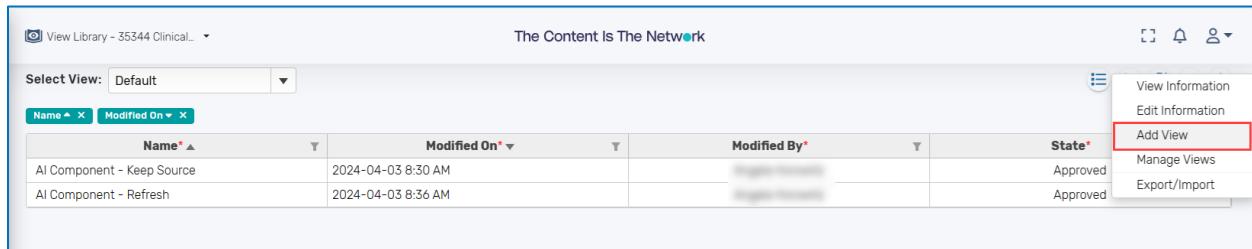
Multiple selected Library Components can be Disabled/Enable in bulk:

Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt
Accelerated Stability Studies Figure	Approved	crt

Create Task/Lifecycle Transition
Enable Components
Disable Components
Edit Information
Remove

Note: A disabled library component will not be available in the export package using either the library-level or Utilities export/import functionality.

Once components have been disabled, users have the option to add a view to display disabled components. In the datasheet view, click on the ellipses and select **Add View**.

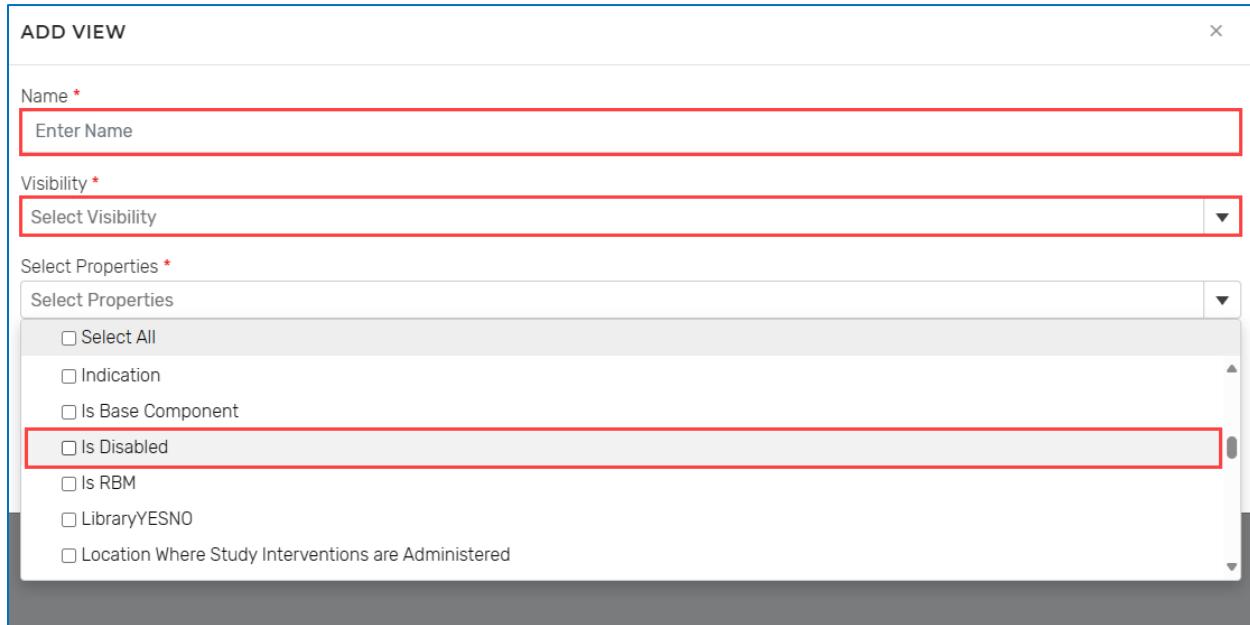


The screenshot shows a table view of library components. The last row, 'Accelerated Stability Studies Figure', is marked with a '☒' icon. A context menu is open over this row, with the 'Add View' option highlighted in red. Other options visible in the menu include 'View Information', 'Edit Information', 'Manage Views', and 'Export/Import'.

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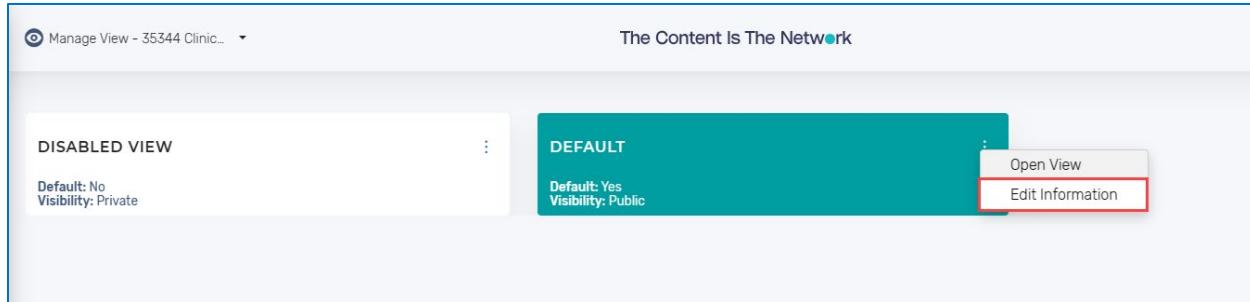
The **Add View** window will display. Fill out the required fields and choose **Is Disabled** from the dropdown menu, along with any other properties desired (see [Section 5.2](#) for instructions on adding properties to components in non-managed libraries) and click **Save**.



The screenshot shows the 'ADD VIEW' dialog box. It has fields for 'Name *' (containing 'Enter Name') and 'Visibility *' (containing 'Select Visibility'). Below these is a 'Select Properties *' section with a dropdown menu showing various options like 'Select All', 'Indication', 'Is Base Component', 'Is Disabled' (which is highlighted with a red box), 'Is RBM', 'LibraryYESNO', and 'Location Where Study Interventions are Administered'. A large red box surrounds the entire 'Select Properties' section.

OR

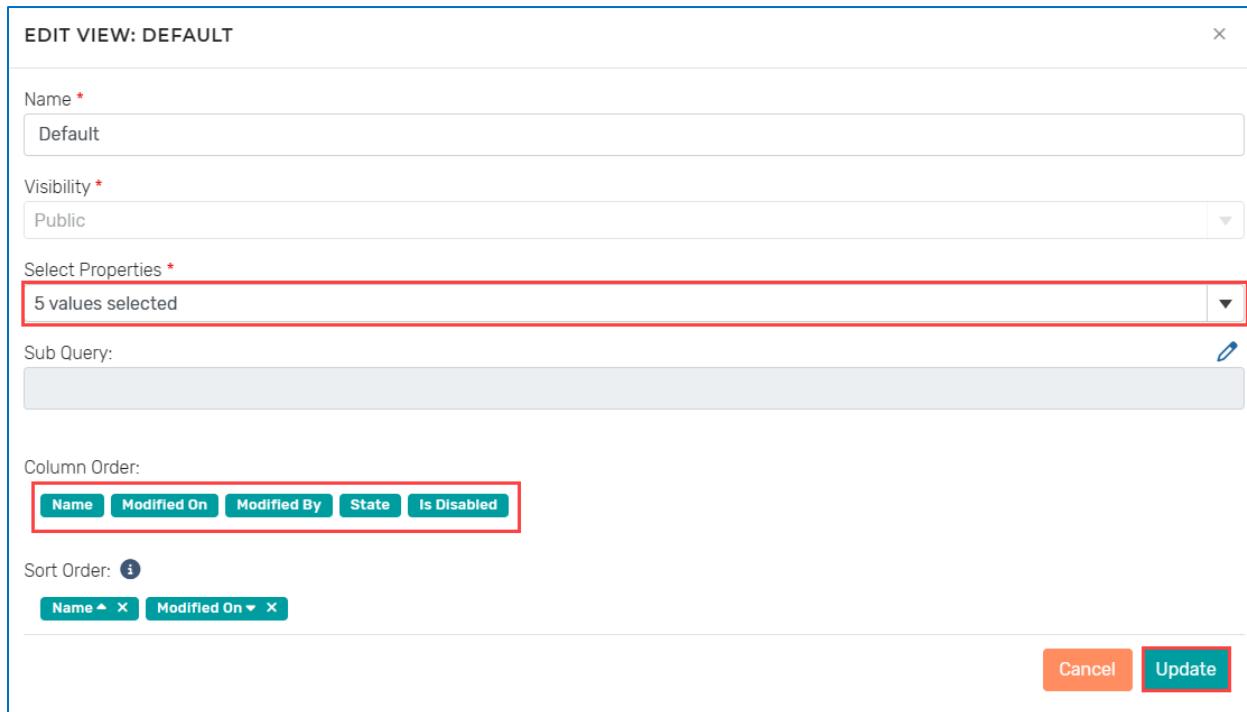
Is Disabled can be added to an existing view by navigating to the Manage Views page, clicking the ellipses on the applicable view and choosing **Edit Information**.



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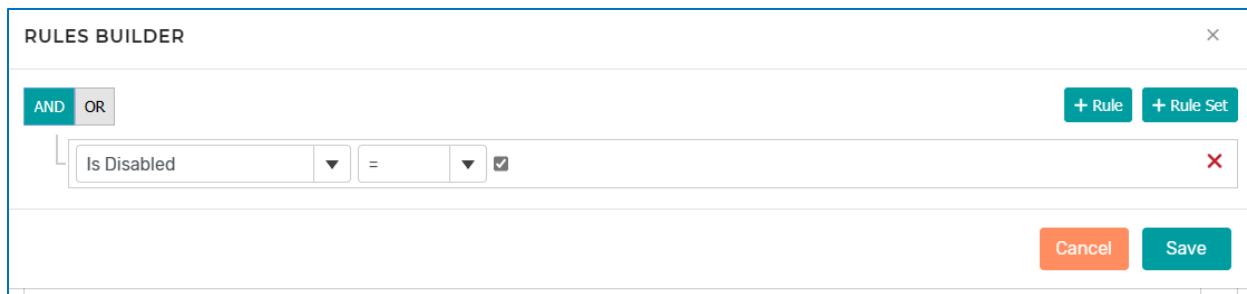
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The **Edit View** window will display. Add **Is Disabled** to the other properties selected, order the column as desired, and click **Update**.



The screenshot shows the 'Edit View: DEFAULT' window. It includes fields for 'Name' (Default), 'Visibility' (Public), and a 'Select Properties' dropdown containing '5 values selected'. A red box highlights the 'Sub Query' section, which contains a text input field and a pencil icon. Below it is a 'Column Order' section with buttons for 'Name', 'Modified On', 'Modified By', 'State', and 'Is Disabled', with 'Is Disabled' highlighted by a red box. Under 'Sort Order', there are two buttons: 'Name ▲ X' and 'Modified On ▼ X'. At the bottom right are 'Cancel' and 'Update' buttons, with 'Update' highlighted by a red box.

If the user chooses to have only disabled components displayed in all views, click the Sub Query rules builder and choose Is Disabled from the drop-down menu, click the checkbox, and press **Save**. This will create a rule excluding all enabled components from all columns of the applicable datasheet library view.



The screenshot shows the 'RULES BUILDER' window. It features an 'AND' button and an 'OR' button. Below them is a condition row: 'Is Disabled' followed by a dropdown menu, an equals sign, another dropdown menu, and a checked checkbox. At the bottom right are 'Cancel' and 'Save' buttons, with 'Save' highlighted by a red box.

6.6 MIGRATING LIBRARY COMPONENTS

See the sections below for information on the steps necessary to migrate library components from one managed library to another, and how to export a library and its components.

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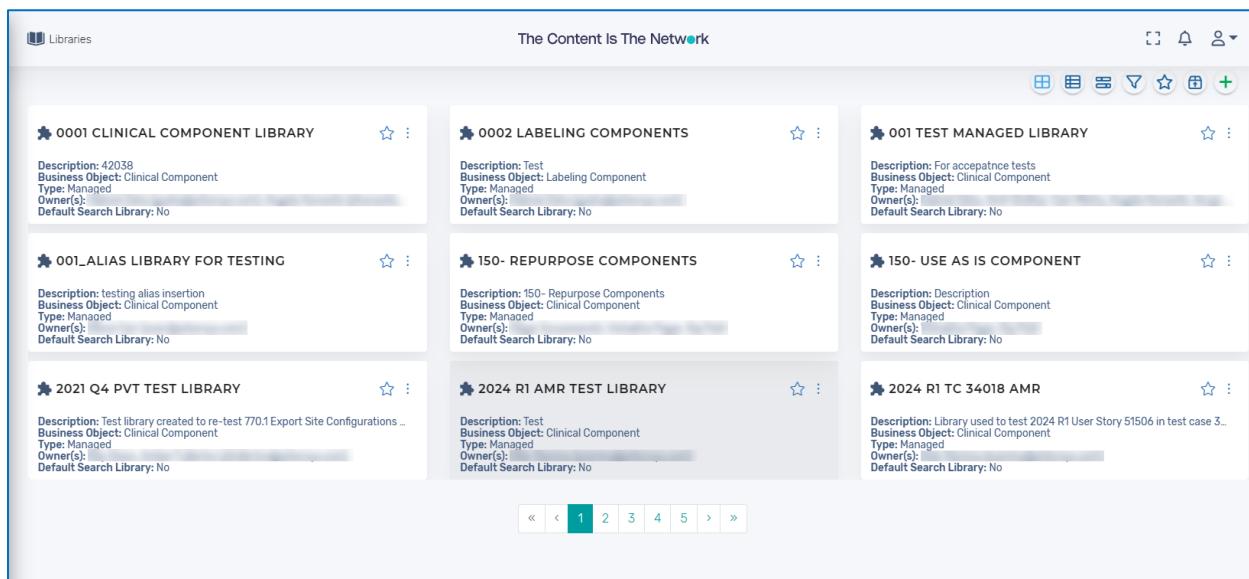
6.6.1 Migrating Library Components from One Managed Library to Another

Moving a library component(s) from one managed library to another is possible with the following conditions:

- An authorized user can move managed library components only from 1 managed library to another managed library, regardless if the component had already been reused into a document and that document is currently checked out for authoring under the following conditions: move 1 component or select many and move them together, it is not possible to move the component to a library that is for a different Business Object class, and cannot move component if it is checked out.
- After moving a library component from 1 library to another, if that component had previously been reused into an existing document, the Reuse Report for the corresponding component will be updated to display the new library name.
- When moving a library component from 1 library to another: the existing properties associated with that component will not change, the existing State assigned to component will NOT change, and the component will NOT up-version.
- All changes will appear in the audit and import report with details.

Follow the steps listed below to move a library component or components from one managed library to another.

1. In the *Web Console* left-hand navigation pane, click on **Libraries**. The libraries page will display.



The screenshot shows the 'Libraries' page in the InteliNotion Web Console. The page title is 'The Content Is The Network'. The interface includes a top navigation bar with icons for search, notifications, and user profile. Below the title, there is a toolbar with various icons for managing libraries. The main content area displays a grid of library cards. Each card contains the library's name, a star icon, and three vertical dots for more options. The libraries listed are:

- 0001 CLINICAL COMPONENT LIBRARY**: Description: 42038, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 0002 LABELING COMPONENTS**: Description: Test, Business Object: Labeling Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 001 TEST MANAGED LIBRARY**: Description: For acceptance tests, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 001_ALIAS LIBRARY FOR TESTING**: Description: testing alias insertion, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 150- REPURPOSE COMPONENTS**: Description: 150- Repurpose Components, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 150- USE AS IS COMPONENT**: Description: Description, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 2021 Q4 PVT TEST LIBRARY**: Description: Test library created to re-test 770.1 Export Site Configurations ..., Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 2024 R1 AMR TEST LIBRARY**: Description: Test, Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No
- 2024 R1 TC 34018 AMR**: Description: Library used to test 2024 R1 User Story 51506 in test case 3..., Business Object: Clinical Component, Type: Managed, Owner(s): [redacted], Default Search Library: No

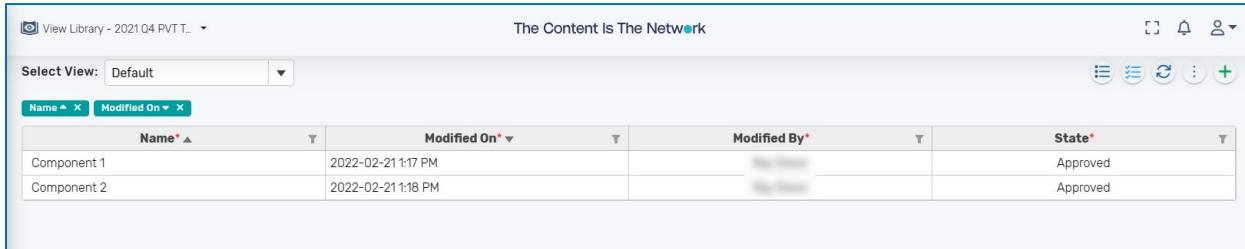
At the bottom of the page, there is a navigation bar with icons for back, forward, and search, followed by a page number indicator (1 of 5).

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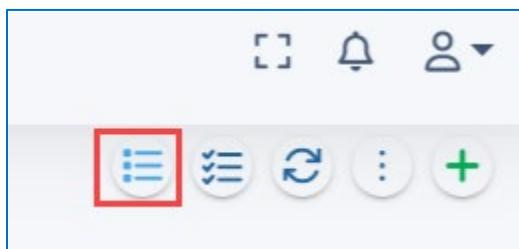
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2. On the libraries page, locate the library containing the components to be moved, and double click on the library card. The datasheet view with the library components listed will display.

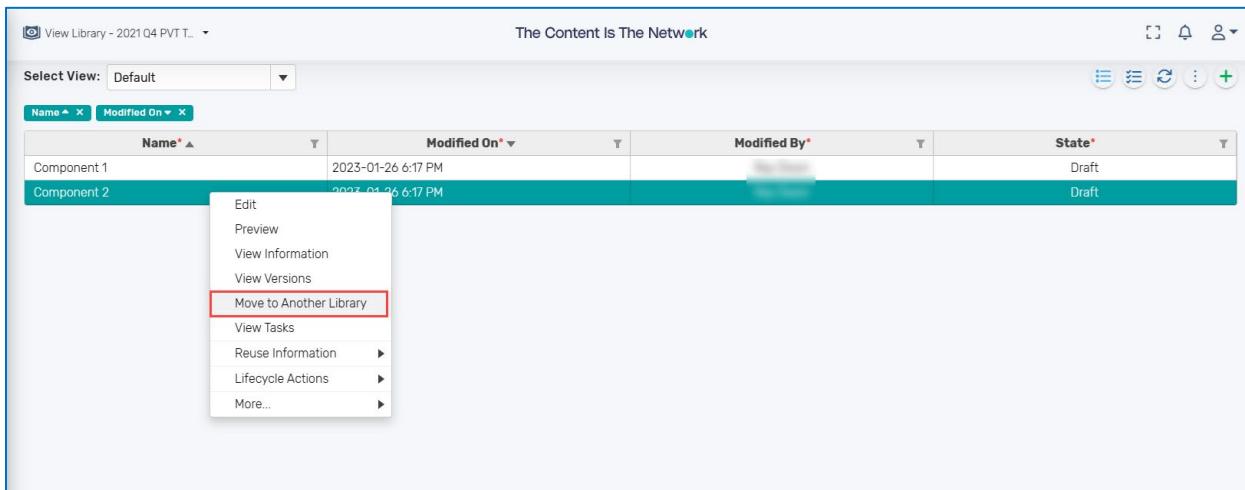


Name*	Modified On*	Modified By*	State*
Component 1	2022-02-21 11:17 PM		Approved
Component 2	2022-02-21 11:18 PM		Approved

3. Click the **Show all** icon.



4. Right click on the component (or multiple components using the Ctrl key function) and choose **Move to Another Library**.

