



# **User Guide Module 4: Document Generation**

For InteliNotion Version: 2024.GR2.0

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## Table of Contents

<b>1. GENERATING A DOCUMENT .....</b>	<b>3</b>
1.1 GENERATE A DOCUMENT USING MULTIPLE BASE DOCUMENTS .....	7
1.1.1 <i>Manual Mapping of Components and Component Sets</i> .....	9
<b>2. CREATING A VARIANT OF AN EXISTING DOCUMENT .....</b>	<b>17</b>
2.1 CREATING A DOCUMENT VARIANT .....	17

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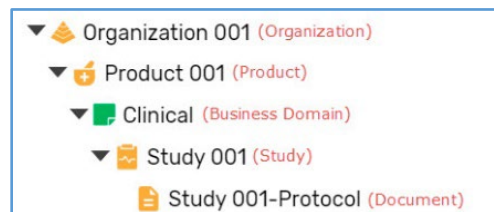
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## 1. GENERATING A DOCUMENT

The structure of the navigation scheme is client-specific but typically adheres to the following structure type for clinical content:

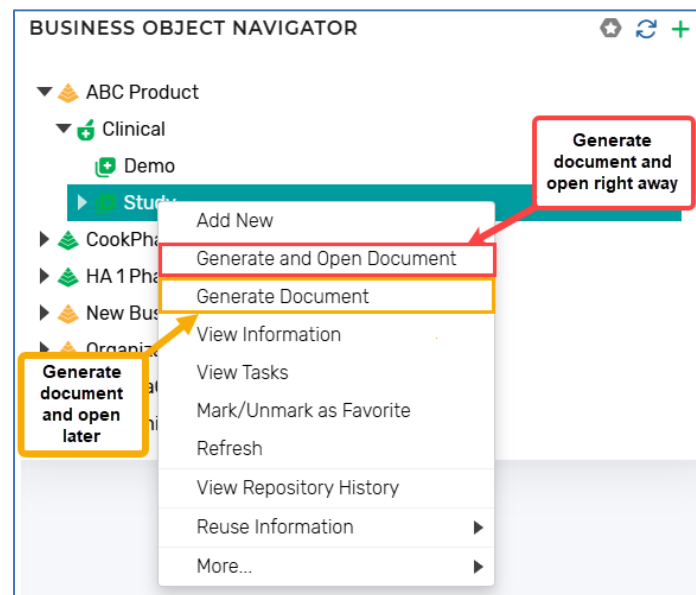
- ▼ Product (eg, Wonderdrug)
  - ▼ Business Type (eg, Clinical)
    - ▼ Study (eg, Study 2018WON-01)
      - ▼ Document (eg, Study 2018WON-01 Protocol)

In the example navigation scheme above, the user can locate a new document generated for a study by navigating through the related product of interest, as shown in this example.



**Note:** Documents may also be generated for other business object types (eg, labeling) according to how the navigation scheme is configured.

1. In the *InteliNotion Word App*, right-click on the **Study** and click **Generate Document**.



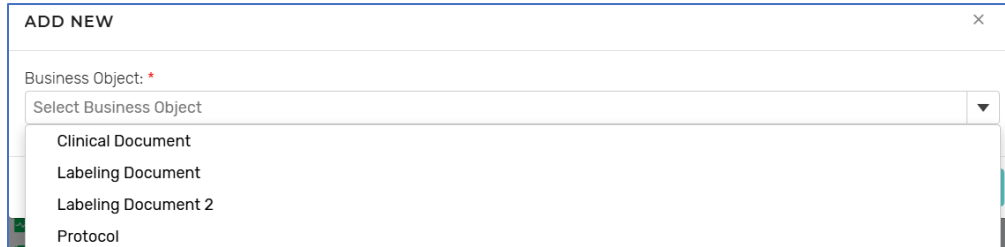
**Note:** It is recommended to use the **Generate Document** option within the *InteliNotion Word App* for optimal performance.

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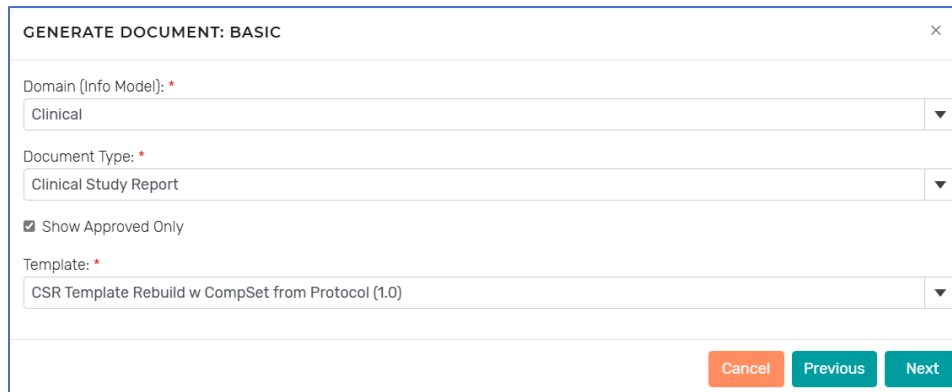
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2. Select the relevant Business Object for the document to be generated in the **Add New** window and click **Next**.



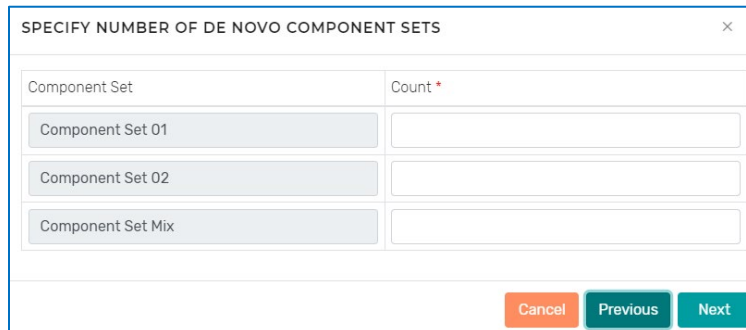
3. Select the relevant **Domain (Info Model)**, **Document Type**, and **Template** for the document to be generated, then click **Next**.



**Notes:**

- The template version number is enclosed in curved brackets ( ) next to the Template name.
- The **Show Approved Only** checkbox is displayed and can only be modified by the users with **Admin** privileges or by the users with **Templates** functional permission.