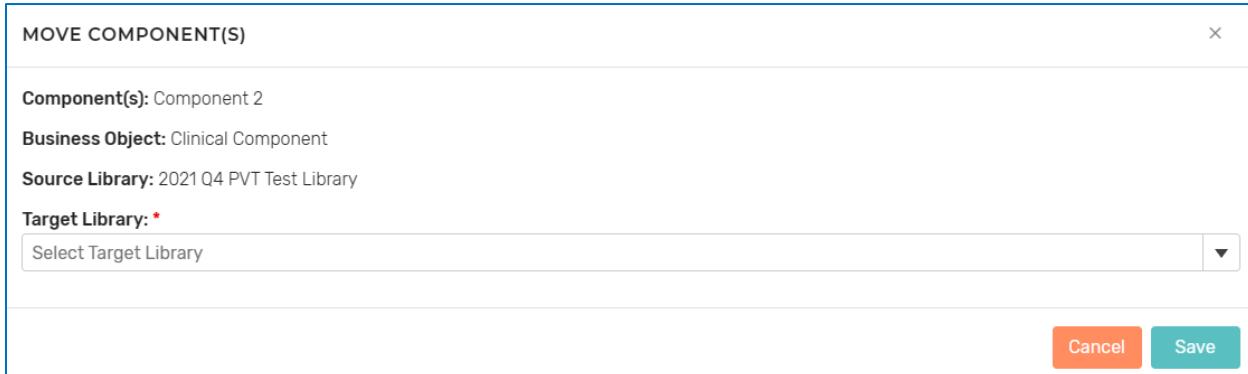


Name*	Modified On*	Modified By*	State*
Component 1	2023-01-26 6:17 PM		Draft
Component 2	2023-01-26 6:17 PM		Draft

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5. The **Move Components** pop up window will display.



MOVE COMPONENT(S)

Component(s): Component 2

Business Object: Clinical Component

Source Library: 2021 Q4 PVT Test Library

Target Library: *

Select Target Library

Cancel **Save**

6. From the drop-down menu, select the desired managed library as the target library. Click **Save**.



MOVE COMPONENT(S)

Component(s): Component 2

Business Object: Clinical Component

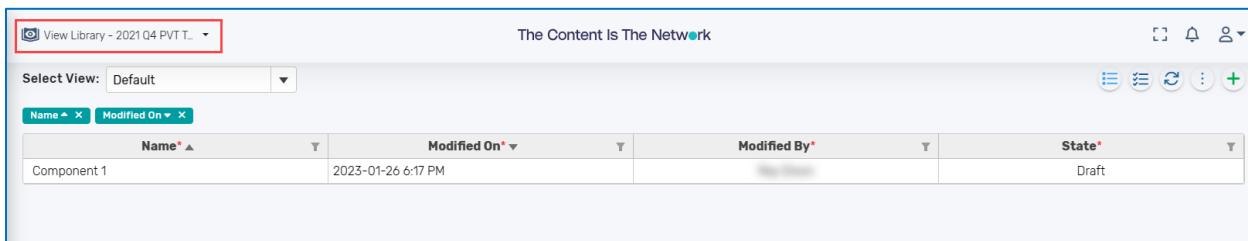
Source Library: 2021 Q4 PVT Test Library

Target Library: *

2024 R1 AMR Test Library

Cancel **Save**

7. The components will be removed from the original library and appear in the target library's datasheet view.

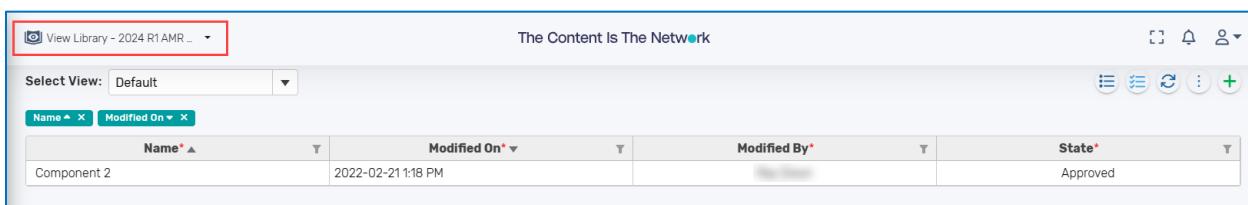


View Library - 2021 Q4 PVT...

The Content Is The Network

Select View: Default

Name*	Modified On*	Modified By*	State*
Component 1	2023-01-26 6:17 PM	[Redacted]	Draft



View Library - 2024 R1 AMR...

The Content Is The Network

Select View: Default

Name*	Modified On*	Modified By*	State*
Component 2	2022-02-21 11:18 PM	[Redacted]	Approved

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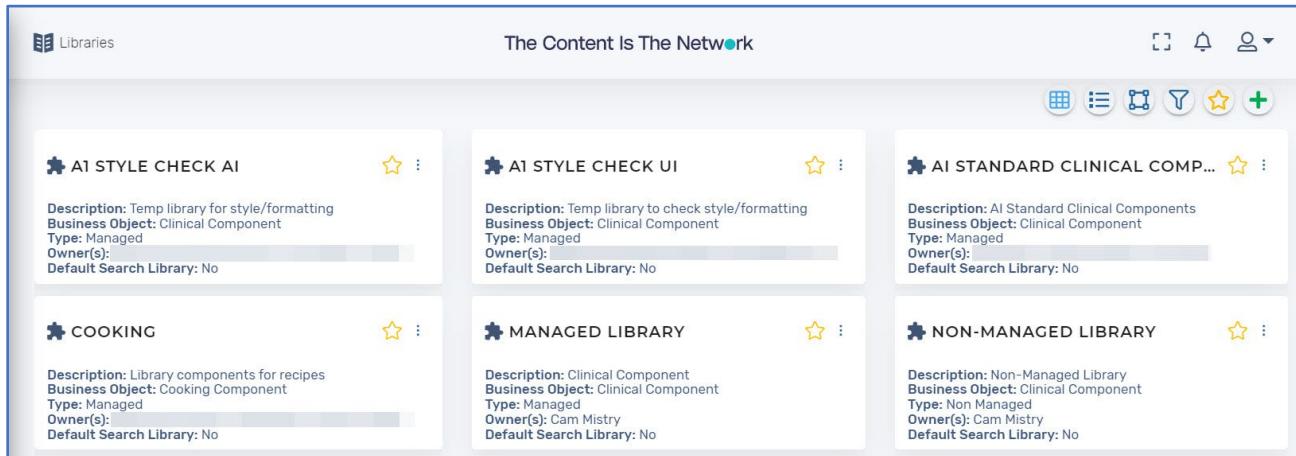
Note: If configured (see **InteliNotion Application Admin Guide**), the audit log captures the **Move to Another Library** event. When viewing audit logs for components that have been moved, they will show the **Move to Another Library** event, and the version number will remain unaffected by the move.

6.6.2 Migrating Library Components from One Site to Another

To migrate all library components, including their properties and instructional text, from one site to another, follow the steps below.

Note: Library components exported from 1 managed library cannot be imported into another managed library in the same site.

1. Click on the **Libraries** option in the left-hand side pane of the *Web Console*.
 - A grid view of the libraries existing in the system (if any) will appear on the screen.



The screenshot shows a grid of library components in the 'Libraries' section of the InteliNotion Web Console. Each component card includes its name, a yellow star icon, a vertical ellipsis button, and a detailed description. The cards are arranged in two rows of three.

Library Name	Description	Type	Owner(s)	Default Search Library
A1 STYLE CHECK AI	Description: Temp library for style/formatting Business Object: Clinical Component Type: Managed Owner(s): Default Search Library: No	Managed		No
A1 STYLE CHECK UI	Description: Temp library to check style/formatting Business Object: Clinical Component Type: Managed Owner(s): Default Search Library: No	Managed		No
AI STANDARD CLINICAL COMP...	Description: AI Standard Clinical Components Business Object: Clinical Component Type: Managed Owner(s): Default Search Library: No	Managed		No
COOKING	Description: Library components for recipes Business Object: Cooking Component Type: Managed Owner(s): Default Search Library: No	Managed		No
MANAGED LIBRARY	Description: Clinical Component Business Object: Clinical Component Type: Managed Owner(s): Cam Mistry Default Search Library: No	Managed	Cam Mistry	No
NON-MANAGED LIBRARY	Description: Non-Managed Library Business Object: Clinical Component Type: Non Managed Owner(s): Cam Mistry Default Search Library: No	Non-Managed	Cam Mistry	No

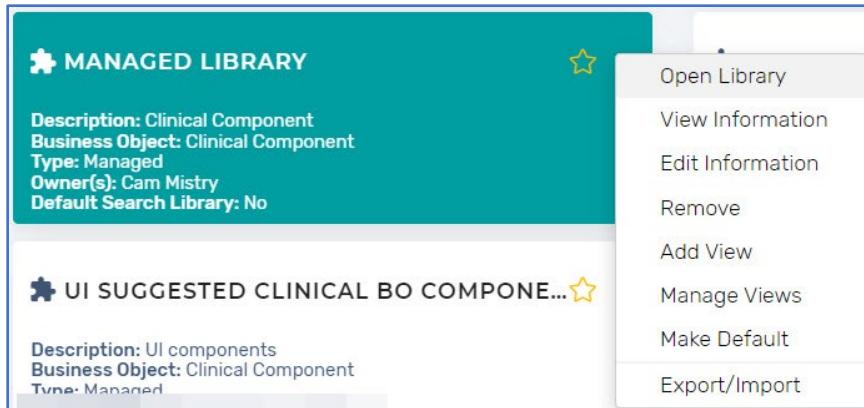
2. To migrate to the other site, click on the **vertical ellipsis** button beside the existing library name.



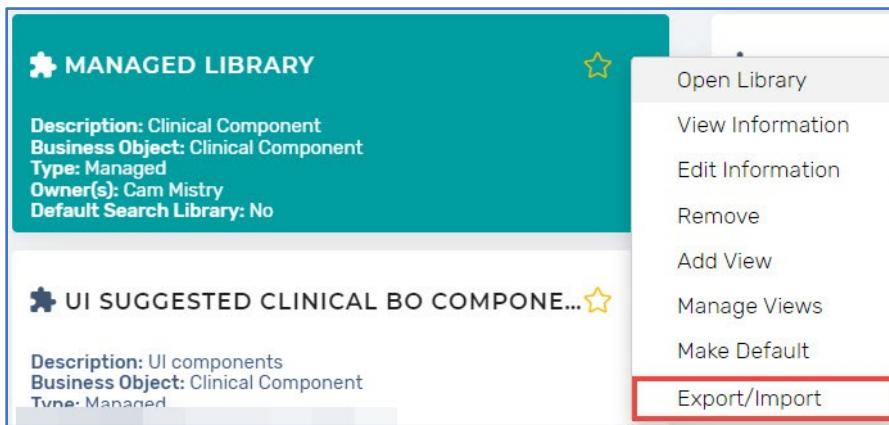
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- A list of options will appear on the screen.



- Click on the **Export/Import** option.



- The **Export/Import Settings** page should appear on the screen.



EXPORT/IMPORT SETTINGS

- Export Jobs
- Import Jobs

- Expand the **Export Jobs** option.



LIBRARY EXPORT/IMPORT JOBS

- Export Jobs
- Import Jobs

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5. A tabular list of existing export jobs (if any) and the option to create a job and refresh jobs will appear on the screen.



LIBRARY EXPORT/IMPORT JOBS

Export Jobs  

Jobs not available.

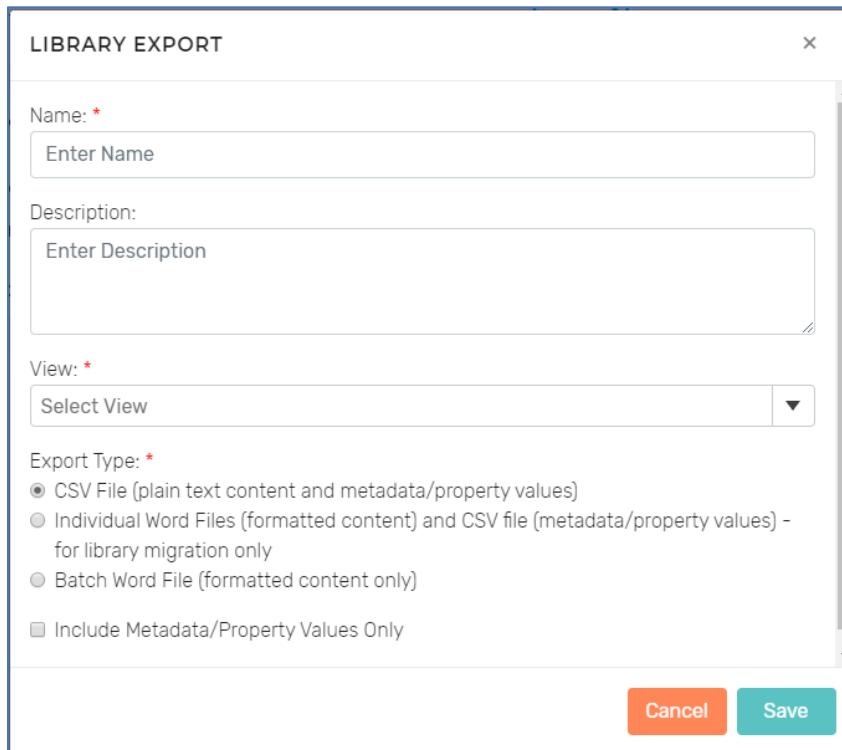
6. Click on the **plus sign icon**  to create a new export job.



Export Jobs  

Jobs not available.

7. A form to create an **Export Job** will appear on the screen.



LIBRARY EXPORT

Name: *

Enter Name

Description:

Enter Description

View: *

Select View

Export Type: *

CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only
 Batch Word File (formatted content only)

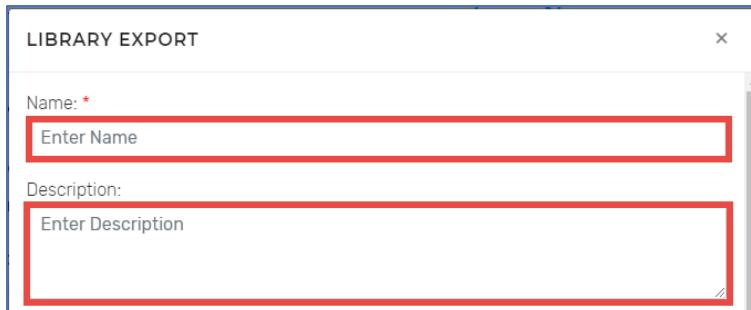
Include Metadata/Property Values Only

Cancel 

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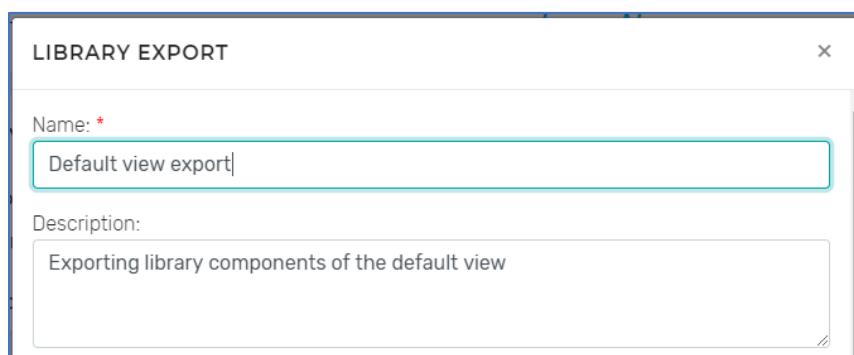
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8. Fill in the **Name** and **Description** of the export job.



The screenshot shows the 'LIBRARY EXPORT' dialog box. It has two main input fields: 'Name:' with a red border around the input field containing 'Enter Name' and 'Description:' with a red border around the input field containing 'Enter Description'.

For example:



The screenshot shows the 'LIBRARY EXPORT' dialog box with sample data. The 'Name:' field contains 'Default view export' with a blue border. The 'Description:' field contains 'Exporting library components of the default view'.

9. Select the appropriate view of the library for export (if multiple views have been created).



The screenshot shows the 'LIBRARY EXPORT' dialog box. It includes the 'Name:' and 'Description:' fields from the previous screenshot. A new section at the bottom is highlighted with a red border, labeled 'View:' with a red asterisk. It contains a dropdown menu labeled 'Select View' with a red border, showing two options: 'Default' and 'Test view'.

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For example:

LIBRARY EXPORT

Name: *

Description:

View: *

10. Select the Individual Word Files (formatted content) and CSV file (metadata/property values) export type as it is specifically for library migration.

Export Type: *

CSV File (plain text content and metadata/property values)

Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only

Batch Word File (formatted content only)

Include Metadata/Property Values Only

Cancel **Save**

For example:

Export Type: *

CSV File (plain text content and metadata/property values)

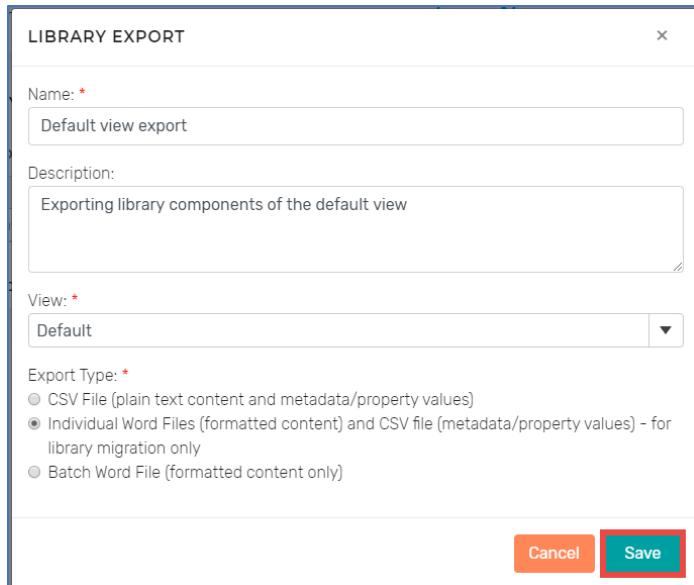
Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only

Batch Word File (formatted content only)

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11. Click **Save** to complete the export job.



LIBRARY EXPORT

Name: *
Default view export

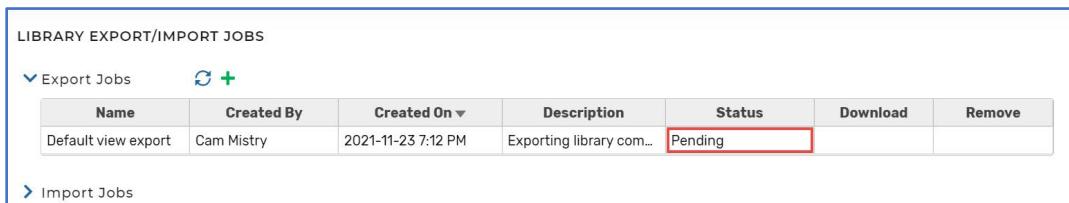
Description:
Exporting library components of the default view

View: *
Default

Export Type: *
 CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only
 Batch Word File (formatted content only)

Cancel **Save**

- The new export job will appear in the tabular list with a **Pending** status.



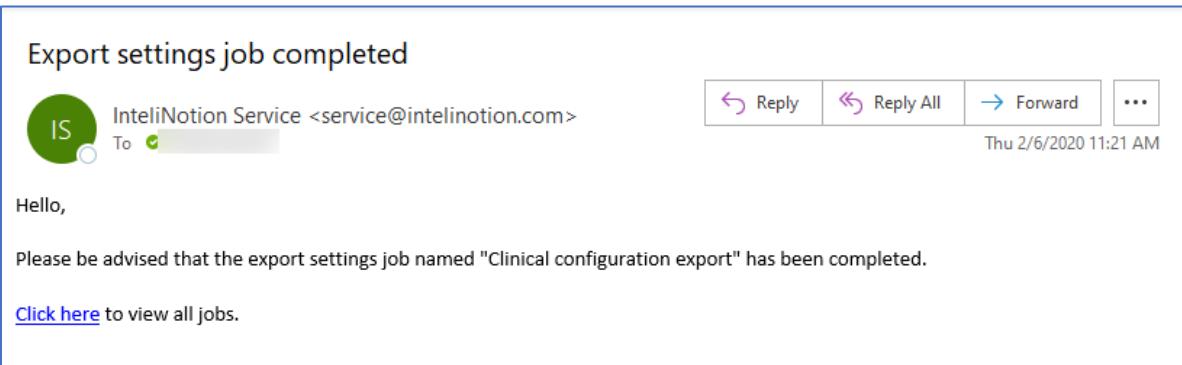
LIBRARY EXPORT/IMPORT JOBS

Name	Created By	Created On	Description	Status	Download	Remove
Default view export	Cam Mistry	2021-11-23 7:12 PM	Exporting library com...	Pending		

Export Jobs Import Jobs

Note: When viewing export/import jobs, library owners with Manage Libraries functional permissions or full control administrators will be able to view all import/export jobs and download those packages, regardless of the originator.

12. Once the **Export** is completed, the user will receive a job completion email. Click on the link in the email to access the export jobs page.



Export settings job completed

IS InteliNotion Service <service@intelinotion.com>
To: [Click here](#)

Thu 2/6/2020 11:21 AM

Hello,

Please be advised that the export settings job named "Clinical configuration export" has been completed.

[Click here](#) to view all jobs.

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- The **Export/Import Job** page will appear on the screen with the completed job listed below.

LIBRARY EXPORT/IMPORT JOBS

Export Jobs  

Name	Created By	Created On ▾	Description	Status	Download	Remove
Default view export	Cam Mistry	2021-11-23 7:12 PM	Exporting library com...	Complete		

Import Jobs

13. Click on the download link of the completed job and the zip file will be downloaded to the user's machine. The export of the library components of that view will be complete.

Today (15)

 Default view export	2/6/2020 2:12 PM	Compressed (zipp...)	18 KB
---	------------------	----------------------	-------

14. To import the components, click on the **vertical ellipsis**  button beside the existing library on another site name.

 **MANAGED LIBRARY**  

Description: Clinical Component
Business Object: Clinical Component
Type: Managed
Owner(s): Cam Mistry
Default Search Library: No

Note: **Only** library owners and admin users can add/create components into that library.

15. A list of options will appear on the screen.

 **MANAGED LIBRARY** 

Description: Clinical Component
Business Object: Clinical Component
Type: Managed
Owner(s): Cam Mistry
Default Search Library: No

 UI SUGGESTED CLINICAL BO COMPONE... 

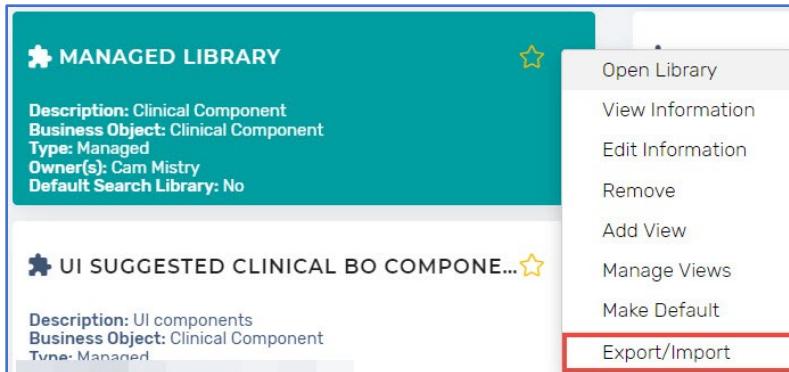
Description: UI components
Business Object: Clinical Component
Type: Managed

Open Library
View Information
Edit Information
Remove
Add View
Manage Views
Make Default
Export/Import

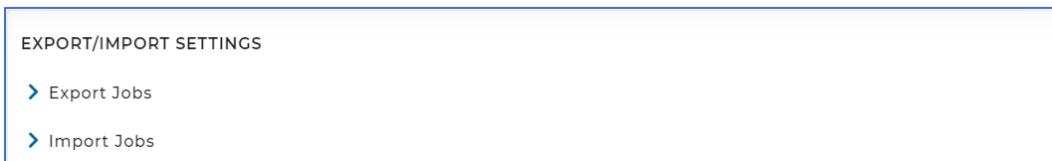
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16. Click on the **Export/Import** option.



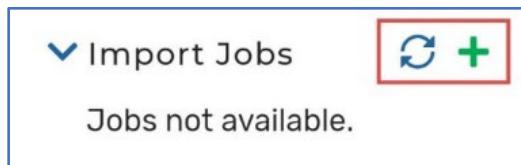
- The **Export/Import Settings** page should appear on the screen.

A screenshot of the "EXPORT/IMPORT SETTINGS" page. It has a section titled "LIBRARY EXPORT/IMPORT JOBS" containing "Export Jobs" and "Import Jobs". The "Import Jobs" option is highlighted with a red box.

17. Expand the **Import Jobs** option.

A screenshot of the "LIBRARY EXPORT/IMPORT JOBS" page. It shows "Export Jobs" and "Import Jobs". The "Import Jobs" section is expanded, revealing a sub-section with a "refresh" icon and a plus sign icon, which is highlighted with a red box.

18. A tabular list of existing import jobs (if any), the option to create a job, and refresh jobs will appear on the screen.

A screenshot of the "Import Jobs" list page. It shows a header with a dropdown arrow and the text "Import Jobs", followed by a "refresh" icon and a plus sign icon (highlighted with a red box). Below this, it says "Jobs not available."

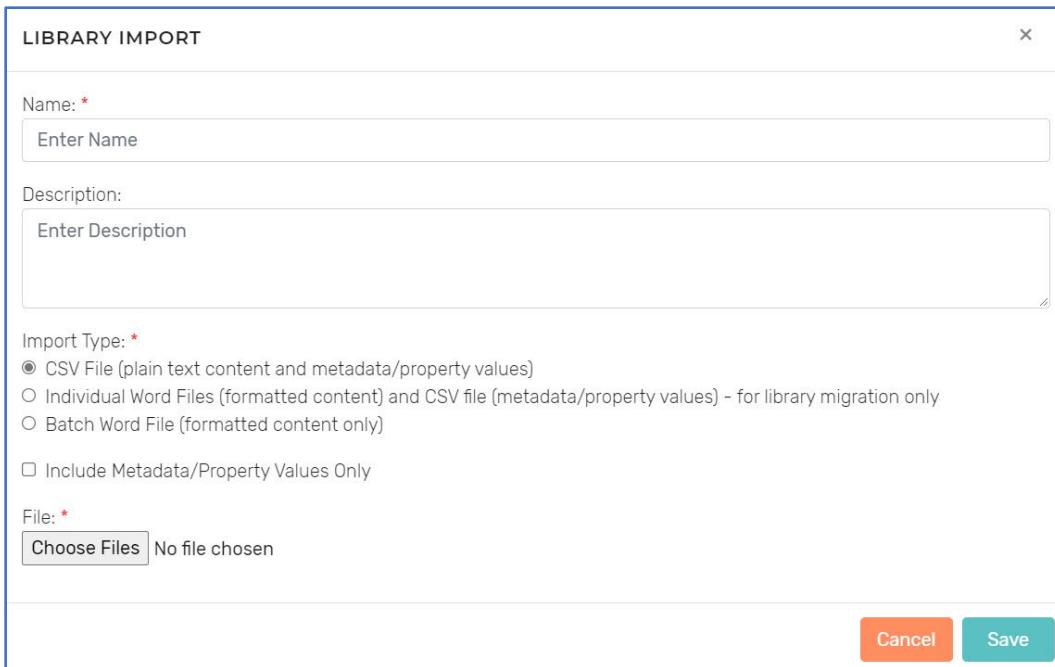
19. Click on the plus sign icon  to create a new import job.

A screenshot of the "Import Jobs" list page, identical to the previous one except that the plus sign icon is now highlighted with a red box.

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- A form to create an **Import** job will appear on the screen.



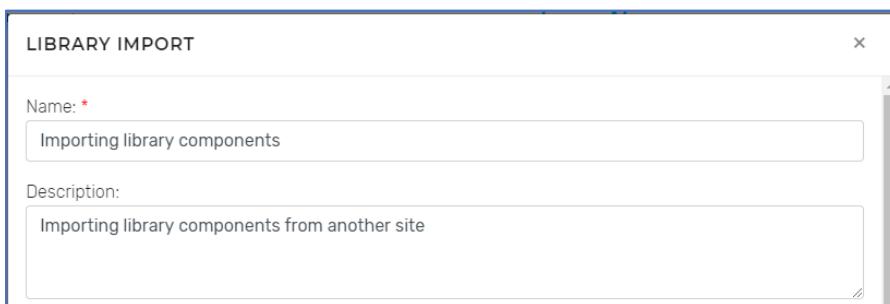
The screenshot shows the 'LIBRARY IMPORT' form. It includes fields for 'Name:' (with a red asterisk) and 'Description:', both with placeholder text 'Enter Name' and 'Enter Description'. Below these are three radio button options for 'Import Type': CSV File (selected), Individual Word Files, and Batch Word File. There is also a checkbox for 'Include Metadata/Property Values Only'. A file upload section with 'Choose Files' and 'No file chosen' is present. At the bottom are 'Cancel' and 'Save' buttons.

20. Enter a **Name** and **Description** in the form fields.



The screenshot shows the 'IMPORT' form with its 'Name:' and 'Description:' fields highlighted by a red rectangle. Both fields have placeholder text 'Enter Name' and 'Enter Description' respectively.

For example:

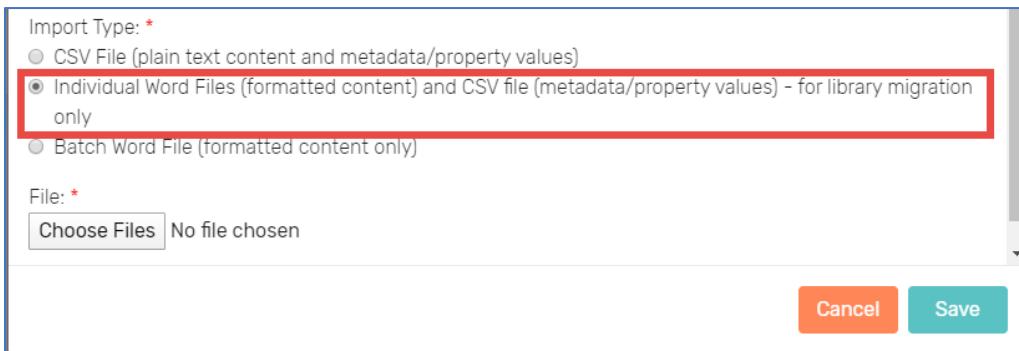


The screenshot shows the 'LIBRARY IMPORT' form with 'Name:' set to 'Importing library components' and 'Description:' set to 'Importing library components from another site'.

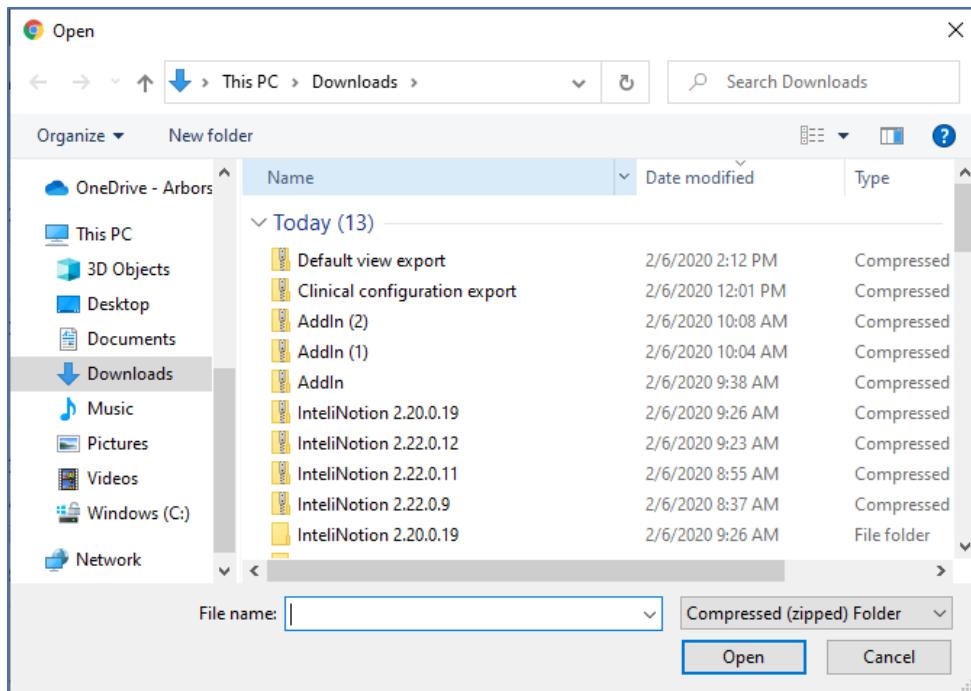
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21. Select **Individual Word Files (formatted content) and CSV file (metadata/property values)** option for **Import Type** and click on **Browse** or **Choose Files** to select a file from the local system.



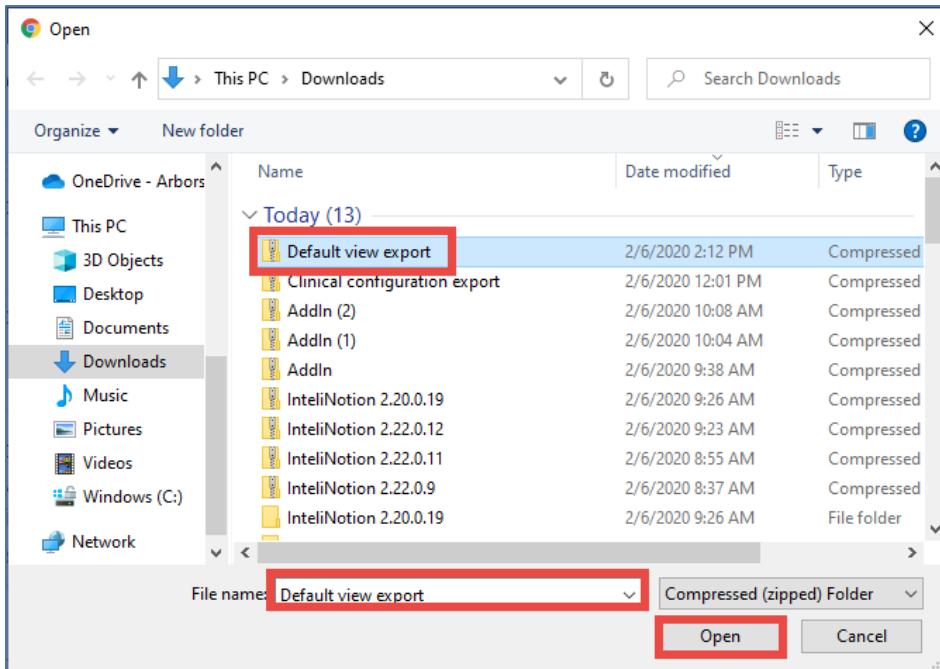
- A file explorer from the local system will appear on the screen allowing the user to choose a file.



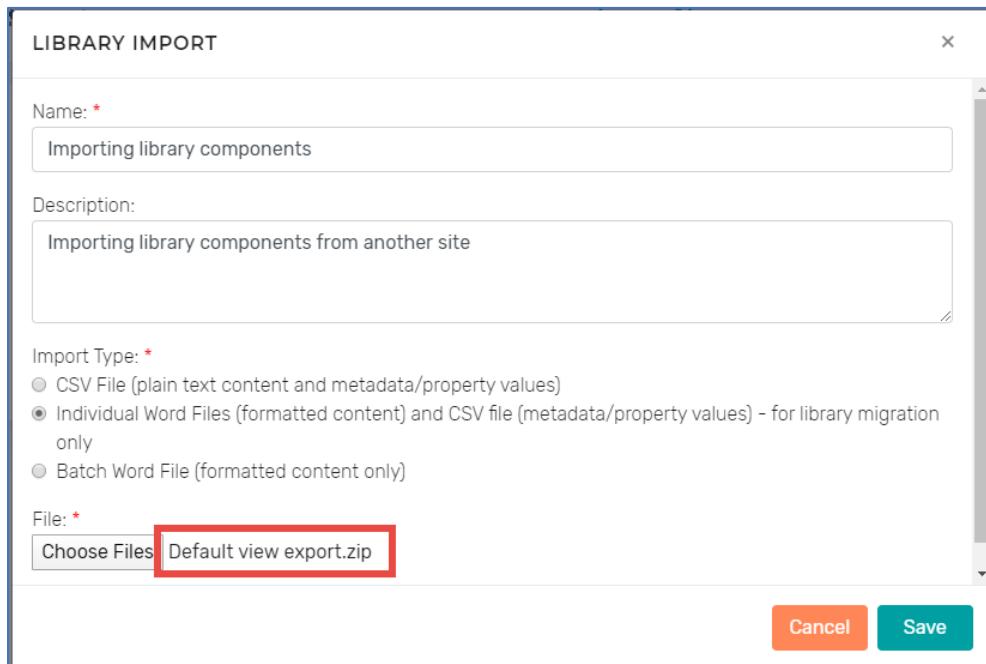
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22. Select the appropriate file and click **Open**.



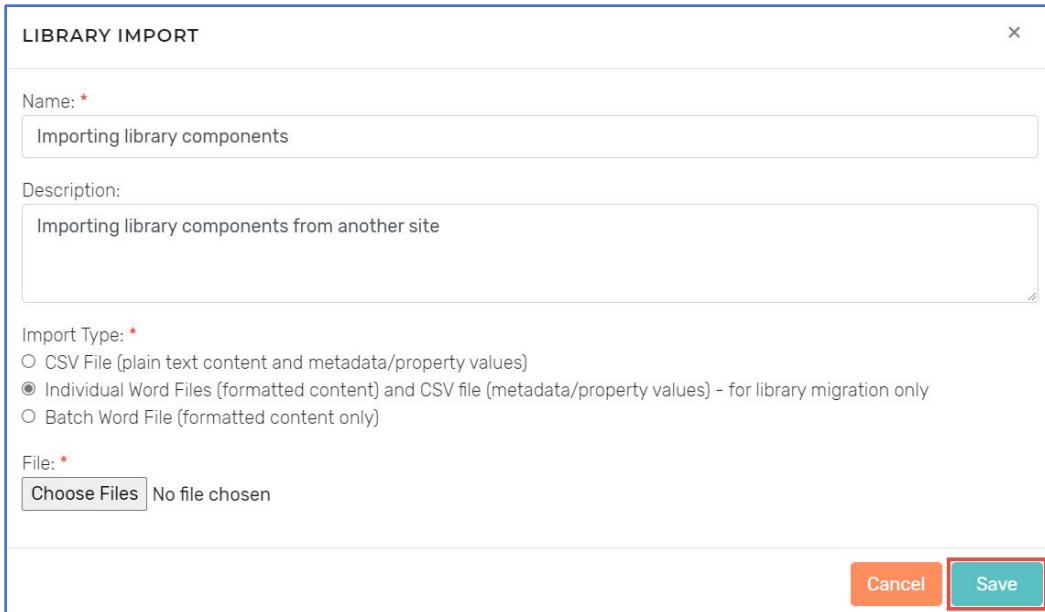
- The selected file name will appear beside the **Choose File** button in the **Import Job** form.



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23. Click on **Save** to complete the creation of an import job.



LIBRARY IMPORT

Name: *
Importing library components

Description:
Importing library components from another site

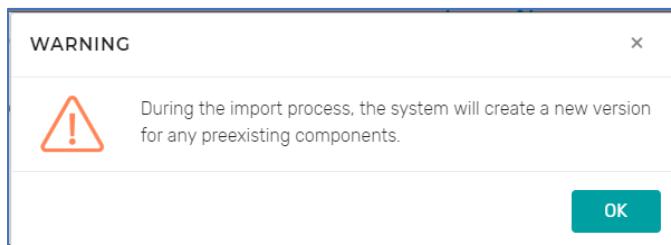
Import Type: *

CSV File (plain text content and metadata/property values)
 Individual Word Files (formatted content) and CSV file (metadata/property values) - for library migration only
 Batch Word File (formatted content only)

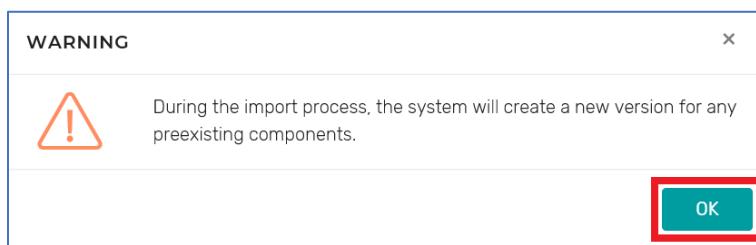
File: *
Choose Files No file chosen

Cancel **Save**

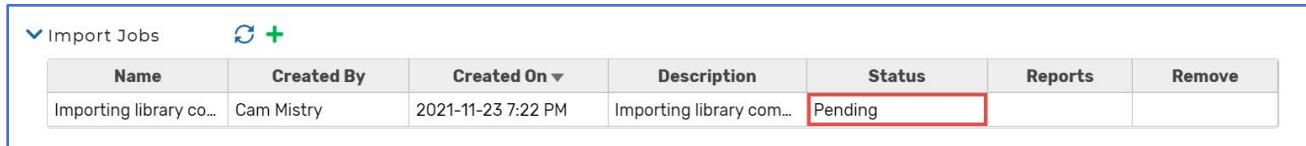
- A **Warning** message will display on the screen.