4. If a template containing component sets was chosen in Step 3, a pop up prompting the user to specify the number of de novo component sets will display. Otherwise, skip to Step 5.

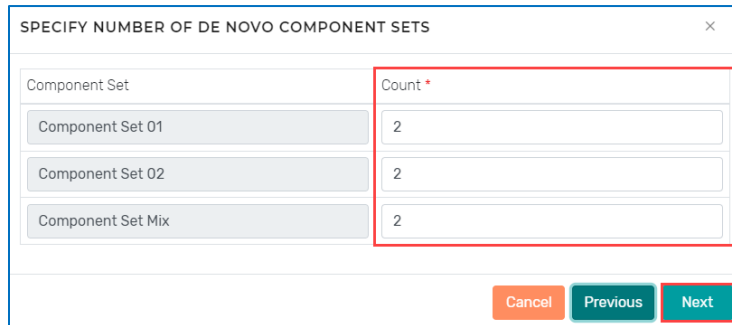


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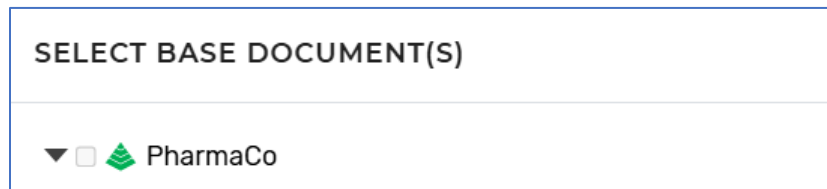
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- Specify the number of component sets desired for each type of component set present in the template, and click **Next**.



- The **Select Base Document(s)** window will display. Refer to Section 1.1 if selecting a base document. Otherwise, skip this step and click **Next**.



- The **Generate Document: Properties** form will display. Some values are pre-populated based on the associated properties for the document's parent business objects (eg, Product, Study). Enter, select, and/or update the properties, as appropriate, noting that some pre-populated values cannot be edited based on the system's configuration. The following special characters are not allowed in the **Name**: \, /, :, #, %, \*, ?, <, >, |, ".

**Notes:**

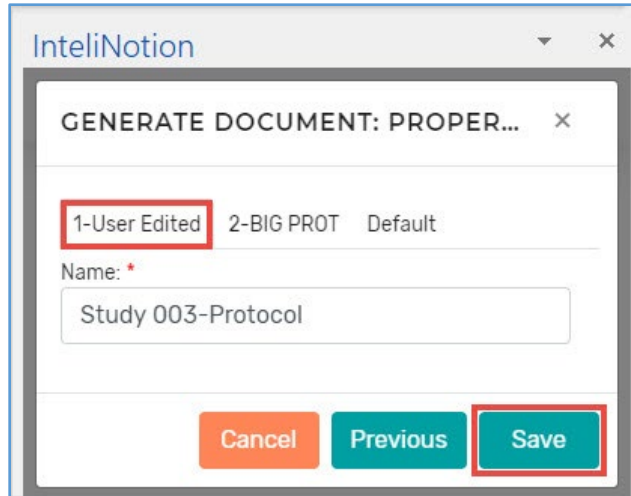
- When selecting certain property values, other values may be auto populated or filtered based on the configuration. For example, if configured to do so by an admin, a document will be saved to the repository according to its lifecycle state.
- If a user tries to generate a document using properties that result in the user not having access to that document (eg Medical Writing Lead Author role restricted), an error message will display and generation will be cancelled.

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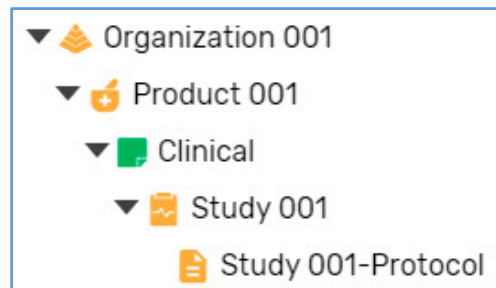
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7. Click **Save**.



8. Verify the document is generated. It will appear under the study (or elsewhere based on the navigation scheme) for which it was generated.



#### **Notes:**

- The **Name** of the document must not exceed 100 characters.
- The fields in the **Generate Document: Properties** form may be grouped in separate pages. The user must click on each tab (eg, AA-User Defined) to view and complete the relevant fields, as appropriate.
- Some of the properties may have cascading filter property sets configured; if so, after the user selects 1 property value (eg, **Oncology for the Therapeutic Area**), a filtered list of value(s) will be displayed for another related property (eg, for the **Indication** property, **only** a subset of values will display, such as breast cancer and melanoma, instead of all available values included in the metadata catalog).
- To remove a selected property value, click in the property's field and click **Backspace** or **Delete** on the keyboard.
- If the **Generate and Open Document** option was selected, the document also opens automatically after its generation is complete.

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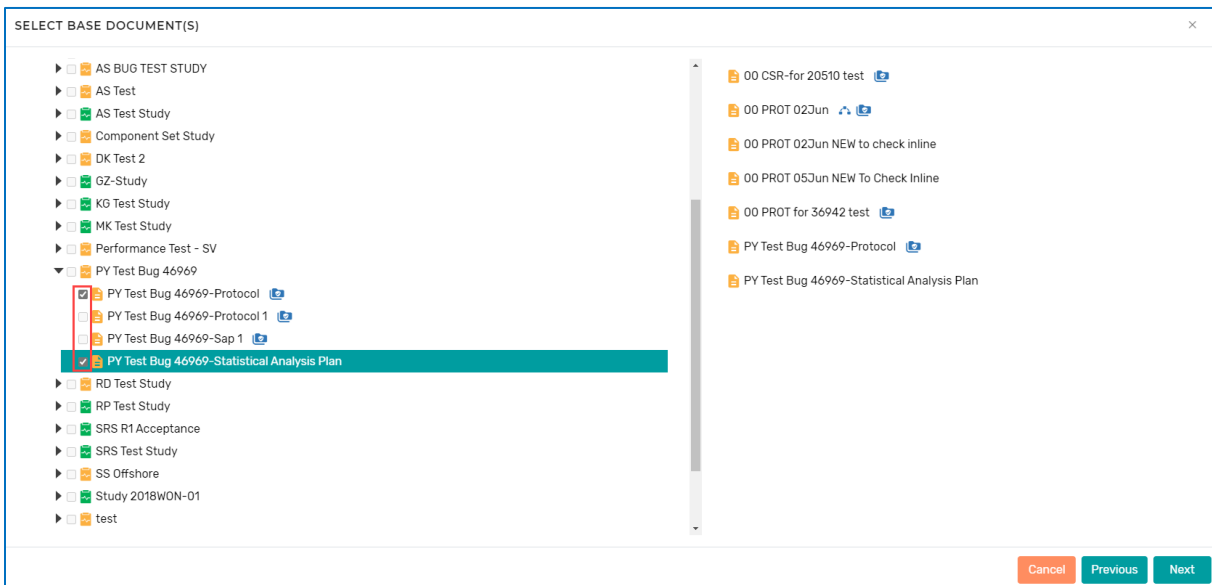
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- If applicable, after generating a new document, the information regarding the base documents used for the new document can be viewed by right-clicking on the document in the **Navigation** pane and selecting the **View Information** option. Scroll down to the end of the **View Information** pane to view the base documents used.
- If needed, the document or component's properties can be modified by selecting the **Edit Information** option under **More** in the right-click menu. Modification of certain properties will require the user to add a comment to be saved in the version history. Any manual property edits will result in a new version being created.

## 1.1 GENERATE A DOCUMENT USING MULTIPLE BASE DOCUMENTS

As an authorized user, it is possible to generate a document by selecting multiple base documents of the same type per reuse definition. The user shall be allowed to select a base document(s) where reused is defined per the info model *OR* the same type of document as the one to be generated. If multiple documents of the same type are selected (eg, 2 protocols for 1 CSR document), or the same type of document is selected (eg, 1 protocol for a new protocol), then Manual Mapping of the reused components will be required as described in this section.

1. Starting from Step 5 of [Section 1](#), navigate to the desired base documents and click the applicable checkboxes to add them to the document being generated.



**Note:** If a new document is generated from a base (existing) document that does not contain any content within a certain component, if/when content gets added to the base document's component, the system will refresh the reused component's content in the downstream document according to the pre-configured auto-update rules (eg,

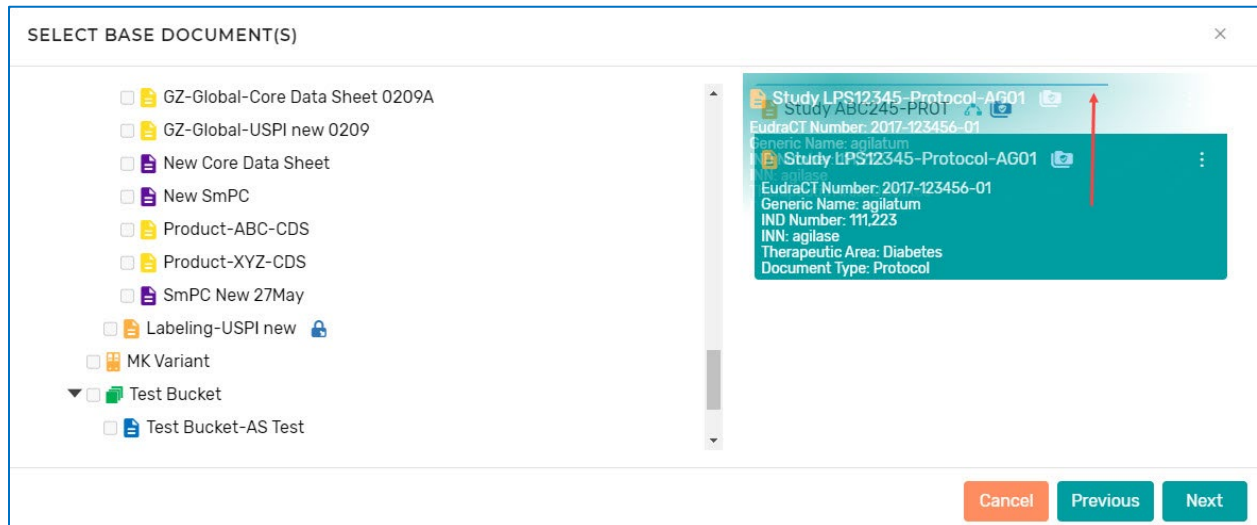
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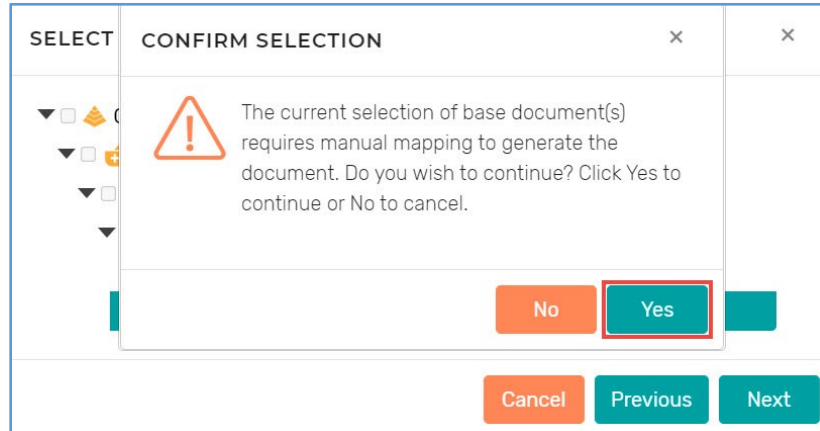
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the user is notified that the reused component was changed and the user is able to take action to refresh the component's new version/contents into the new document).

2. If necessary, reorder base documents by dragging and dropping them into the desired order.



3. Click **Next**. If manual mapping is required, the user will see the following warning message. Click **Yes** to continue to **Manual Mapping** and refer to Section 1.1.1.