24. Click **OK** to continue.



- The new import job will appear in the tabular list with a **Pending** status.



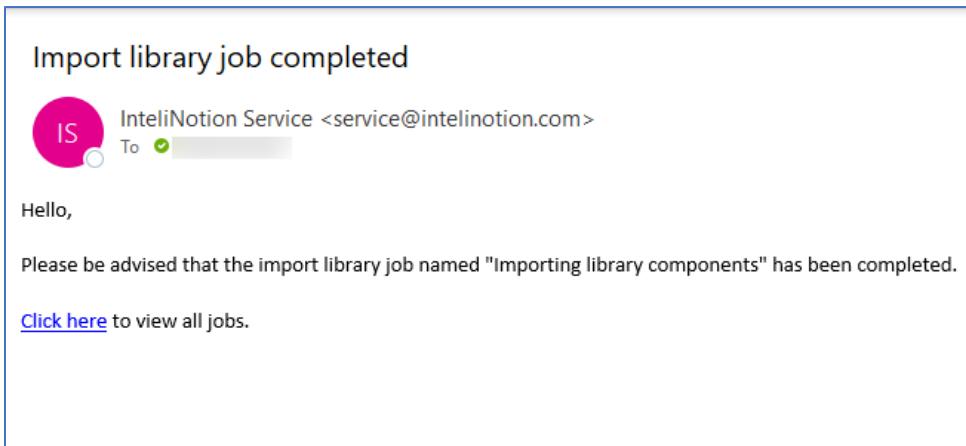
Import Jobs  

Name	Created By	Created On ▾	Description	Status	Reports	Remove
Importing library co...	Cam Mistry	2021-11-23 7:22 PM	Importing library com...	Pending		

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25. Once the **Import** is completed, the user will receive a job completion email. Click on the link in the email to access the import jobs page.



Import library job completed

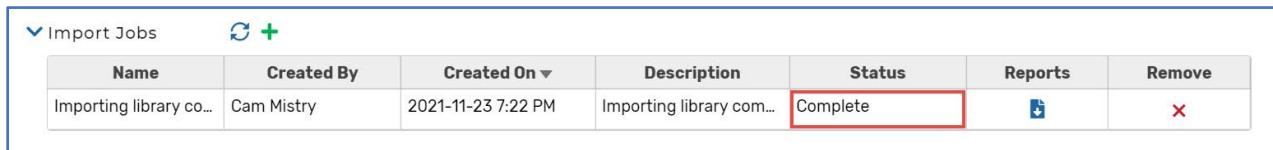
IS InteliNotion Service <service@intelinotion.com>
To: Cam Mistry

Hello,

Please be advised that the import library job named "Importing library components" has been completed.

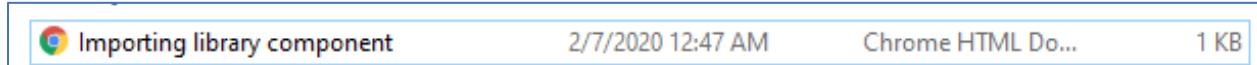
[Click here](#) to view all jobs.

- The **Export/Import Job** page will appear on the screen with the completed job listed below.



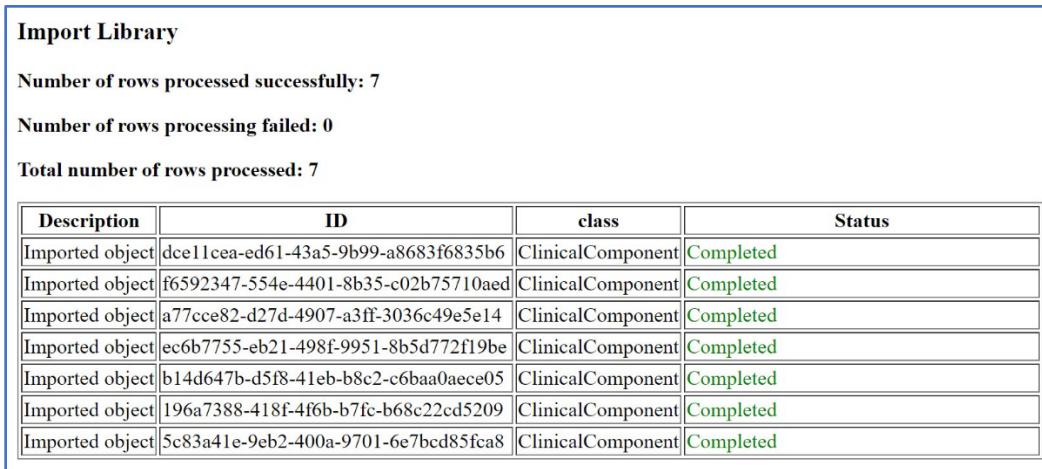
Name	Created By	Created On	Description	Status	Reports	Remove
Importing library co...	Cam Mistry	2021-11-23 7:22 PM	Importing library com...	Complete		

26. Click on the download link of the completed job and an HTML file will be downloaded to the user's machine. Double click on the file to open it and determine the status of importing each library component.



Importing library component 2/7/2020 12:47 AM Chrome HTML Do... 1 KB

27. The status of the import of each library component will be listed in the status file.



Import Library

Number of rows processed successfully: 7

Number of rows processing failed: 0

Total number of rows processed: 7

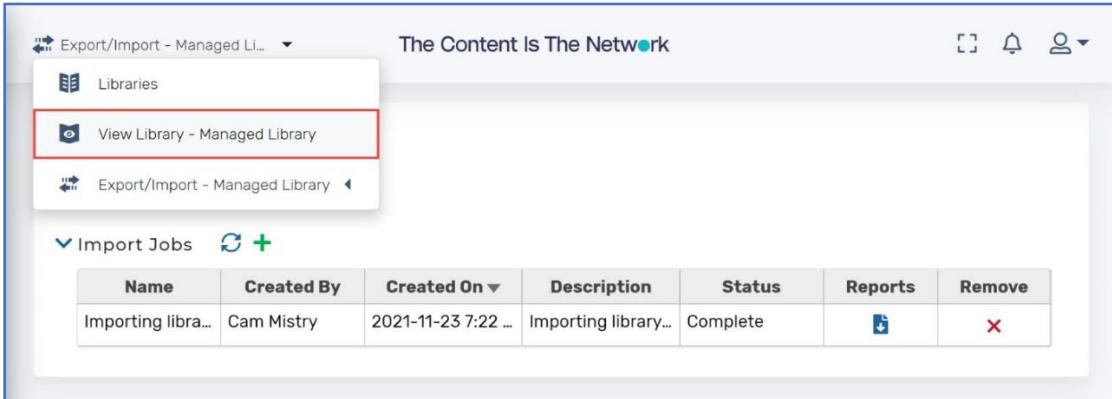
Description	ID	class	Status
Imported object	dce11cea-ed61-43a5-9b99-a8683f6835b6	ClinicalComponent	Completed
Imported object	f6592347-554e-4401-8b35-c02b75710aed	ClinicalComponent	Completed
Imported object	a77cce82-d27d-4907-a3ff-3036c49e5e14	ClinicalComponent	Completed
Imported object	ec6b7755-eb21-498f-9951-8b5d772f19be	ClinicalComponent	Completed
Imported object	b14d647b-d5f8-41eb-b8c2-c6baa0aece05	ClinicalComponent	Completed
Imported object	196a7388-418f-4f6b-b7fc-b68c22cd5209	ClinicalComponent	Completed
Imported object	5c83a41e-9eb2-400a-9701-6e7bcd85fca8	ClinicalComponent	Completed

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Note: After a library component is deleted, but left in the Recycle Bin, if it is included in the imported bulk library file, it will be auto-restored and up-versioned after the import completes.

28. Switch back to the library view by selecting **Library View** from the drop-down list as shown below.

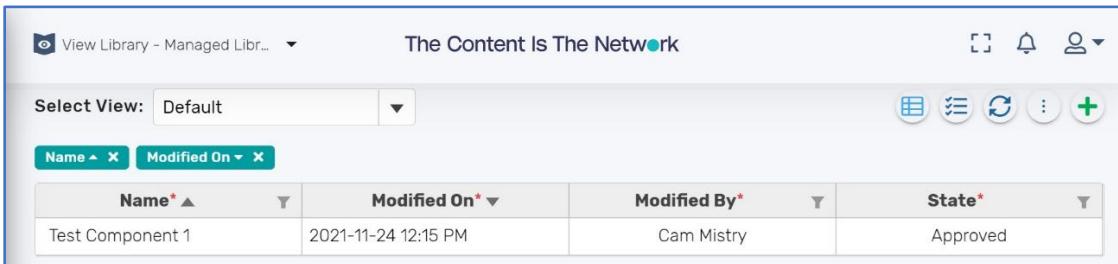


The Content Is The Network

Export/Import - Managed Li... Libraries View Library - Managed Library Export/Import - Managed Library Import Jobs +

Name	Created By	Created On	Description	Status	Reports	Remove
Importing libra...	Cam Mistry	2021-11-23 7:22 ...	Importing library...	Complete		

- The existing library components (if any) or empty space with the **Show approved only** button displayed at the top-right corner will appear on the screen.



The Content Is The Network

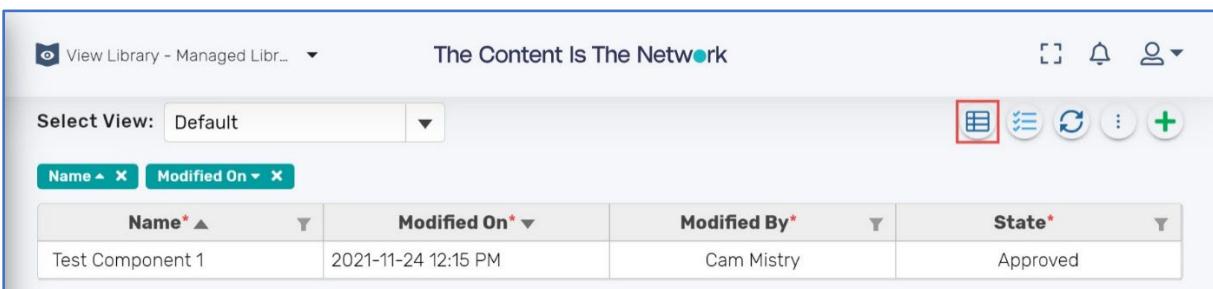
Select View: Default

Name ▲ X Modified On ▼

Name*	Modified On*	Modified By*	State*
Test Component 1	2021-11-24 12:15 PM	Cam Mistry	Approved

Note: If the **Show Approved Only icon** has as an active icon displayed, then only the most recently approved versions of existing components are shown.

29. Click on the icon to switch the view to **Show all**, which will display all the components in their current states.



The Content Is The Network

Select View: Default

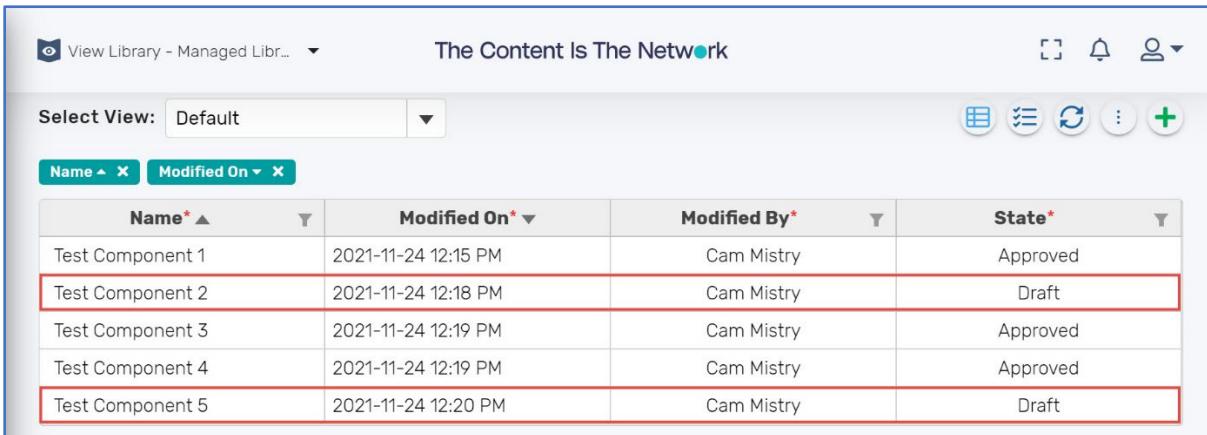
Name ▲ X Modified On ▼

Name*	Modified On*	Modified By*	State*
Test Component 1	2021-11-24 12:15 PM	Cam Mistry	Approved

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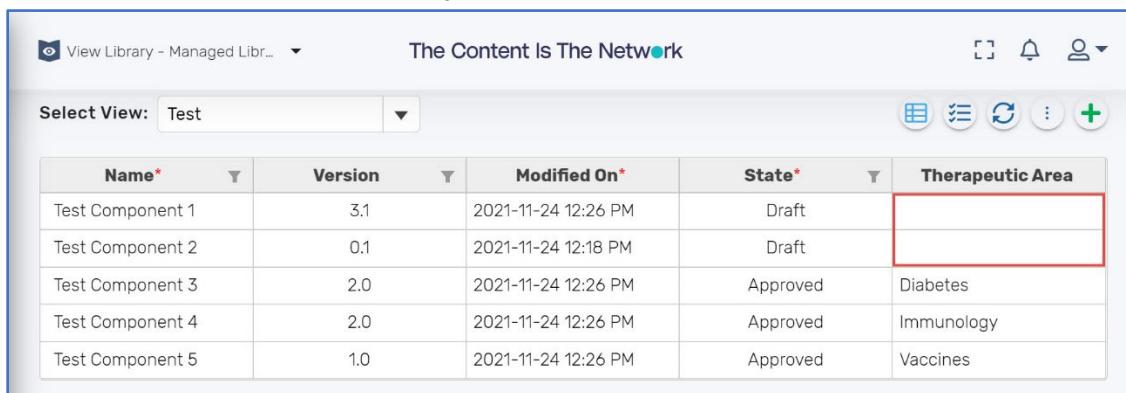
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- The newly added components will be in a **Draft** state as **Version 0.1** with no metadata assigned to them.



Name*	Modified On*	Modified By*	State*
Test Component 1	2021-11-24 12:15 PM	Cam Mistry	Approved
Test Component 2	2021-11-24 12:18 PM	Cam Mistry	Draft
Test Component 3	2021-11-24 12:19 PM	Cam Mistry	Approved
Test Component 4	2021-11-24 12:19 PM	Cam Mistry	Approved
Test Component 5	2021-11-24 12:20 PM	Cam Mistry	Draft

30. Assign metadata/properties as appropriate and approve the components so that they appear in **Show approved only** list to all the users.



Name*	Version	Modified On*	State*	Therapeutic Area
Test Component 1	3.1	2021-11-24 12:26 PM	Draft	
Test Component 2	0.1	2021-11-24 12:18 PM	Draft	
Test Component 3	2.0	2021-11-24 12:26 PM	Approved	Diabetes
Test Component 4	2.0	2021-11-24 12:26 PM	Approved	Immunology
Test Component 5	1.0	2021-11-24 12:26 PM	Approved	Vaccines

For example:

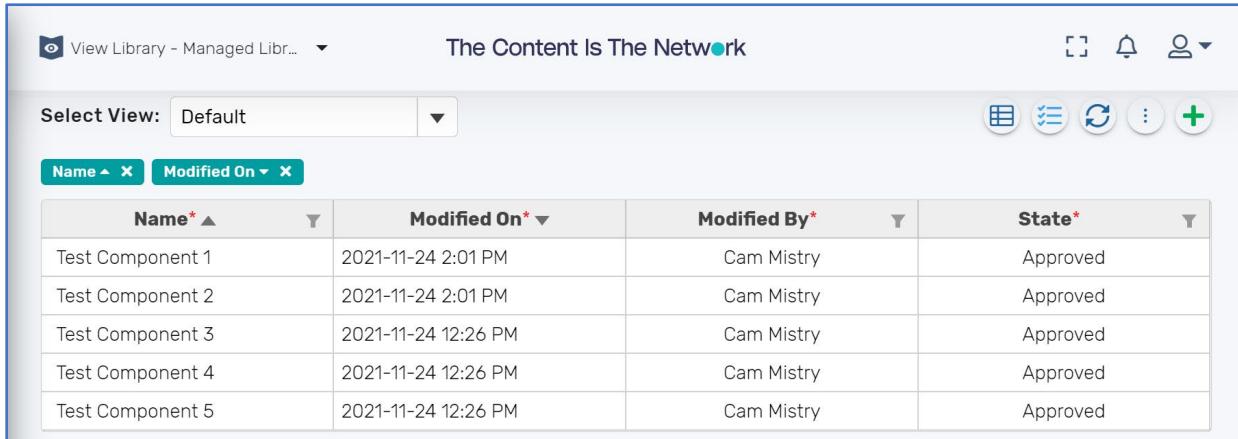


Name*	Version	Modified On*	State*	Therapeutic Area
Test Component 1	4.0	2021-11-24 2:01 PM	Approved	Oncology
Test Component 2	1.0	2021-11-24 2:01 PM	Approved	Oncology
Test Component 3	2.0	2021-11-24 12:26 PM	Approved	Diabetes
Test Component 4	2.0	2021-11-24 12:26 PM	Approved	Immunology
Test Component 5	1.0	2021-11-24 12:26 PM	Approved	Vaccines

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31. Click on the  icon to view the most recently approved versions of the components. For example:



The screenshot shows a software application window titled "The Content Is The Network". At the top, there's a navigation bar with a "View Library - Managed Libr..." dropdown, a search bar containing "The Content Is The Network", and user icons for notifications and profile. Below the navigation is a toolbar with icons for "Select View: Default", "grid icon", "list icon", "refresh icon", "more options icon", and a "plus sign icon". Underneath the toolbar is a table with the following data:

Name*	Modified On*	Modified By*	State*
Test Component 1	2021-11-24 2:01 PM	Cam Mistry	Approved
Test Component 2	2021-11-24 2:01 PM	Cam Mistry	Approved
Test Component 3	2021-11-24 12:26 PM	Cam Mistry	Approved
Test Component 4	2021-11-24 12:26 PM	Cam Mistry	Approved
Test Component 5	2021-11-24 12:26 PM	Cam Mistry	Approved

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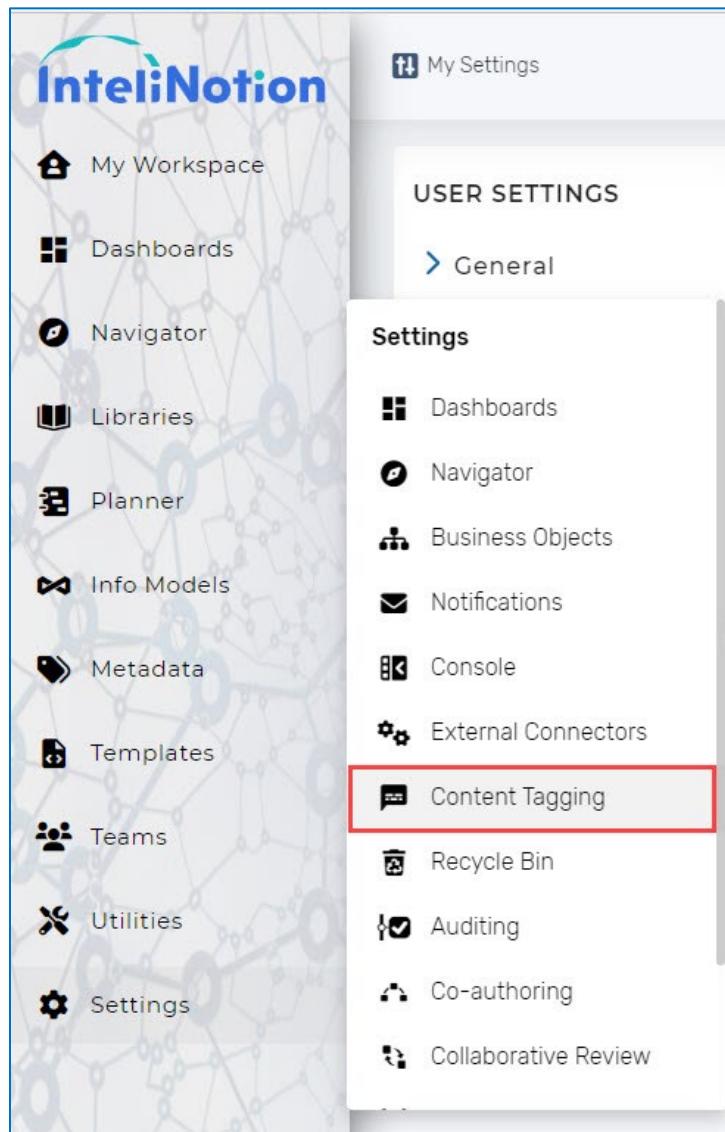
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7. CONTENT TAGGING

Applying component and content tags allows a user to redact specific information in a document, as per policies, such as in European Medicines Agency (EMA) Policy 70.