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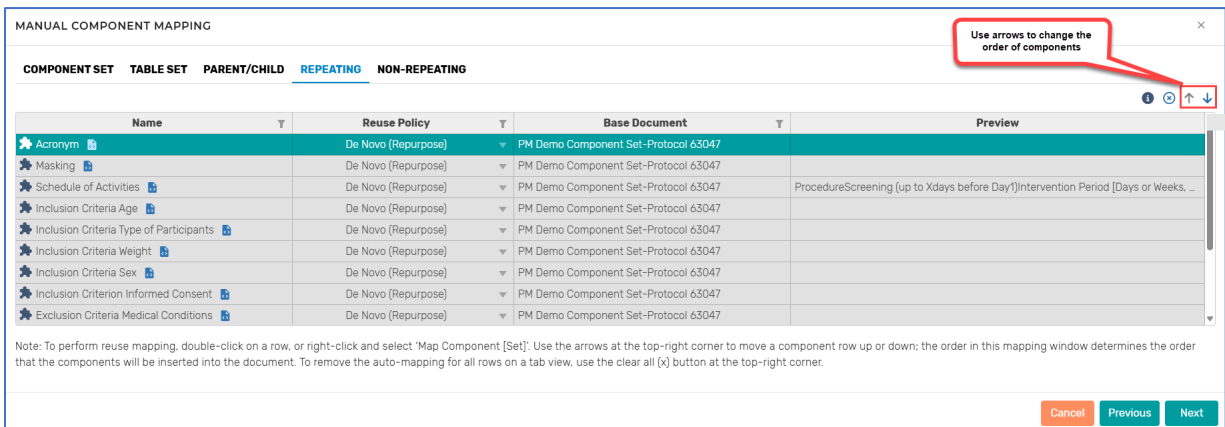
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### 1.1.1 Manual Mapping of Components and Component Sets

1. A **Manual Component Mapping** form will display. Components are separated into tabs by type of component. Each table on all tabs will be listed with the following basic information:
  - Name
  - Reuse policy
  - Base Document
  - Preview



MANUAL COMPONENT MAPPING

COMPONENT SET TABLE SET PARENT/CHILD **REPEATING** NON-REPEATING

Name	Reuse Policy	Base Document	Preview
Acronym	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Masking	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Schedule of Activities	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	ProcedureScreening (up to Xdays before Day1)Intervention Period [Days or Weeks, ...]
Inclusion Criteria Age	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Inclusion Criteria Type of Participants	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Inclusion Criteria Weight	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Inclusion Criteria Sex	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Inclusion Criterion Informed Consent	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	
Exclusion Criteria Medical Conditions	De Novo (Repurpose)	PM Demo Component Set-Protocol 63047	

Note: To perform reuse mapping, double-click on a row, or right-click and select 'Map Component [Set]'. Use the arrows at the top-right corner to move a component row up or down; the order in this mapping window determines the order that the components will be inserted into the document. To remove the auto-mapping for all rows on a tab view, use the clear all (x) button at the top-right corner.

Cancel Previous Next

2. If base documents with reuse configured in the info model are selected, the user will be able to map which components from which base document(s) are to be reused. In this case, the user can **only** do mapping for the components with reuse configured and cannot change the reuse policy of the base document.

#### Notes

- The user should not be able to remove the components mapping from the info model.
- The order of the components in the Manual Component Mapping view can be rearranged by using the arrows at the top right of the screen. This order will be used while inserting the components into the generated document.
- When moving a component that has a child component, this child component will also be moved along with the parent component.
- Without manual mapping, the order AND set number is carried from parent to child document, so if any set was deleted from parent, that set number will never get reapplied to a new set in either the parent or child.
- With manual mapping, the order AND set number are based on manual mapping. The user must be aware that if/when rows are moved up or down,

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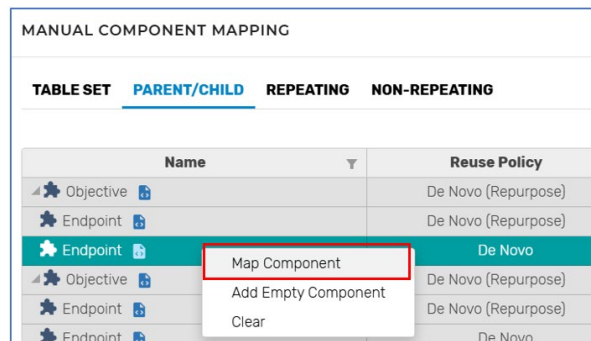
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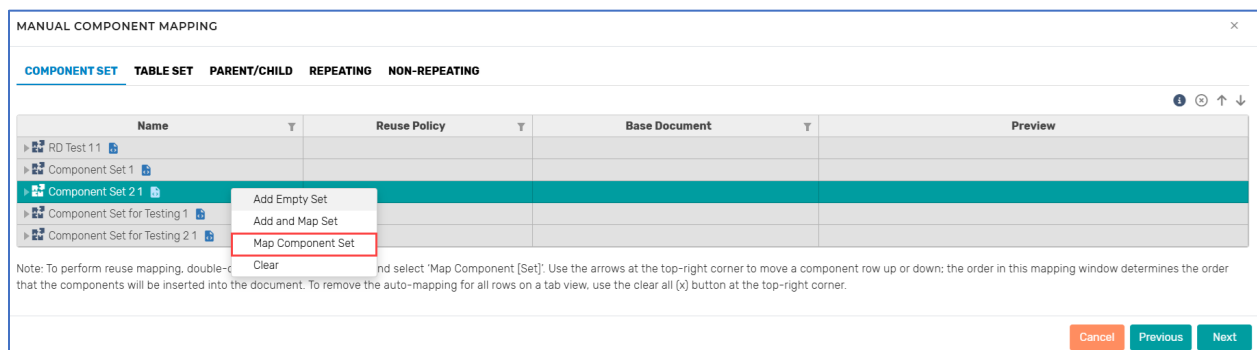
the set number does not change. This could lead to set numbering not being in sequence within the generated document.

- If base document(s) of the same type are selected, the user will be able to map which components from which base document(s) are to be reused. In this case, the user can complete mapping for any number of the components and specify a reuse policy to apply. To map the reused components, follow one of the two steps listed below.
- If a component set was not mapped for reuse from a selected base document, but at least 1 other related component set was selected for reuse and present in child document, then omitted component set will be listed in "Ignored" section of child document's Component Status Report
- Up to 25 component sets can be inserted and mapped into a document

- To map a single component, click on the tab for the type of component to be mapped, right-click and choose **Map Component**.



- To map a component set, right click on the set to be mapped from the Component Set tab. Click **Map Component Set**.

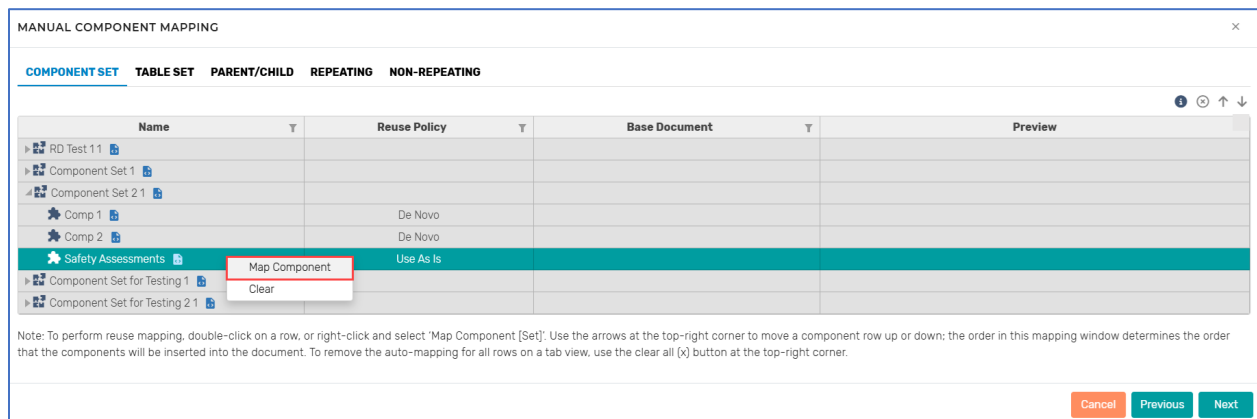


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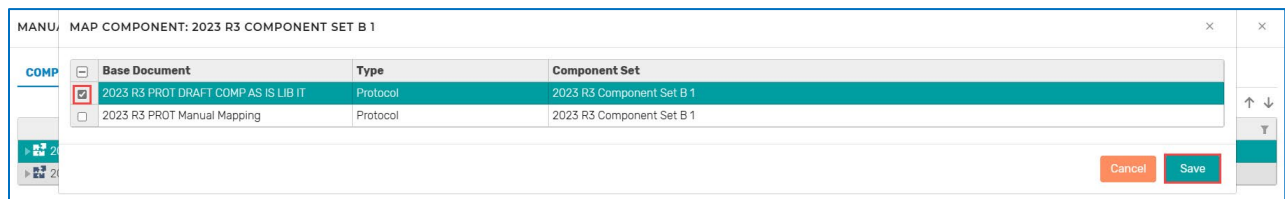
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- When mapping a component set, the following actions can also be taken, as shown in the figure above:
  - **Add Empty Set** – this action adds an identical component set to the component set selected
  - **Add and Map Set** – this action adds and identical set to the component set selected and triggers the component mapping screen (as shown in step 9a-iii)
  - **Clear** – this action clears all current mapping from the selected component set
- c. To map an individual component within a component set, click on the drop-down arrow next to the component set to expand it, then right click on the applicable component to be mapped, and select **Map Component**.



- d. The component mapping screen will appear. Select the checkbox next to the applicable base document and click **Save**.



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e. To preview the component, click the **Preview** icon.

MAP COMPONENT: SUBELEMENT 1

<input type="checkbox"/>	Base Document	Type	Component	Short Preview	Preview
<input type="checkbox"/>	Test Study_SV-Protocol_compset	Protocol	Subelement 1		

Cancel Save

**Note:** The **Short Preview** column gives a short summation of the component's content.

MAP COMPONENT: SUBELEMENT 1

<input type="checkbox"/>	Base Document	Type	Component	Short Preview
<input type="checkbox"/>	Test Study_SV-Protocol_compset	Protocol	Subelement 1	This content has been entered as a test of the component set preview function for component

Cancel

f. A preview of the component will display. Click the **X** in the upper right-hand corner to exit out of the preview.

MANU: SUBELEMENT 1(0.1)


COMP

This content has been entered as a test of the component set preview function for component mapping

Next

g. Map the component and click **Save**.

MANU: MAP COMPONENT: SUBELEMENT 1

<input checked="" type="checkbox"/>	Base Document	Type	Component	Short Preview	Preview
<input checked="" type="checkbox"/>	Test Study_SV-Protocol_compset	Protocol	Subelement 1		

Cancel Save

Subelement 1 Repurpose Test Study\_SV-Protocol\_compset

Subelement 2 Repurpose Test Study\_SV-Protocol\_compset

Component Set for Testing 2.1

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- h. All the components in the mapped set will appear as configured in the manual component mapping table.

MANUAL COMPONENT MAPPING			
COMPONENT SET   TABLE SET   REPEATING   NON-REPEATING			
Name	Reuse Policy	Base Document	Preview
2023 R3 Component Set B 1			
2023 R3 Element 2	De Novo (Repurpose)	2023 R3 PROT DRAFT COMP AS IS LIB IT	Test 01
2023 R3 Element 1	De Novo (Repurpose)	2023 R3 PROT DRAFT COMP AS IS LIB IT	Test 02
Element 02	De Novo (Repurpose)	2023 R3 PROT DRAFT COMP AS IS LIB IT	Test 03
2023 R3 Component Set A 1			

- i. For other bulk tasks – press the **Ctrl** or **Shift** key on the keyboard, click on the components to be mapped, then right-click and choose **Clear**.

MANUAL COMPONENT MAPPING			
TABLE SET   PARENT/CHILD   REPEATING   NON-REPEATING			
Name	Reuse Policy	Base Document	Preview
Status	De Novo		
CSR Date	De Novo		
Protocol Title	Use As Is	Study 2023-Demo-Protocol-10Apr	A Randomized, Phase II/III trial evaluating the efficacy and safety of lenalidomide, b...
Protocol Short Title	Use As Is	Study 2023-Demo-Protocol-10Apr	Effect of lenalidomide, bortezomib and dexamethasone (RVD) with or without pano...
Sponsor Name	Use As Is	Study 2023-Demo-Protocol-10Apr	
Medical Officer Name	De Novo		
Study Initiation Date	De Novo		
Study Completion Date	De Novo		
Investigator(s) and Study Centers	De Novo		

### Notes:

- Single components can also be manually mapped by double clicking on the component to be mapped.
  - The Preview column will only populate once a reused component is fully mapped.
- Once the component/s have been selected for manual mapping following the applicable sub-steps above, a pop-up form will display for the individual type of component(s).
  - To map the component(s), click the checkbox next to the component to be mapped, repeat as necessary, and click **Save** to close the **Map Component** pop-up form.