7.1 CREATING A COMPONENT OR CONTENT TAG

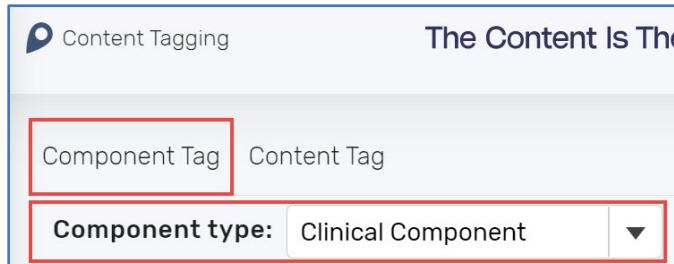
1. Select Settings from the left navigation pane and click **Content Tagging**.



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2. To apply a component-level tag, ensure the **Component Tag** tab is highlighted, and select the relevant **Component Type** from the drop-down (based on the type of Component business object for which a tag needs to be created).



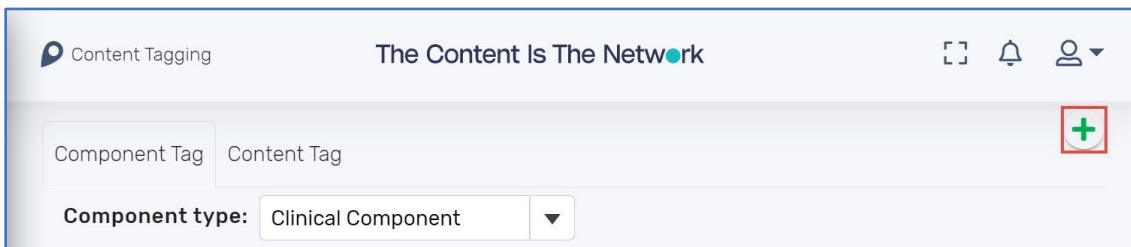
The Content Is The Network

Content Tagging

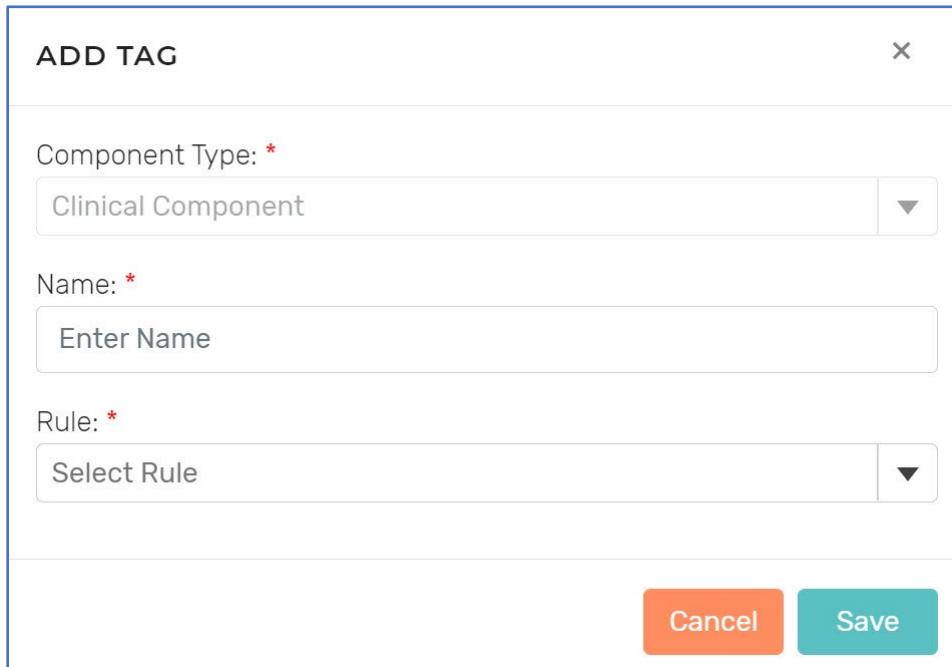
Component Tag Content Tag

Component type: Clinical Component

3. Click on the plus sign icon .



4. The **Add Tag** form will display.



ADD TAG

Component Type: *

Clinical Component

Name: *

Enter Name

Rule: *

Select Rule

Cancel

Save

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5. Enter the **Name** and the **Rule** in the form and click **Save**.

ADD TAG

Component Type: *

Clinical Component

Name: *

Test Tag

Rule: *

Delete

Cancel Save

Note: The **only** rule currently supported is Delete.

6. The form is saved, and the tag is displayed.

Test Tag	Delete	Cam Mistry	2021-11-24 3:27 PM
----------	--------	------------	--------------------

7. To apply a content-level tag, follow the steps outlined above in 4-7, but choose the **Content Tag** tab.

Content Tagging The Content Is The Network

Component Tag Content Tag

Component type: Clinical Component

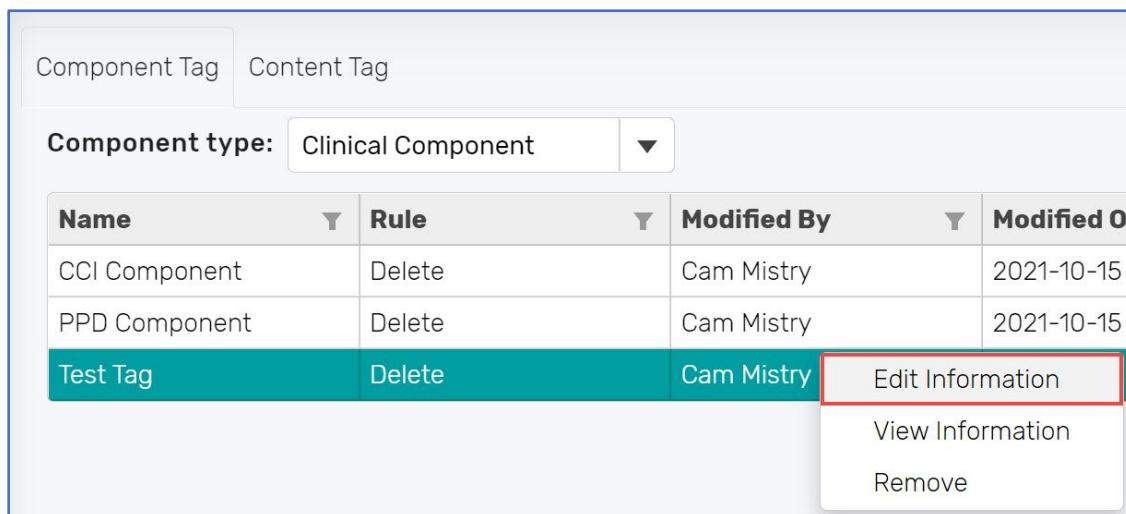
Name	Rule	Modified By	Modified On
CCI Component	Delete	Cam Mistry	2021-10-15 4:17 PM
PPD Component	Delete	Cam Mistry	2021-10-15 4:17 PM
Test Tag	Delete	Cam Mistry	2021-11-24 3:27 PM

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7.2 EDITING A COMPONENT OR CONTENT TAG

1. Select the recently created tag in the steps above, right-click on the tag, and select **Edit Information**.

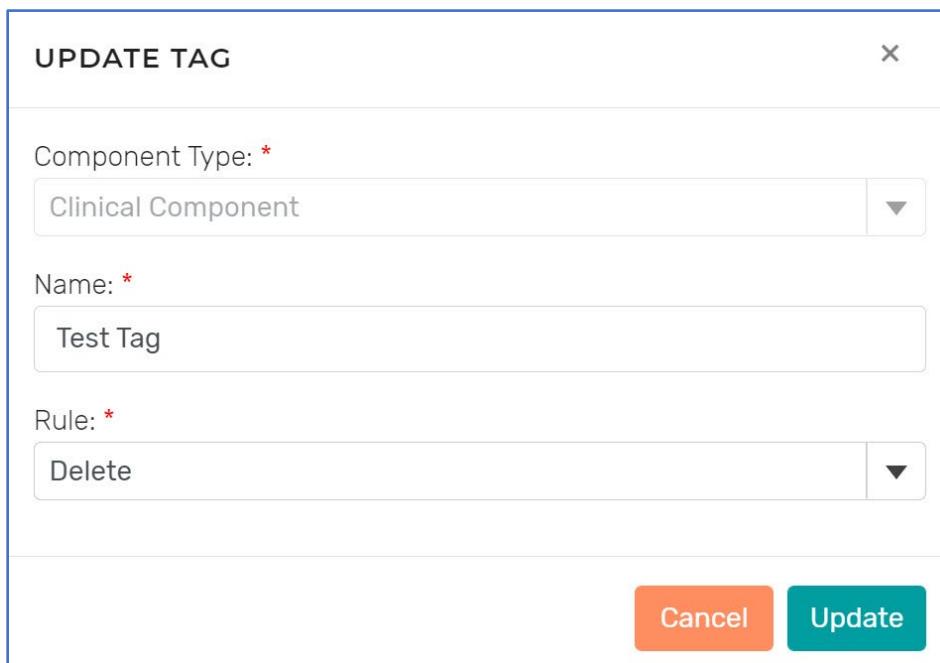


A screenshot of a software interface showing a list of components. At the top, there are two tabs: "Component Tag" and "Content Tag". Below the tabs, a dropdown menu shows "Component type: Clinical Component". The main area is a table with columns: Name, Rule, Modified By, and Modified On. There are four rows in the table:

Name	Rule	Modified By	Modified On
CCI Component	Delete	Cam Mistry	2021-10-15 4:30:00 PM
PPD Component	Delete	Cam Mistry	2021-10-15 4:30:00 PM
Test Tag	Delete	Cam Mistry	2021-10-15 4:30:00 PM

A context menu is open over the last row ("Test Tag"). The menu items are: "Edit Information" (highlighted with a red box), "View Information", and "Remove".

2. The **Update Tag** form will display.



A screenshot of the "UPDATE TAG" form. The title bar says "UPDATE TAG" and has a close button "X". The form fields are:

- Component Type: *
Clinical Component
- Name: *
Test Tag
- Rule: *
Delete

At the bottom right are two buttons: "Cancel" (orange) and "Update" (green).

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3. Update the tag's information (eg, Name), as needed, and click **Update**.

UPDATE TAG

Component Type: *	<input type="text" value="Clinical Component"/>
Name: *	<input type="text" value="Test Delete Tag"/>
Rule: *	<input type="text" value="Delete"/>

Cancel
Update

4. The tag is updated.

Component Tag		Content Tag	
Component type: Clinical Component			
Name	Rule	Modified By	Modified On
CCI Component	Delete	Cam Mistry	2021-10-15 4:17 PM
PPD Component	Delete	Cam Mistry	2021-10-15 4:17 PM
Test Delete Tag	Delete	Cam Mistry	2021-11-24 3:38 PM

5. To view a tag's information, right-click on the tag and click **View Information**.

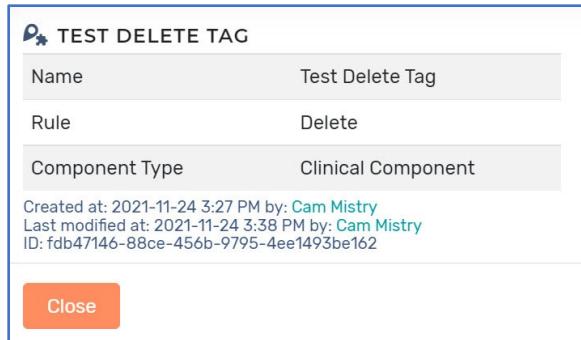
Component type: Clinical Component			
Name	Rule	Modified By	Modified On
CCI Component	Delete	Cam Mistry	2021-10-15 4:17 PM
PPD Component	Delete	Cam Mistry	2021-10-15 4:17 PM
Test Delete Tag	Delete	Cam Mistry	2021-11-24 3:38 PM

Edit Information
View Information
Remove

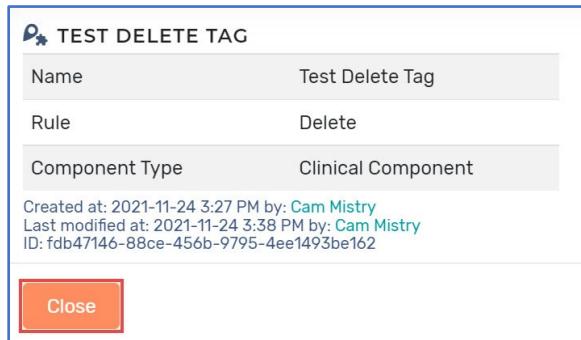
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6. The **View Component Tag Information** tab will display.



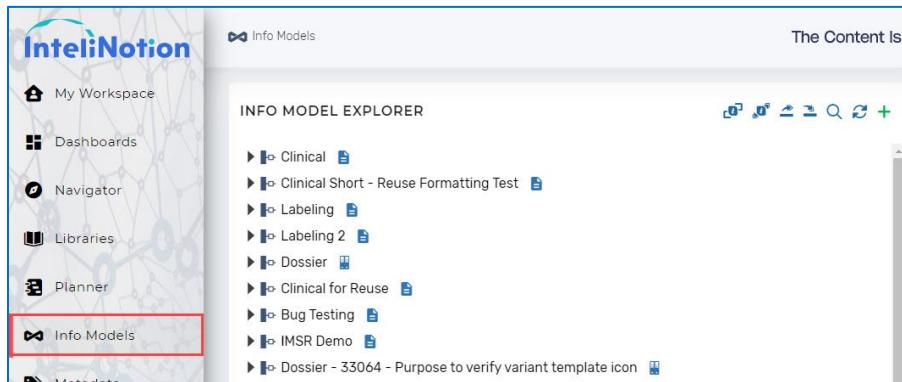
7. After viewing the relevant information about the tag, click **Close**.



7.3 ADDING A COMPONENT TAG TO AN ELEMENT IN THE INFO MODEL AND TEMPLATE

After a component tag has been created, it can be added to an element in the info model. The element can then be inserted into a document template so that once a document is generated from it, the instantiated component will already be tagged.

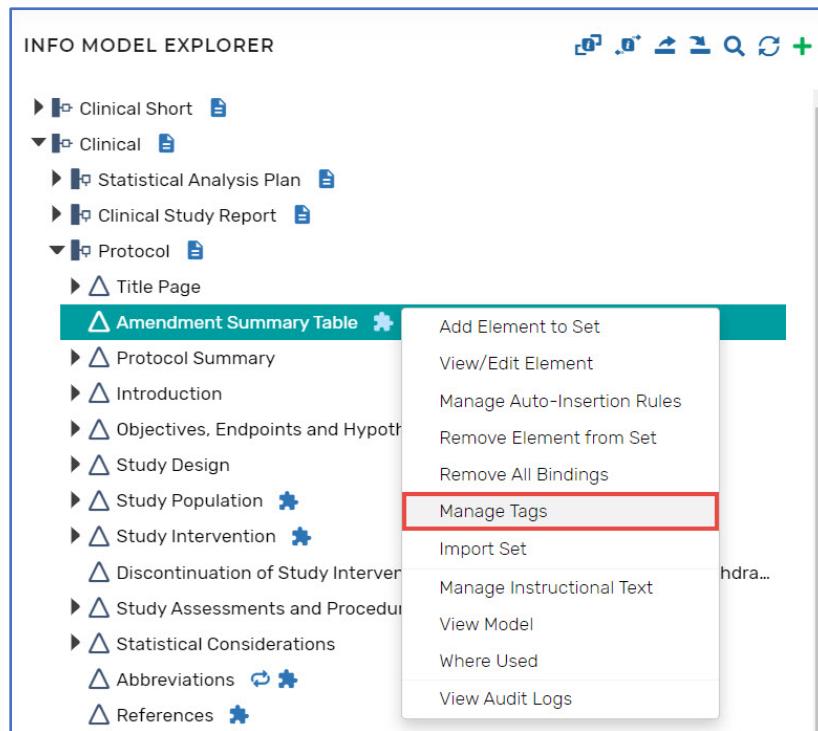
1. In the *Web Console*, select **Info Models** from the left Navigator pane. The Info Model Explorer will display.



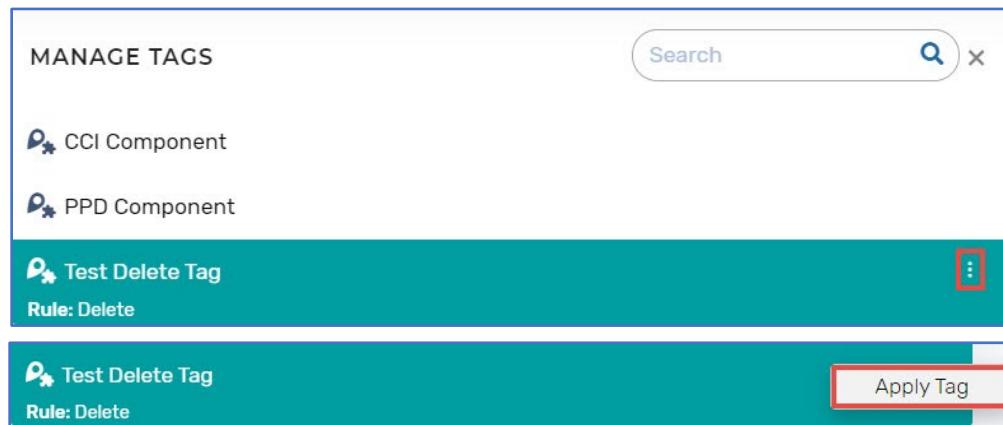
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2. Navigate to the preferred element in the info model, the element is highlighted. Right-click on the element and click **Manage Tags**.



3. The **Manage Tags** menu will display on the right-hand side. Select the preferred tag to apply to the element, click on the vertical ellipsis ⋮ button next to it, and click **Apply Tag**.