MANU... MAP COMPONENT: INCLUSION CRITERIA AGE			
Base Document	Type	Component	Preview
<input checked="" type="checkbox"/> Study 2023-Demo-Protocol-10Apr	Protocol	Inclusion Criteria Age	
<input type="checkbox"/> Study ABC245-Protocol Test 020223	Protocol	Inclusion Criteria Age	
<input type="checkbox"/> 2022 R2 HF2 TC 34034 TEST	Protocol	Inclusion Criteria Age	
<input type="checkbox"/> 2022 R2 HF2 TC 34034 TEST	Protocol	Inclusion Criteria Age	
<input type="checkbox"/> Study LPS12345-Protocol-AG01	Protocol	Inclusion Criteria Age	
<div>Cancel Save</div>			
Inclusion Criteria Sex	Repurpose	Study 2023-Demo-Protocol-10Apr	
Inclusion Criteria Weight	Repurpose	Study 2023-Demo-Protocol-10Apr	
Inclusion Criteria Informed Consent	Repurpose	Study 2023-Demo-Protocol-10Apr	
Exclusion Criteria Medical Conditions	Repurpose	Study 2023-Demo-Protocol-10Apr	

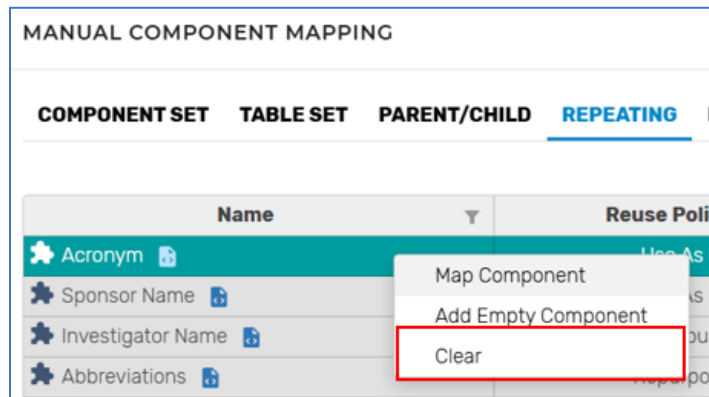
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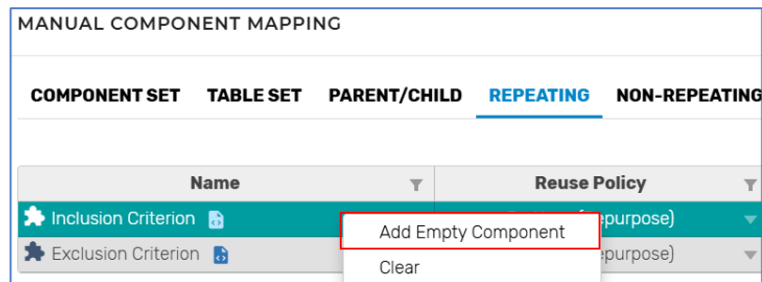
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**Note:** When mapping individual components from a component set, only the components for that set are available for mapping. Components from different sets cannot be mapped from different source component sets

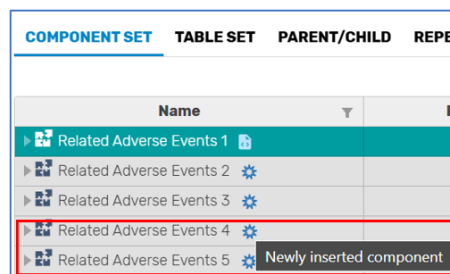
- Users can clear mappings, and remove extra ones added for repeating components by right-clicking on the component in the **Manual Component Mapping** window and selecting **Clear**.



- If desired, the user can add another instance of a Parent/Child, Repeating component, or Component Set by right clicking on the component to be duplicated and choosing **Add Empty Component** (or **Add Empty Set** if component set). The new, duplicate component will appear below the original component.



**Note:** When adding a duplicate component set, the entire set will be duplicated, as shown in the figure below and indicated with a star icon next to the duplicated name:

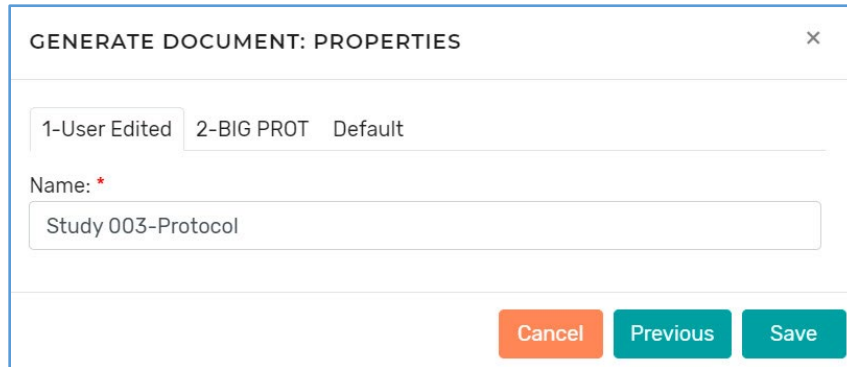


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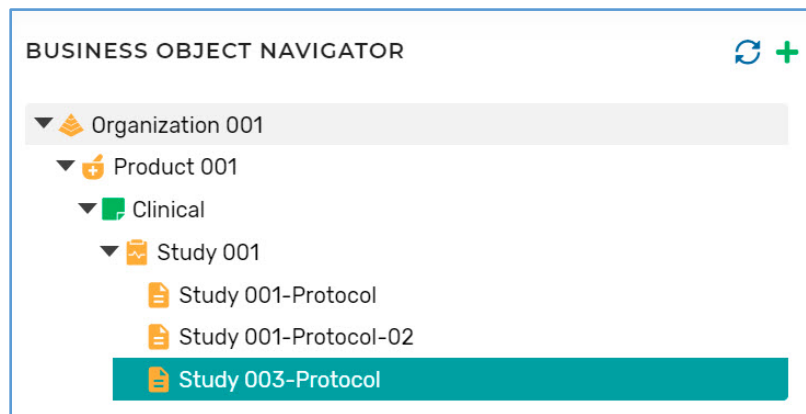
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7. After mapping all items, the user can provide a name and update inherited properties, if applicable, based on the selected location for the new document.



8. To generate and save the document click **Save**. The document will be saved to the selected location. The user can view information for the document and see a list of base document(s) used.



#### **Notes:**

- Components reused from the selected base document will be reused into the new document as per preconfigured or user selected reuse policy. For repeating components, all instances in the base document will be reused into child document. If applicable, multiple matching library components will get inserted into the document (if the target component is configured as repeating) due to their matching criteria.
- A full control admin or a user with C-R-U permissions on relevant document BO and component BO, or their subclasses can insert components sets into a child document with the following behaviors:

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- If a component exists in the child template's component set configuration but not in selected base document's component set, it is created as a de novo component in the respective component set of the child document.
  - If a component doesn't exist in the child template's component set configuration but does exist in the selected base document's component set, it is not included in the respective component set of the child document and the user will not receive a warning about the extra component(s) in the parent's component set not getting reused into the child document
  - If NO base document is selected OR a base document is selected but the selected template has a component set of a different 'type' (ie, a component set is NOT reused according to the info model), the specified number of de novo sets are generated in the child document, based on the child template's configuration regardless of how the components were ordered within their respective component set in the original base document.

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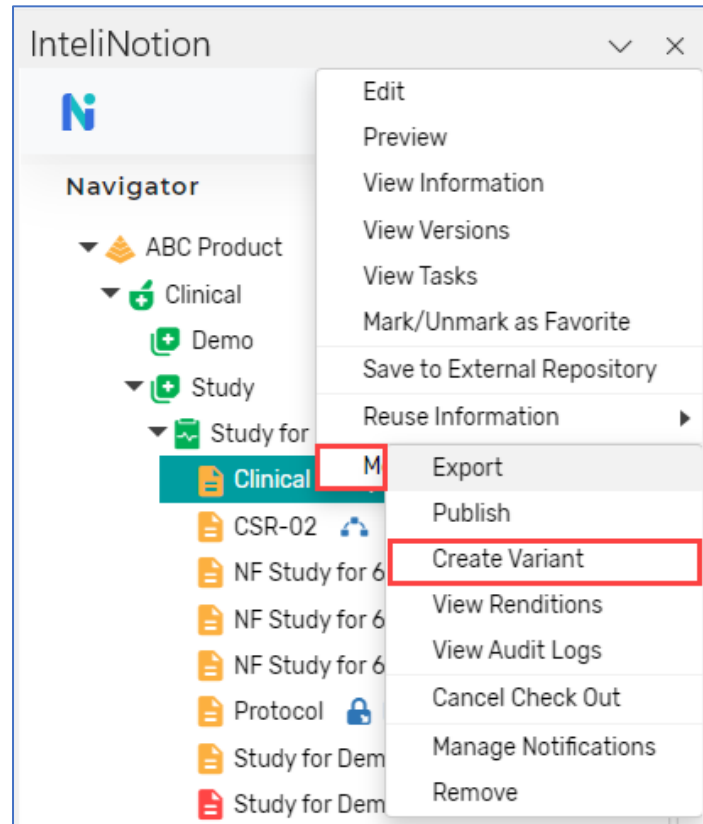


## 2. CREATING A VARIANT OF AN EXISTING DOCUMENT

The variant of an existing document can be created including *or* excluding the components of that document in the target document.

### 2.1 CREATING A DOCUMENT VARIANT

1. Right-click on an existing document's name and under **More**, click **Create Variant**.

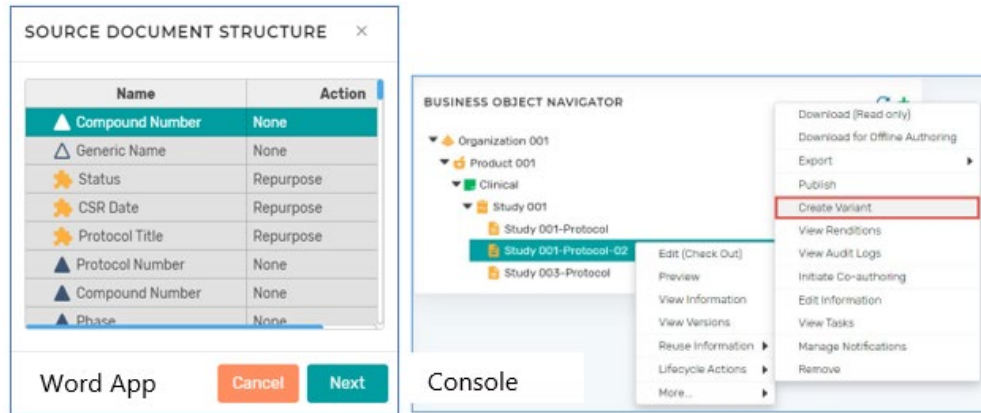


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- The app will display a **Source Document Structure** box wherein appropriate actions on the existing components of the source document can be taken to be included or removed in the variant document.



**Note:**

- The Policy column displays the reuse policy of the component within the source document.
- The *InteliNotion Word App* can be resized to see the entire Source Document Structure box.
- In the *InteliNotion Word App*, the Policy column is not displayed due to limited space

- Take appropriate action to include, change reuse policy (if any) by right clicking on the component or selecting an option from the drop-down menu or remove the component from the variant document:

**Note:** Within the newly generated variant document, any reused components may have their reuse into that document removed using the **Clear Reuse** function, if needed.

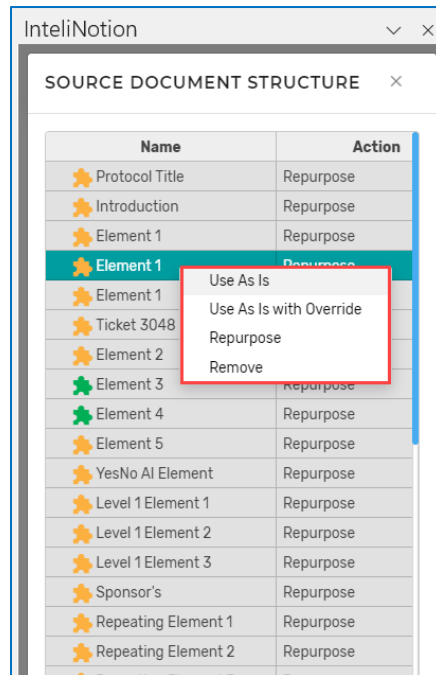
- None** - To include the variable component into the variant document (this option is only available for variables)
- Use As Is** - To include the content component with no change to the existing component; modification of the reused component is not allowed in the variant document
- Use As Is with Override** - To include the content component with the option to override existing content restriction and make alterations to previously locked components
- Repurpose** - To include the content component as a new branch from the existing component; modification of the reused component is allowed in the variant document

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- e. **Remove** - To remove the content or variable component from the variant document



#### **Notes:**

An action can also be applied to multiple variable components and/or content components at once, as follows:

- For individual components – click on the row of one component in the **Source Document Structure** box While pressing the **Ctrl** key on the keyboard and click on the other relevant components to select them. Then, right-click on one of the selected components and choose the appropriate action.
- For a range of components – click on the row of one component in the **Source Document Structure** box. While pressing the **Shift** key on the keyboard, click on the row of the last component in the range to select all the components in that range. Then, right-click on one of the selected components and choose the appropriate action.
- Any variable components that were bulk selected for action **None** will be included in the document.
- Any variable component(s) and/or content component(s) that were bulk selected for action **Remove** will no longer exist in the document (ie, were deleted).
- Any content components that were bulk selected for action **Use As Is** will be included in the document and will be locked for editing.