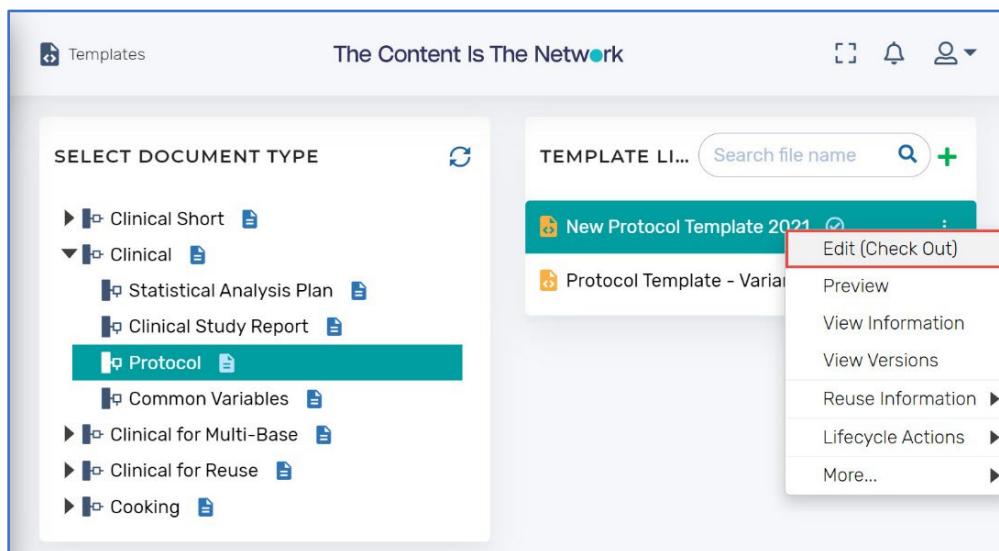
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4. The tag is applied to the element and the **Component tag binding icon**  will display next to the element.



5. To make the tag effective, the recently tagged element will have to be updated in the existing template where it was previously used. Navigate to a recent template and **Edit (Check Out)** the template.



Notes:

If applied to an element inserted in a template, tag is retained on the instantiated component in the generated document in the following cases:

- De novo (empty)
- AI library components - as is or repurpose
- Reused components from upstream document - as is or repurpose

If applied to a component within document (either via original element or manually in document by user), the tag is not retained in the following cases:

If the component has another component reused into it via the Word App

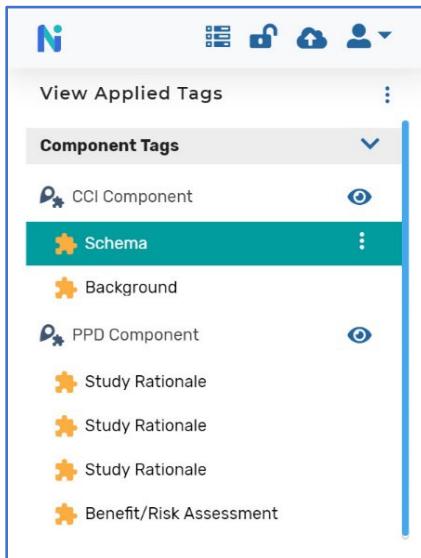
With the component if/when it gets reused in other documents

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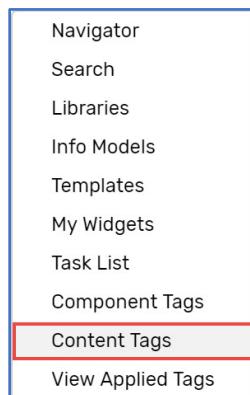
6. As a component tag change to a single element will not be detected in the IMSR, the user must manually delete the existing element, save the template, insert the updated element, then save (and check in) the template (see [Section 3.3.3](#)).
7. Click the **vertical ellipsis**  button on the top of the *IntelNotion Word App* and select **View Applied Tags** to see which tags are applied to elements/components in the template.



7.4 ADDING A CONTENT TAG TO A TEMPLATE

After a content tag has been created, it can be added to any prepopulated content within a template (eg, the content within a base component; see [Section 4](#)). Once a document is generated from the template, the prepopulated content from the template will already be tagged.

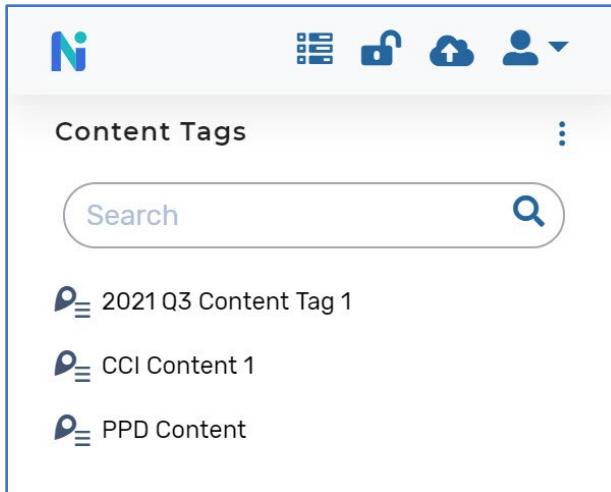
1. **Edit (Check out)** the relevant template.
2. From the top of the *IntelNotion Word App*, click on the **vertical ellipsis**  button and select **Content Tags**.



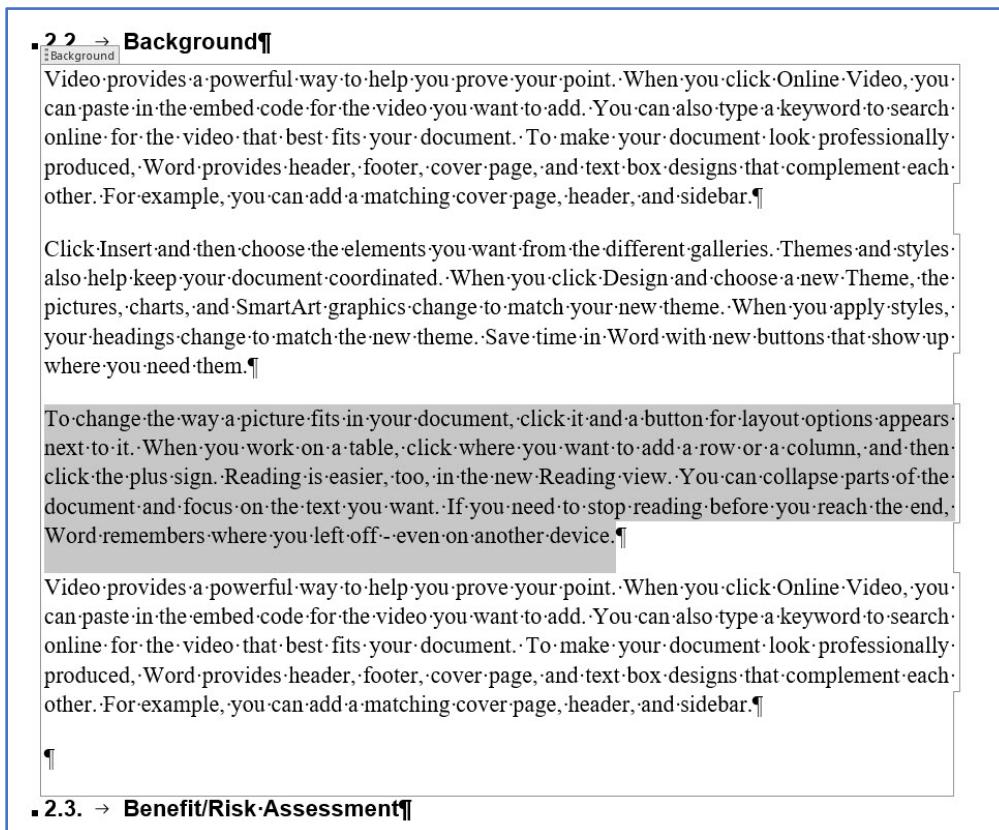
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3. Available **Content Tags** will be listed.



4. Navigate to the relevant content within an existing base component (or within the document itself) that needs to be tagged and select (highlight) the text.



2.2 → Background

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. You can also type a keyword to search online for the video that best fits your document. To make your document look professionally produced, Word provides header, footer, cover page, and text box designs that complement each other. For example, you can add a matching cover page, header, and sidebar.

Click Insert and then choose the elements you want from the different galleries. Themes and styles also help keep your document coordinated. When you click Design and choose a new Theme, the pictures, charts, and SmartArt graphics change to match your new theme. When you apply styles, your headings change to match the new theme. Save time in Word with new buttons that show up where you need them.

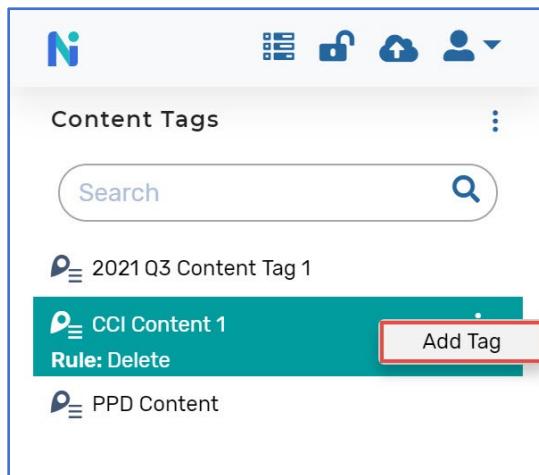
To change the way a picture fits in your document, click it and a button for layout options appears next to it. When you work on a table, click where you want to add a row or a column, and then click the plus sign. Reading is easier, too, in the new Reading view. You can collapse parts of the document and focus on the text you want. If you need to stop reading before you reach the end, Word remembers where you left off--even on another device.

2.3. → Benefit/Risk-Assessment

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5. From the list of available content tags, select the one to be used, click on the ellipsis next to it, and click **Add Tag**.



6. A *Tag applied successfully* message will display, and the tag is applied to the content itself with **Content Tag** as its title.

 Tag applied successfully.

▪ 2.2 → **Background¶**

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. You can also type a keyword to search online for the video that best fits your document. To make your document look professionally produced, Word provides header, footer, cover page, and text box designs that complement each other. For example, you can add a matching cover page, header, and sidebar.¶

Click Insert and then choose the elements you want from the different galleries. Themes and styles also help keep your document coordinated. When you click Design and choose a new Theme, the pictures, charts, and SmartArt graphics change to match your new theme. When you apply styles, your headings change to match the new theme. Save time in Word with new buttons that show up where you need them.¶

▪ Content Tag

To change the way a picture fits in your document, click it and a button for layout options appears next to it. When you work on a table, click where you want to add a row or a column, and then click the plus sign. Reading is easier, too, in the new Reading view. You can collapse parts of the document and focus on the text you want. If you need to stop reading before you reach the end, Word remembers where you left off—even on another device.¶

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. You can also type a keyword to search online for the video that best fits your document. To make your document look professionally produced, Word provides header, footer, cover page, and text box designs that complement each other. For example, you can add a matching cover page, header, and sidebar.¶

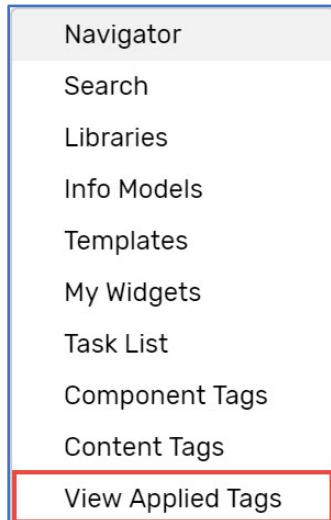
¶

▪ 2.3. → **Benefit/Risk Assessment¶**

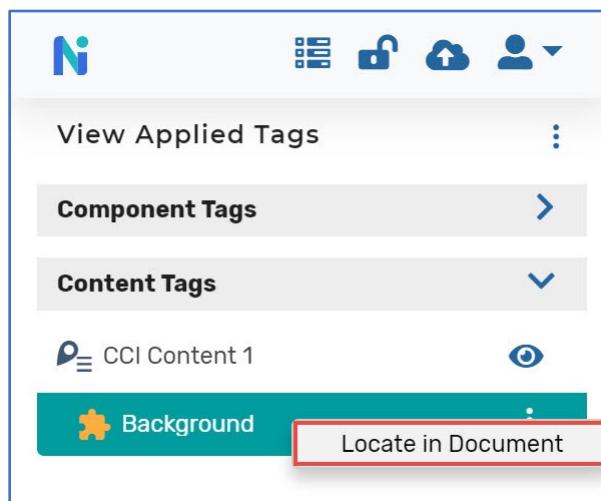
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7. Click on the **vertical ellipsis**  button and choose View Applied Tags.



8. A list of applied tags appears. Click on the **vertical ellipsis**  button and select **Locate in Document**.



9. When finished editing, **Save & Check In** the template.

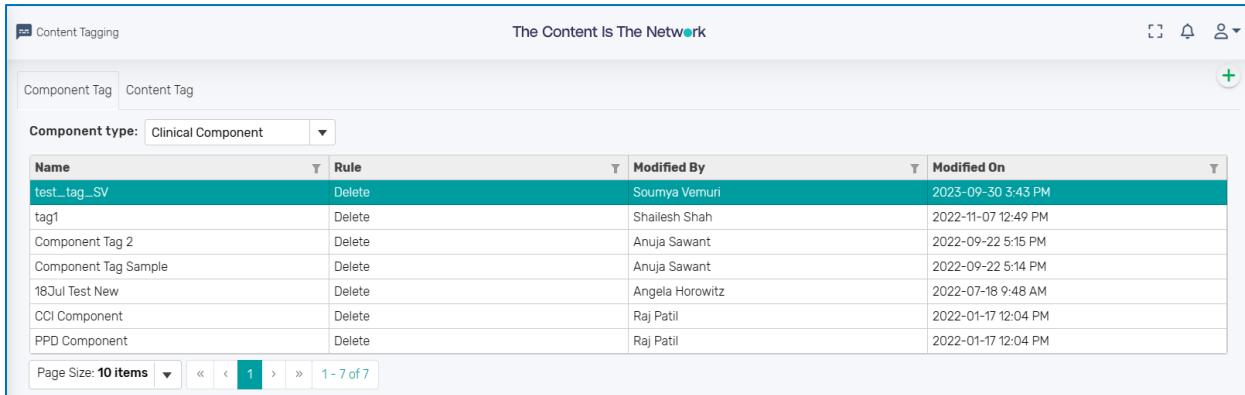
7.5 REMOVING A COMPONENT OR CONTENT TAG

It is possible to remove component or content tags at a system level, or when publishing a rendition of a document. To remove a component or content tag in these situations, follow the steps listed below.

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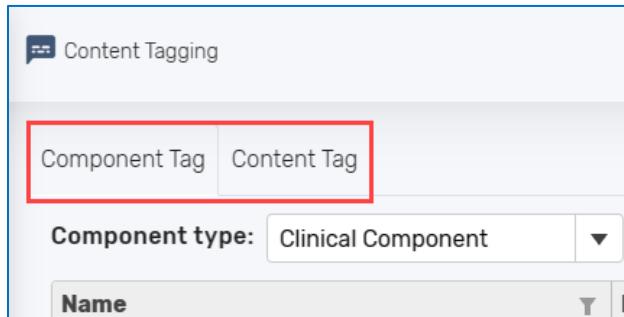
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1. In the *Web Console* left hand navigation pane, hover over **Settings** and click **Content Tagging**. The **Content Tagging** screen will display.



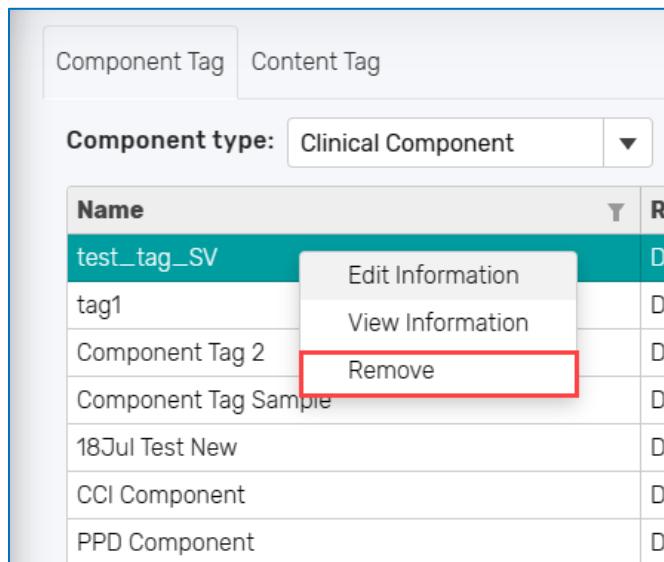
The screenshot shows the 'Content Tagging' screen with a table listing various components. The table has columns for Name, Rule, Modified By, and Modified On. A dropdown menu at the top indicates 'Component type: Clinical Component'. The table includes rows for 'test_tag_SV', 'tag1', 'Component Tag 2', 'Component Tag Sample', '18Jul Test New', 'CCI Component', and 'PPD Component'. The 'test_tag_SV' row is highlighted in green. The 'Modified On' column shows dates ranging from 2022-01-17 to 2023-09-30. At the bottom, there is a page navigation bar showing 'Page Size: 10 items' and '1 - 7 of 7'.

2. Navigate to the applicable area by clicking on either the **Component Tag** or **Content Tag** tabs.



The screenshot shows the 'Content Tagging' screen with the 'Component Tag' tab selected, indicated by a red box around the tab. The 'Content Tag' tab is also visible. A dropdown menu at the top indicates 'Component type: Clinical Component'. Below the tabs, there is a search bar with the placeholder 'Name'.

3. Right click on the component or content tag to be removed and choose Remove.

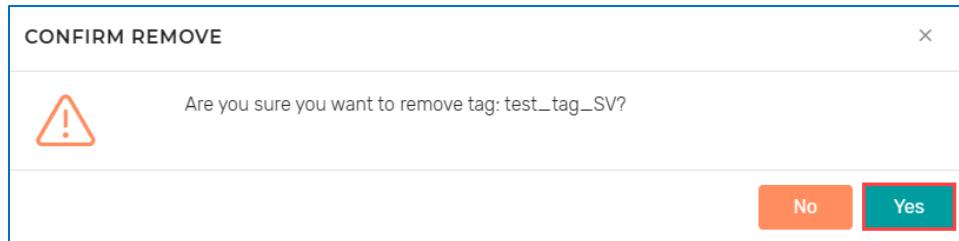


The screenshot shows the 'Content Tagging' screen with the 'Component Tag' tab selected. A context menu is open over the 'test_tag_SV' row, with options 'Edit Information', 'View Information', and 'Remove'. The 'Remove' option is highlighted with a red box. The 'Content Tag' tab is also visible. A dropdown menu at the top indicates 'Component type: Clinical Component'. Below the tabs, there is a search bar with the placeholder 'Name'.

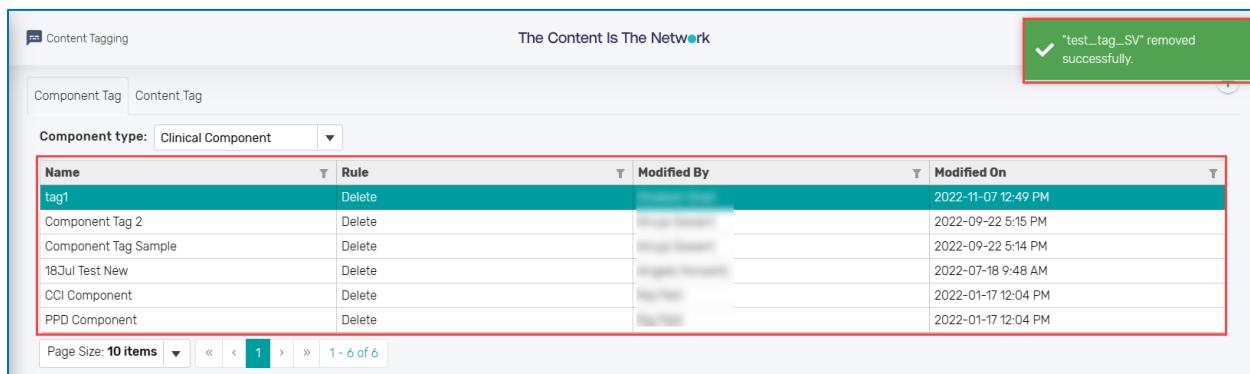
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4. The Confirm Remove pop-up window will display. Click Yes.



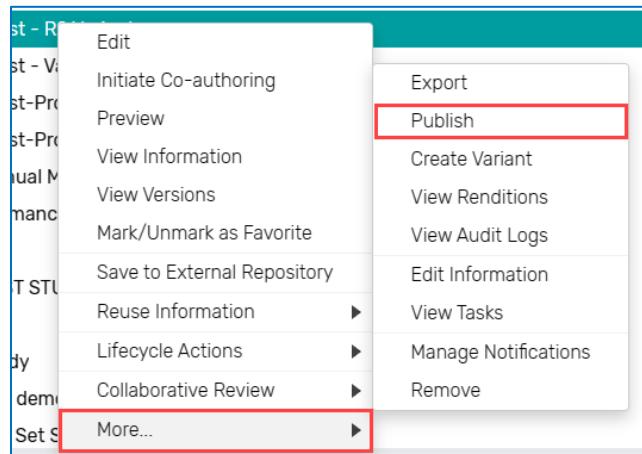
5. A message informing the user that the tag was removed successfully will display, and the tag will no longer appear in the applicable table.