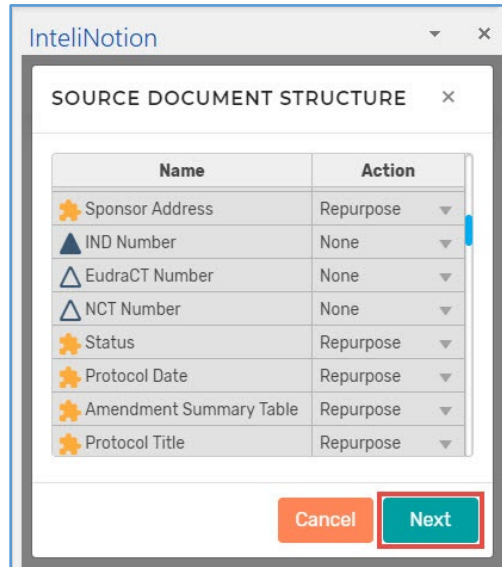
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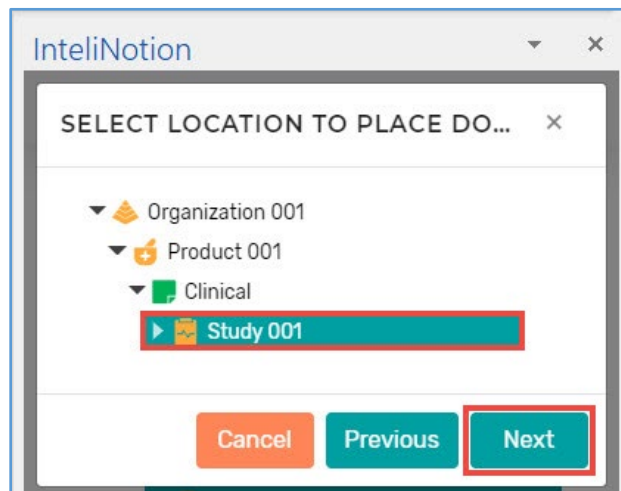
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- Any content components that were bulk selected for action **Repurpose** will be included in the document and will be editable.

- Repeat step 2 until all required actions are specified for the content and variable components and click **Next**.



- Select a location to place the variant of the document and click **Next**.

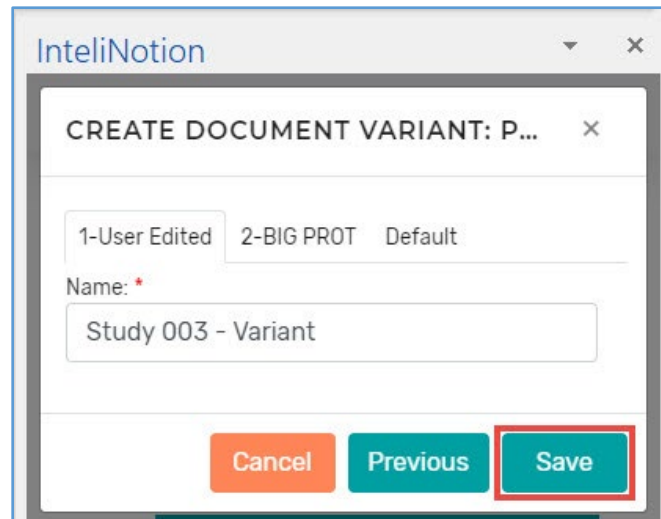


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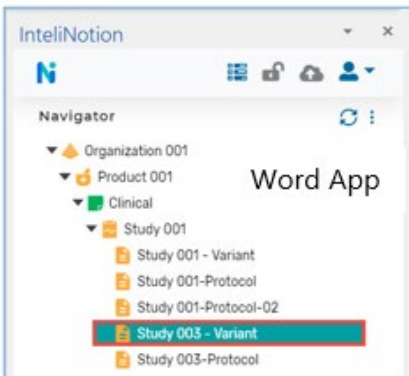
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6. Modify the required form details that are automatically populated based on the selected location, if needed, and click **Save**.



7. After the variant creation is successful, the new document will appear at the selected location.

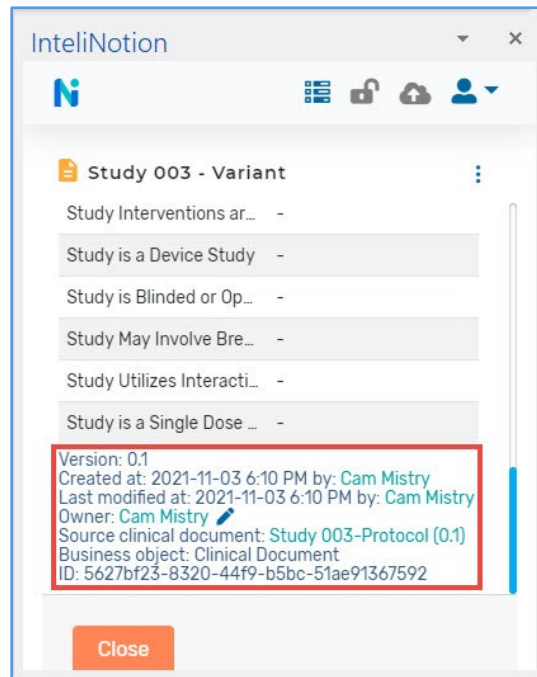


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8. A user can locate information on the Source Document in the **View/Edit Information** pane of the document variant of *IN Word App* or in **View Information** of Console.



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