Name	Rule	Modified By	Modified On
tag1	Delete		2022-11-07 12:49 PM
Component Tag 2	Delete		2022-09-22 5:15 PM
Component Tag Sample	Delete		2022-09-22 5:14 PM
1B3JL Test New	Delete		2022-07-18 9:48 AM
CCI Component	Delete		2022-01-17 12:04 PM
PPD Component	Delete		2022-01-17 12:04 PM

OR

1. In the *Web Console* Navigator, locate the document to be published, right click, hover over **More** and select **Publish**.



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2. The **Publish Document: Basic** pop-up window will display.

PUBLISH DOCUMENT: BASIC

Document Name: *

Component Tags:

Content Tags:

Cancel **Next**

3. Select the component or content tags to be removed from the applicable drop-down menu.

PUBLISH DOCUMENT: BASIC

Document Name: *

Component Tags:

Select All
 CCI Component
 PPD Component

Cancel **Next**

4. The tags to be removed will display underneath the menu once selected. Click **Next** and continue to publish the document as normal (see **InteliNotion User Guide Module 11** for detailed publication steps).

PUBLISH DOCUMENT: BASIC

Document Name: *

Component Tags:

1. CCI Component
2. PPD Component

Content Tags:

Cancel **Next**

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8. SUPPORTING ACTIVITIES FOR DOCUMENT AUTHORING

Please see the section below for instructions on completing various authoring functions in *InteliNotion*.

8.1 REINSERTING A PREVIOUSLY DELETED COMPONENT BACK INTO THE DOCUMENT

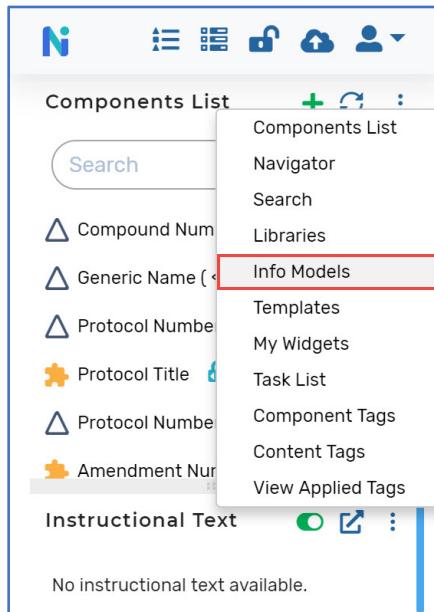
After deleting a component from the document, a new instance of the deleted component can be inserted by an authorized user, if/when deemed necessary. The newly inserted component will be added as an empty placeholder; any prior content added to the component before its deletion will not be included.

Notes

- The user must have the **Info Models** functional permission to perform this action.

If a downstream document had not yet been generated, then reuse of the newly inserted component will still work as expected per the info model's policy, if/when the new document is generated later.

1. **Edit** the relevant document.
2. Navigate to the location in the document where a new instance of the deleted component needs to be inserted. Place the cursor in this location.
3. In the *InteliNotion Word App*, click on the **vertical ellipsis :** button, and click **Info Models**.

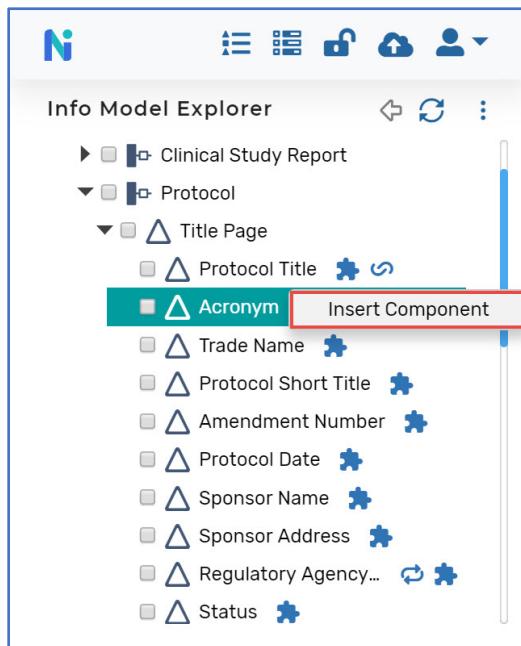


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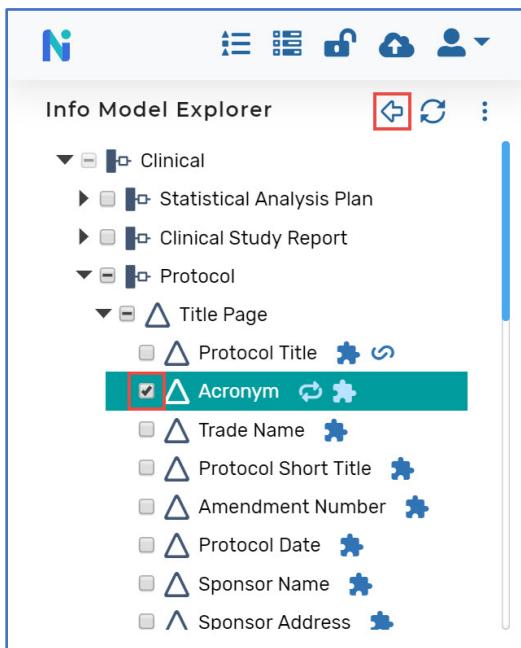
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4. Navigate to the appropriate element (ie, the 1 that relates to the deleted component) in the **Info Model Explorer**, right-click on it, and click **Insert Component**.



OR

1. Check the box beside the element and then click the **Insert selected element arrow icon** shown below.



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2. An empty component is inserted into the document. If the content of the original component that was deleted is needed, see step 4.

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: Enter Acronym

Sponsor Name: Enter Sponsor Name

Legal Registered Address: Enter Sponsor Address

Regulatory Agency Identifier Number(s)

IND: 123,456

EudraCT: 2018-789789-01

3. **Save** and check in the document, and then notify the user that the document has been updated as requested if needed.
4. If the original component needs to be reinserted/reused, the deleted component must first be located in a non-managed library for orphan components, after which it can be reused into the document via the *Word* app search (Branch and Insert option is recommended).

Notes

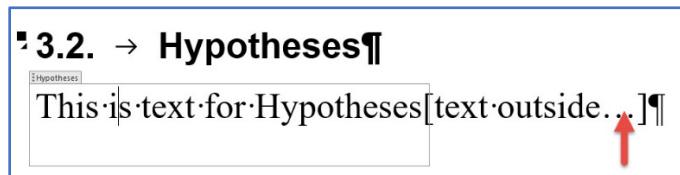
- If a new element/component was added to the document's info model after the document was initially generated, and now must be inserted into the document as a new component, this can be done using the same steps described above.
- After (re-)insertion of a component into a document, please be aware that it **cannot** be deleted if the related info model policy does not allow for deletion.

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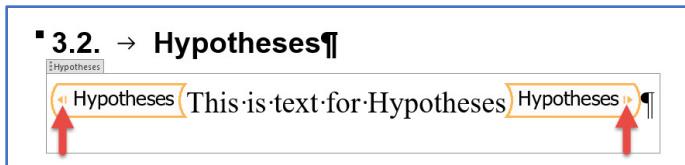
8.2 FIXING A COMPONENT TO ALLOW MULTIPLE PARAGRAPHS

A typical content component is configured as next paragraph and will allow for multiple paragraphs to be entered into it. When a component is inadvertently changed to in-line instead, a user will not be able to enter multiple paragraphs into it any longer. A component is changed to in-line if any characters are typed in the same line next to it, as shown in this example.



To quickly check if a component has been changed to in-line, turn on *MS Word's Design Mode* (on the Developer ribbon).

- Next paragraph: the component's boundaries will include a small arrow



- In-line: the component's boundaries will not include a small arrow



To fix an inline component to make it next paragraph again, follow one of the following two sets of steps:

1. Click on the component so that it is highlighted in the **Components List**.
2. Insert the cursor inside the document itself, outside of the component.
3. Click the **vertical ellipsis :** button for the highlighted component in the **Components List** and select **Insert Identical Instance**.
4. Add a new paragraph by pressing the Enter key, then add text (or a space) inside the newly inserted component.
5. Click anywhere outside the component and this will ensure the edit is synced to the initial [in-line] location, including the appropriate next paragraph setting.
6. Delete the newly inserted component instance.
7. Update the content of the initial instance, if needed (based on the edit made in step 4).

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OR

1. Click inside the inline component to be synched.
2. Press the **left arrow** key until the cursor is outside of the applicable component.
3. Press the **Enter** key.
4. Click inside the same component from steps 1 and 2.
5. Press the **right arrow** key until the cursor is outside the component
6. Press the **Enter** key.
7. Add a new paragraph in the component to verify that the admin level user can add multiple paragraphs.

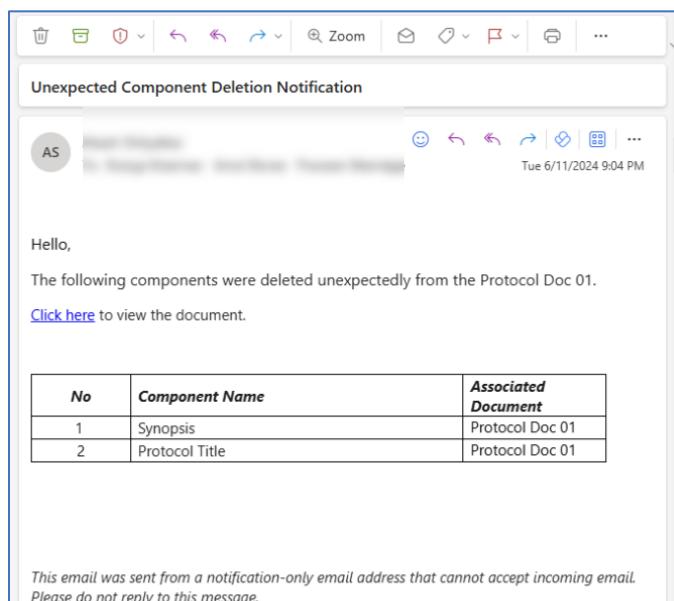
Notes:

- Both sets of steps can only be performed during single authoring, as syncing identical instances cannot be performed during co-authoring.
- Although an end-user (eg, author) could complete these steps him/herself, it is recommended that an admin-user perform this activity given the potential need for **Design Mode**, which is only enabled for users who have full control admin-level permission.

8.3 MANAGING COMPONENT DELETIONS

8.3.1 Unexpected Component Deletion Notification

When a component not configured for deletion is unexpectedly deleted, *InteliNotion* will generate a notification through the system, and send an email to the configured users.



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The following information is populated into the template by default. Some aspects are editable by full control admins or users with **Notification Template Setting** permissions, and some are not, as listed:

Non-Editable

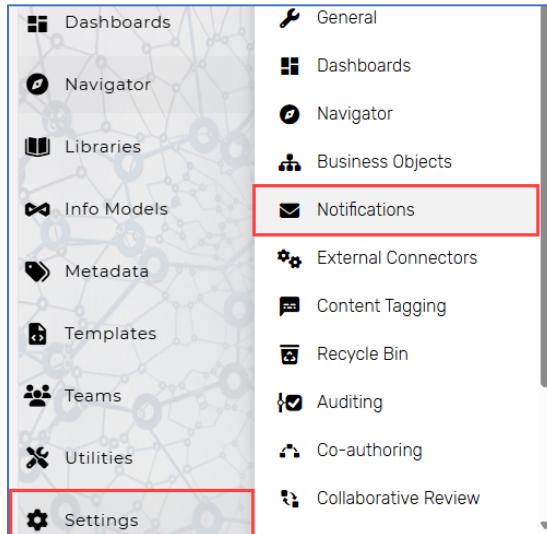
- **Name** – populated with a default value that lists the title of the notification template as "Unexpected Component Deletion Notification"
- **Type** – is listed as a Custom Event
- **Business Object(s)** – are configured as a Document type object
- **Default Business Object(s)** – this field is empty by default
- **Event** – the only event that triggers this notification template is Unexpected Component Deletion. Only one notification template is available in the system per event.

Editable

- **Subject** – the default subject line is auto populated as "Unexpected Component Deletion Notification", but can be customized as desired
- **Content** - is prepopulated as shown in the figure above, however, the text and link bindings can be customized as desired
- **Notify User(s)/Role(s)** - by default this field will be empty, and users/roles will need to be filled in by a full control admin or user with Notification Template Setting permissions

To configure the unexpected component deletion notification, follow the steps listed below.

1. In the Web Console left-hand menu, hover over **Settings** and click **Notifications**.

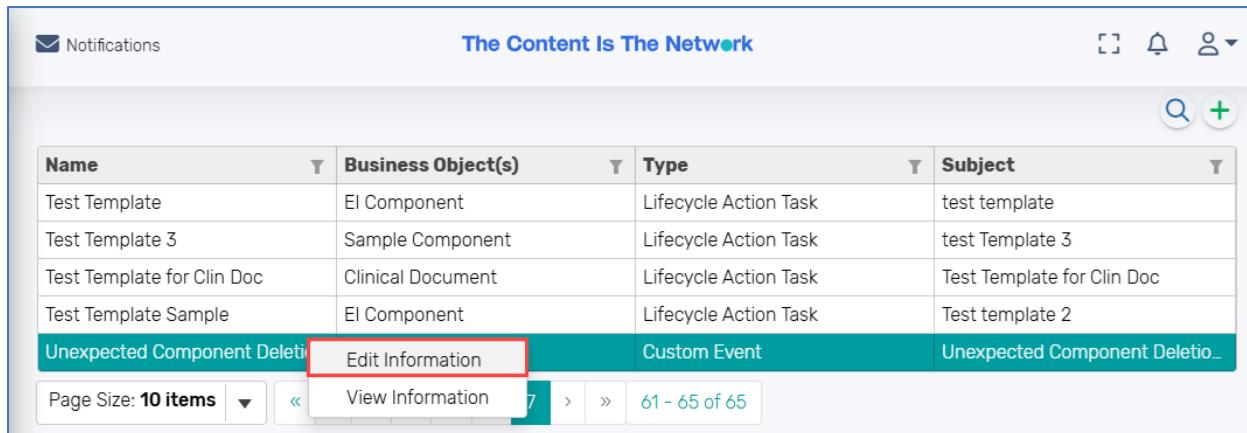


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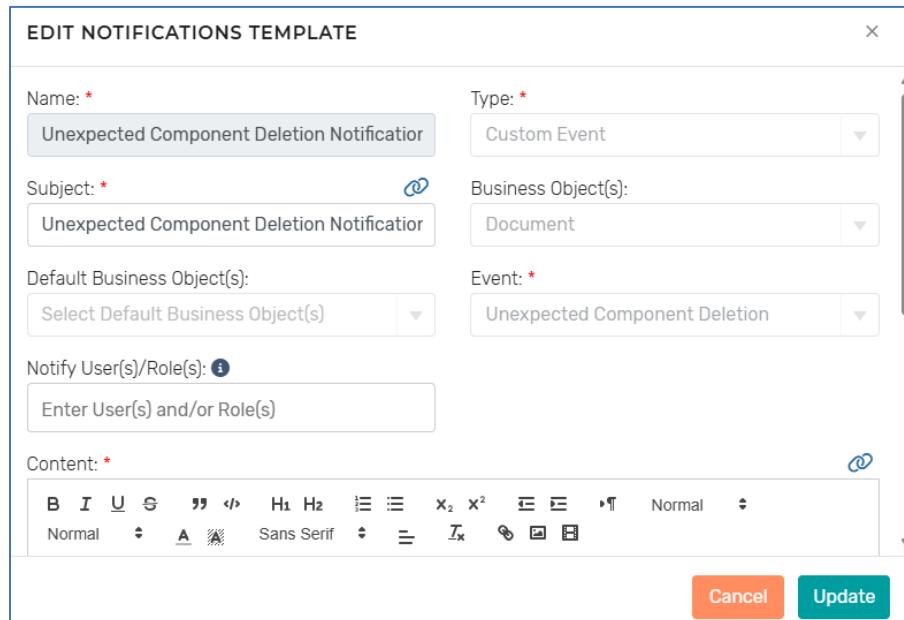
2. The **Notifications** table will display. Navigate to the **Unexpected Deletion** notification, right click and select **Edit Information**.



Name	Business Object(s)	Type	Subject
Test Template	EI Component	Lifecycle Action Task	test template
Test Template 3	Sample Component	Lifecycle Action Task	test Template 3
Test Template for Clin Doc	Clinical Document	Lifecycle Action Task	Test Template for Clin Doc
Test Template Sample	EI Component	Lifecycle Action Task	Test template 2
Unexpected Component Deletion	Edit Information		Custom Event
	View Information		Unexpected Component Deletion

Page Size: 10 items < > 61 - 65 of 65

3. The **Edit Notification Template** page will display.



EDIT NOTIFICATIONS TEMPLATE

Name: * Unexpected Component Deletion Notification

Type: * Custom Event

Subject: * Unexpected Component Deletion Notification

Business Object(s): Document

Default Business Object(s): Select Default Business Object(s)

Event: * Unexpected Component Deletion

Notify User(s)/Role(s): Enter User(s) and/or Role(s)

Content:

Cancel Update

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4. Add the desired names and/or roles to be notified when an unexpected component deletion occurs. Only IN users, not external users, are allowed in the notification.

EDIT NOTIFICATIONS TEMPLATE

Name: *	Type: *
Unexpected Component Deletion Notification	Custom Event
Subject: *	Business Object(s):
Unexpected Component Deletion Notification	Document
Default Business Object(s):	Event: *
Select Default Business Object(s)	Unexpected Component Deletion
Notify User(s)/Role(s): Cam Mistry (cmistry@intelinotion.com) Bill Label (blabel@intelinotion.com) Administrators > Administrator	
Cancel Update	

- *If* desired, more links and binding conditions can be added to the notification template by clicking the link icon by the Content field.

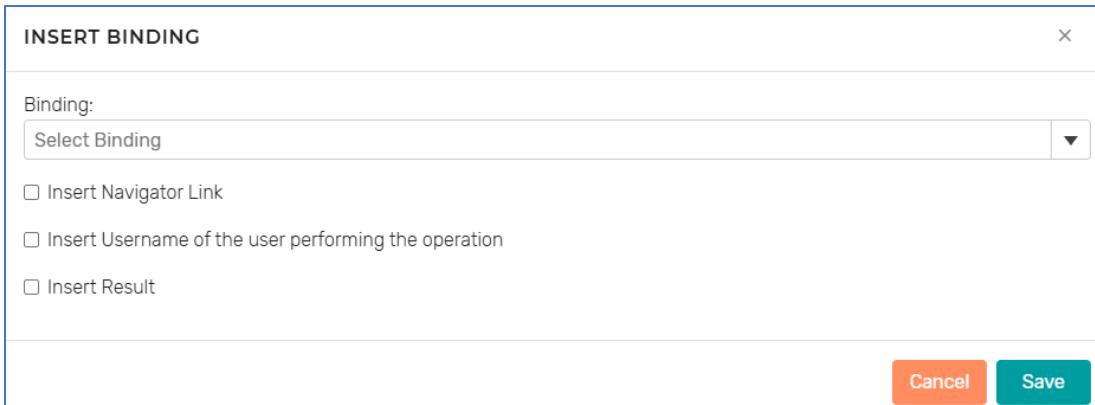
Content:

Hello <@=OperationPerformedBy@>, The following components were deleted unexpectedly from the <@=object.Properties['Name']@>. Click here to view the document. <@=Result@>	@
Cancel Update	

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5. The **Insert Binding** window will display.



INSERT BINDING

Binding:

Select Binding

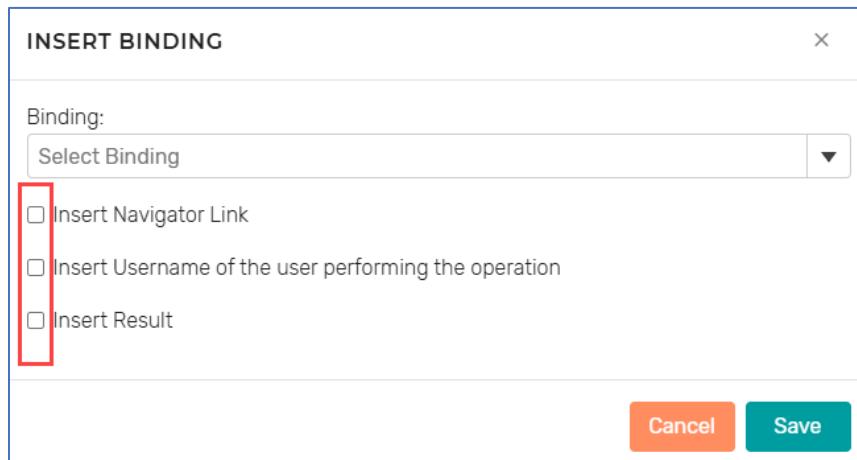
Insert Navigator Link

Insert Username of the user performing the operation

Insert Result

Cancel Save

6. Click the checkboxes next to the additional bindings desired.



INSERT BINDING

Binding:

Select Binding

Insert Navigator Link

Insert Username of the user performing the operation

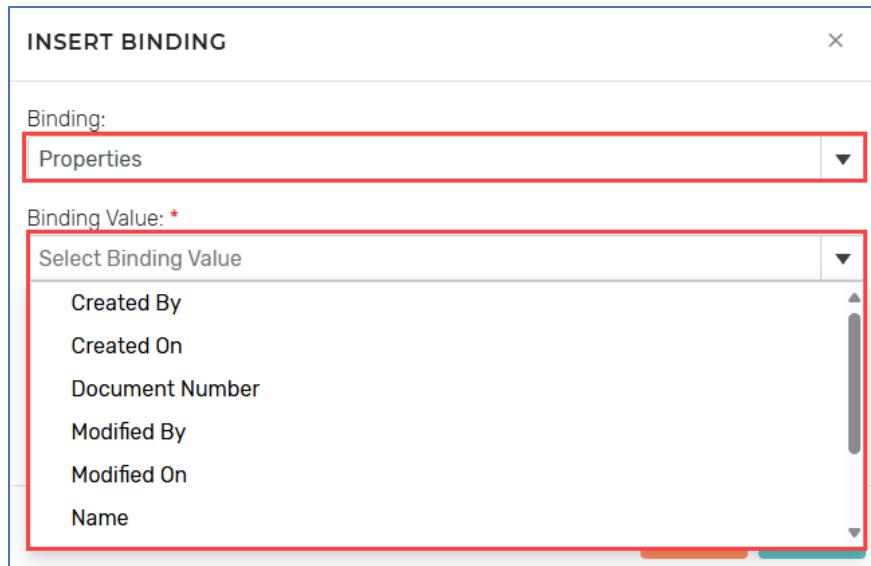
Insert Result

Cancel Save

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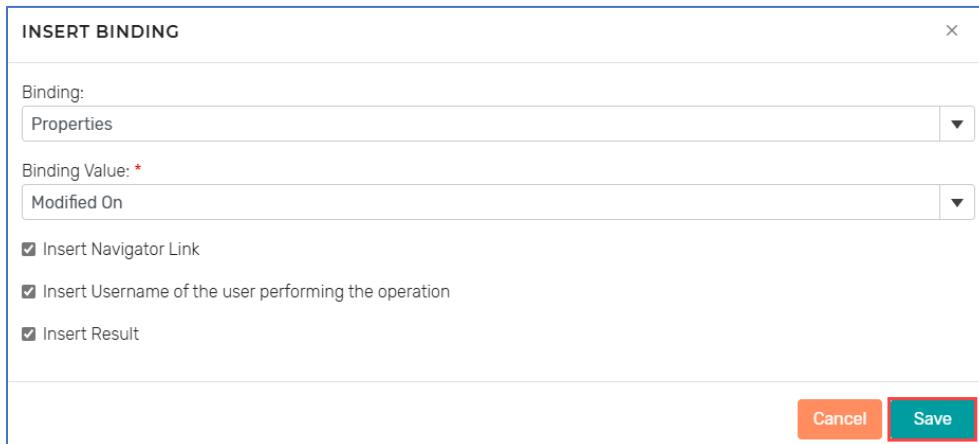
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7. If additional binding conditions are needed, choose **Properties** from the Binding drop-down menu. The **Binding Value** drop-down will display.



The screenshot shows the 'INSERT BINDING' dialog box. The 'Binding:' dropdown is set to 'Properties'. The 'Binding Value:' dropdown is expanded, showing a list of options: 'Created By', 'Created On', 'Document Number', 'Modified By', 'Modified On', and 'Name'. The entire 'Binding Value:' dropdown list is highlighted with a red border.

8. Select the **Binding Value** condition from the drop-down menu and click **Save**.

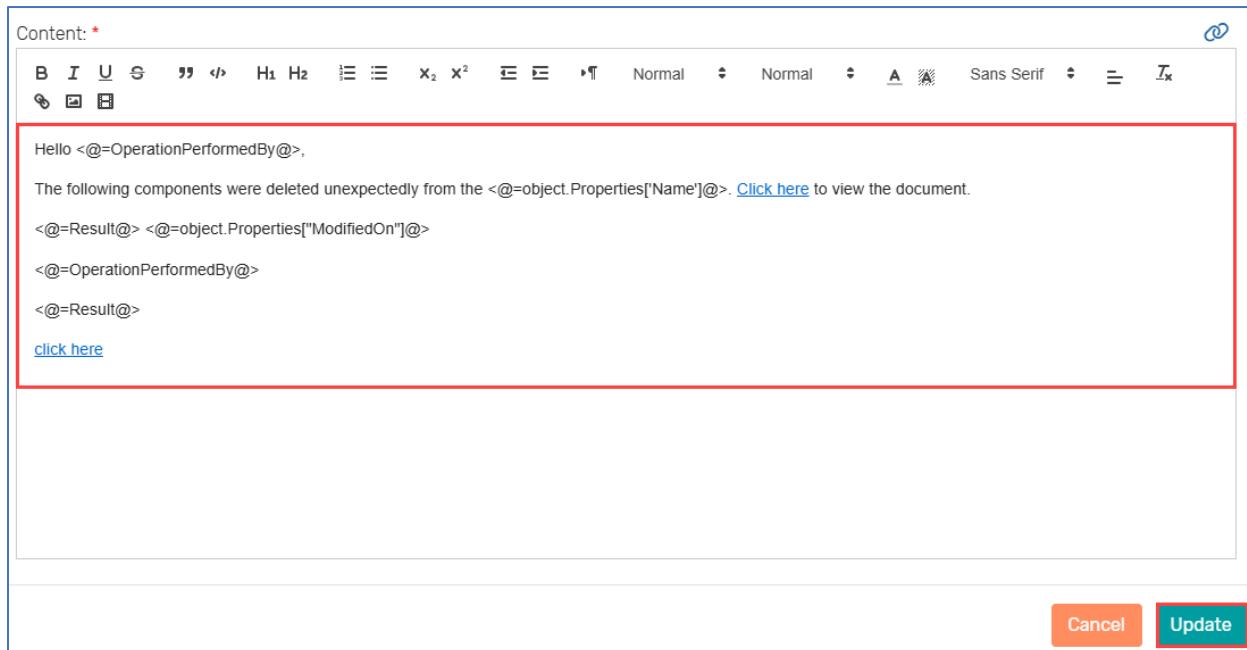


The screenshot shows the 'INSERT BINDING' dialog box. The 'Binding:' dropdown is set to 'Properties'. The 'Binding Value:' dropdown is set to 'Modified On'. Below the dropdown, there are three checked checkboxes: 'Insert Navigator Link', 'Insert Username of the user performing the operation', and 'Insert Result'. At the bottom right of the dialog are two buttons: 'Cancel' and 'Save', with 'Save' highlighted by a red border.

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9. The new body of the notification template will display in the **Content** field. Click **Update** to save the configured notification template.



The screenshot shows the InteliNotion Content editor interface. At the top, there is a toolbar with various formatting options like bold, italic, underline, and alignment. Below the toolbar is a text area containing a notification template. A red box highlights the text area. The text in the area is as follows:

```
Hello <@=OperationPerformedBy@>,  
The following components were deleted unexpectedly from the <@=object.Properties['Name']@>. Click here to view the document.  
<@=Result@> <@=object.Properties["ModifiedOn"]@>  
<@=OperationPerformedBy@>  
<@=Result@>  
click here
```

At the bottom right of the editor are two buttons: "Cancel" and "Update".

10. The Notification template can be exported or imported using the Utilities option in the console.

8.3.2 Manually Deleting a Component that is Not Allowed for Deletion per Policy

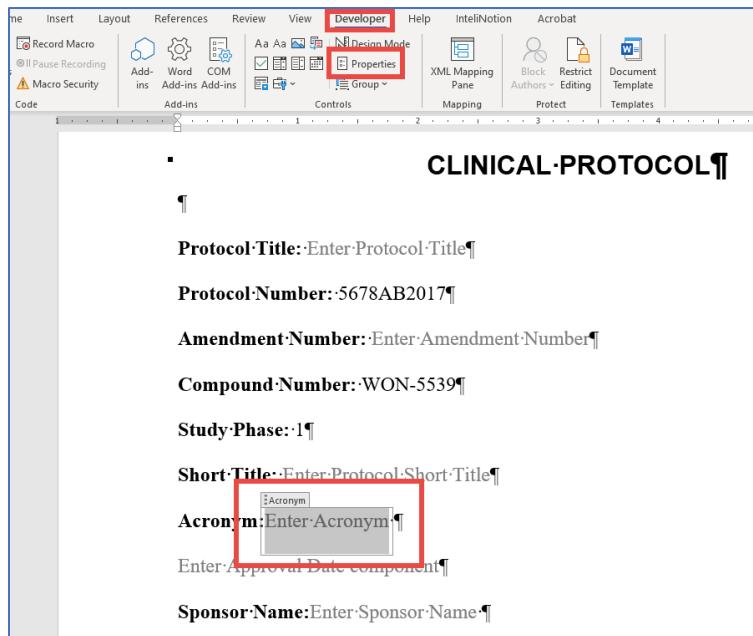
Components can be configured to allow deletion at the Info Model and/or at the template level. However, if a component is not allowed for deletion at either of the levels, the components can be manually deleted using the following steps:

1. Edit/check out the document in single authoring following the steps mentioned in the **InteliNotion User Guide Module 5**. Locate the component to be deleted and click on it.

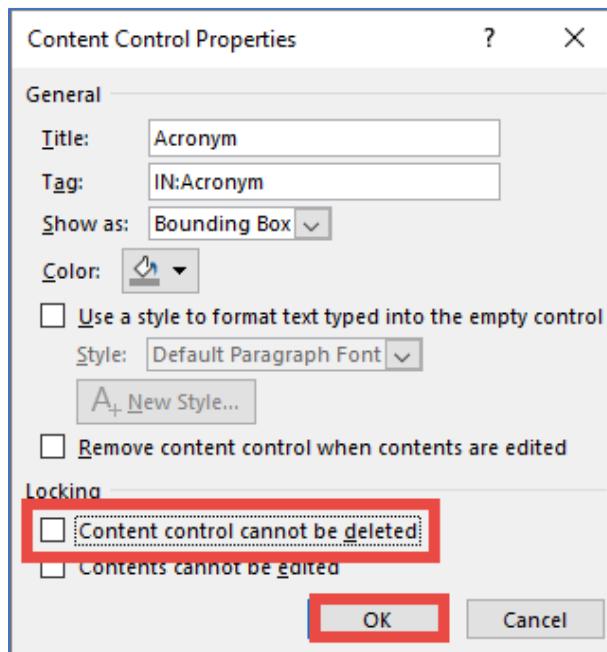
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2. Go to the **Developer** tab and click **Properties** in the Controls group.



3. On the Content Control Properties box, uncheck the **Content control cannot be deleted** box and click **OK**.

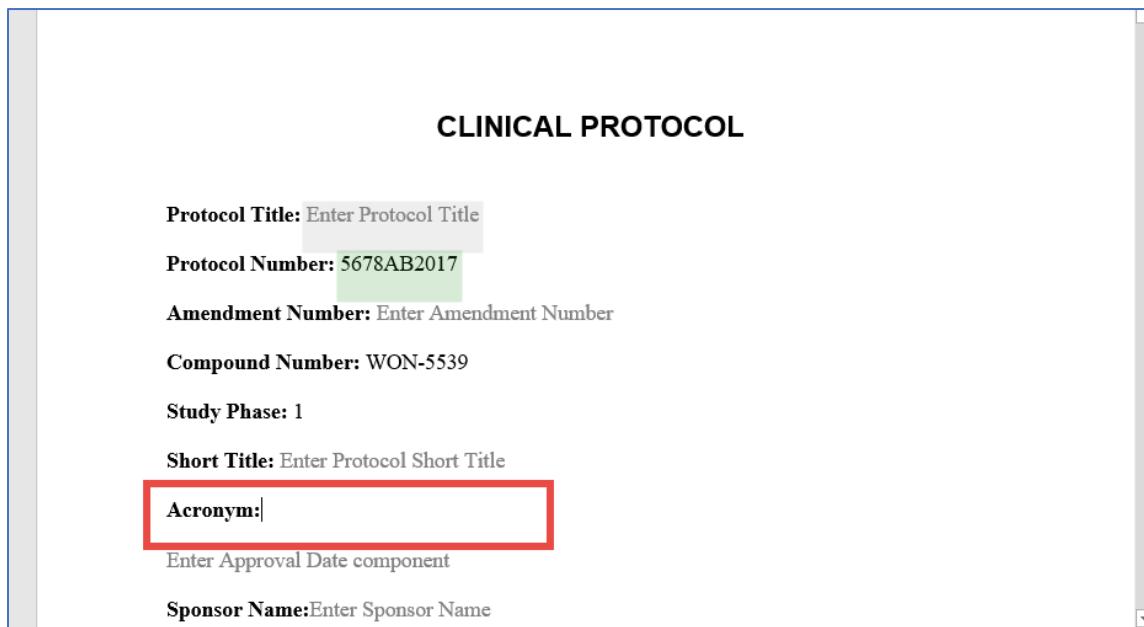


Note: Do not change the **Title** or **Tag** (as shown in the dialog above) for any *InteliNotion* components.

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- Select the entire component and then delete it by clicking either Backspace or Delete on the keyboard.



The screenshot shows a form titled "CLINICAL PROTOCOL". It contains several input fields:

- Protocol Title:** Enter Protocol Title
- Protocol Number:** 5678AB2017
- Amendment Number:** Enter Amendment Number
- Compound Number:** WON-5539
- Study Phase:** 1
- Short Title:** Enter Protocol Short Title
- Acronym:** [This field is highlighted with a red border.]
- Enter Approval Date component**
- Sponsor Name:** Enter Sponsor Name

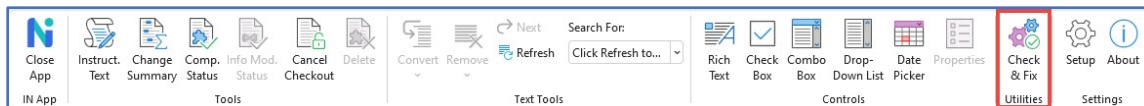
- Save and check in the document following the steps mentioned in the **InteliNotion User Guide Module 5**.

8.4 CHECK AND FIX UTILITY

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

Perform the following steps to use the utility:

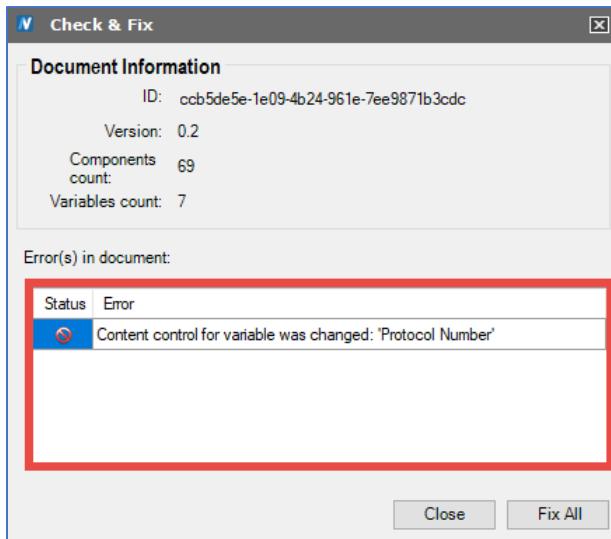
- Click on **Check & Fix** option under the Settings & Utilities section of the *InteliNotion* ribbon.



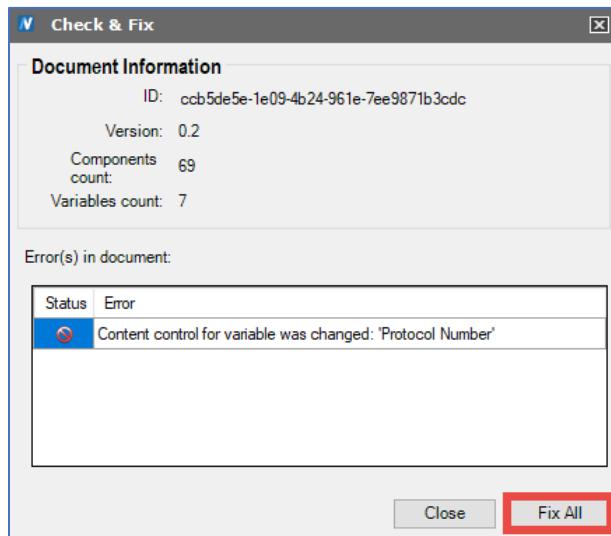
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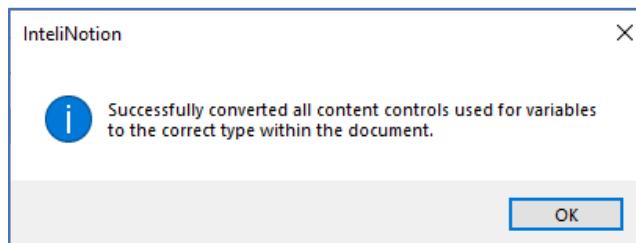
2. A dialog box displaying information about the variables within the document and the list of the corrupted variable(s), will appear on the screen.



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



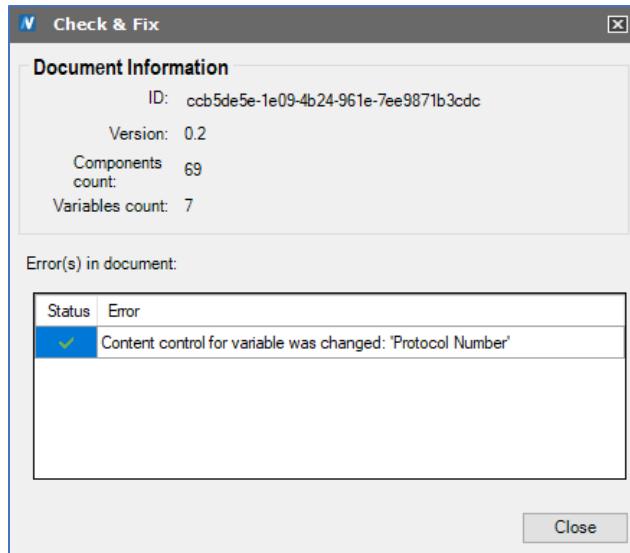
4. A conversion successful message will display on the screen.



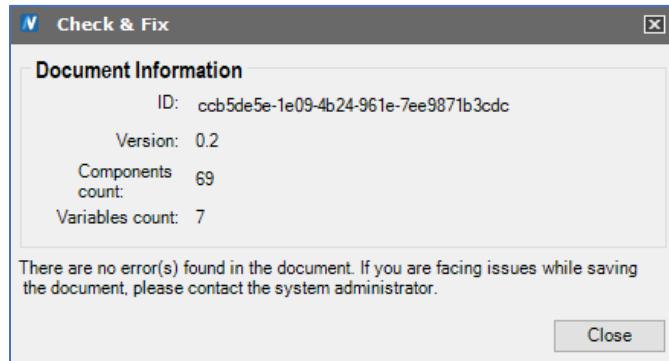
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5. Additionally, the datatype of the corrupted variable(s) changes to the appropriate type.



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



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