



# User Guide Module 8:

# Content Reuse Tracing and

# Update

For InteliNotion Version: 2024.GR2.0

Last Modified: November 2024

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## 1. VIEWING REUSE INFORMATION FOR A BUSINESS OBJECT

*InteliNotion* provides various capabilities to view the reuse information for business objects (eg, documents, components). The **Where Used** and **Relationship Map** functionality, along with the **Reuse Report**, provides relevant reuse information for a specific component. The steps in the subsections below describe how to run these reports for a selected component associated with a document; however, the same actions are also available for components viewed in search results, a library, etc. The **Reuse Deviation Report** provides a summary of the planned and actual reuse policies applied to all components used in a document.

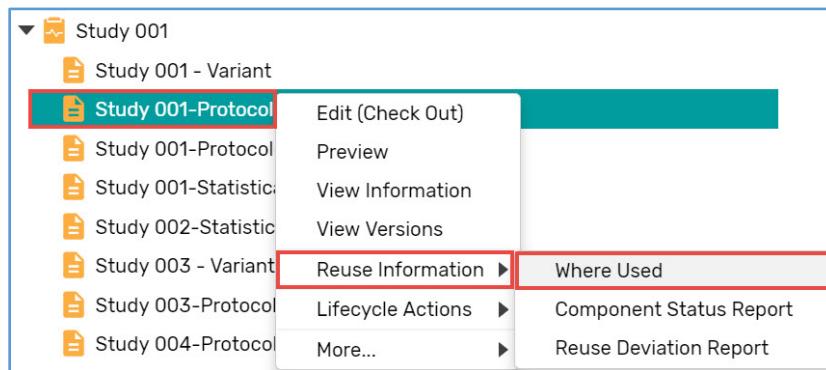
**Note:** The **Where Used** and **Relationship Map** functionality can also be used for other business objects (eg, documents), following the same steps outlined below.

In addition, a user will be notified if/when an update is made to a source component that is reused into other document(s). A user can view the modification made to the source component and accept it into the downstream document, as appropriate. These modifications are viewed and accepted via a separate **Component Status Report** (see [Section 2](#) for details).

### 1.1 VIEWING THE WHERE USED REPORT

The **Where Used** report provides details about what other business object(s) have a relationship to the selected object (eg, document, component). For example, the report for a component that was as-is reused in 1 document, while also repurpose reused in another document, would list the related document and the document's 'parent' objects in the **Navigator** (for as-is reuse) along with the related component that was newly created from it (for repurpose reuse). The steps below are for a component but can also be followed for other business objects.

1. Navigate to the component of a document in the **Navigator** (via *Web Console* or *InteliNotion Word App*) and right-click on it. Under **Reuse Information**, click **Where Used**.



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2. All the business objects under which the component has been used in the **Navigator** (eg, product, study, document), are listed in this report, as well as the parent document/original component, which can be easily distinguished by their relevant icon:

WHERE USED: STUDY 001-PROTOCOL

<input type="checkbox"/>	Name	Created ...	Created On	Modified...	Modified On	Version
<input type="checkbox"/>	Organization 001	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Product 001	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Clinical	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Study 001	Kinjal Gala	2021-10-26 ...	Cam Mistry	2021-11-15 11...	0.2

**Close** **Notify**

3. Right-click on an object in the list. Select **View Information** to know more about the business object OR click **Open Navigator View** to navigate to that business object in the **Navigator**.

WHERE USED: STUDY 001-PROTOCOL

<input type="checkbox"/>	Name	Created ...	Created On	Modified...	Modified On	Version
<input type="checkbox"/>	Organization 001	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Product 001	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Clinical	Kinjal Gala	2021-10-26 ...	Kinjal Gala	2021-10-26 ...	0.1
<input type="checkbox"/>	Study 001	Open Navigator View		View Information		

**Close** **Notify**

4. Select 1 or more of the listed business objects using the checkbox placed beside its name, enter a **Subject** and **Message**, and click **Notify** to notify the owners of the selected business objects about any change to this component.

WHERE USED: STUDY 001-PROTOCOL

<input type="checkbox"/>	Name	Created By	Created On	Modified By	Modified On	Version
<input type="checkbox"/>	Organization 001	Kinjal Gala	2021-10-26 4:33 PM	Kinjal Gala	2021-10-26 4:33 PM	0.1
<input type="checkbox"/>	Product 001	Kinjal Gala	2021-10-26 4:34 PM	Kinjal Gala	2021-10-26 4:34 PM	0.1
<input type="checkbox"/>	Clinical	Kinjal Gala	2021-10-26 4:34 PM	Kinjal Gala	2021-10-26 4:34 PM	0.1
<input checked="" type="checkbox"/>	Study 001	Kinjal Gala	2021-10-26 4:35 PM	Cam Mistry	2021-11-15 11:33 AM	0.2

**Notification:** ⓘ

Subject: \*

Removing Component

Message: \*

Please note that this component is being removed.

**Close** **Notify**

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5. The owner will receive an email notification:

#### Removing component



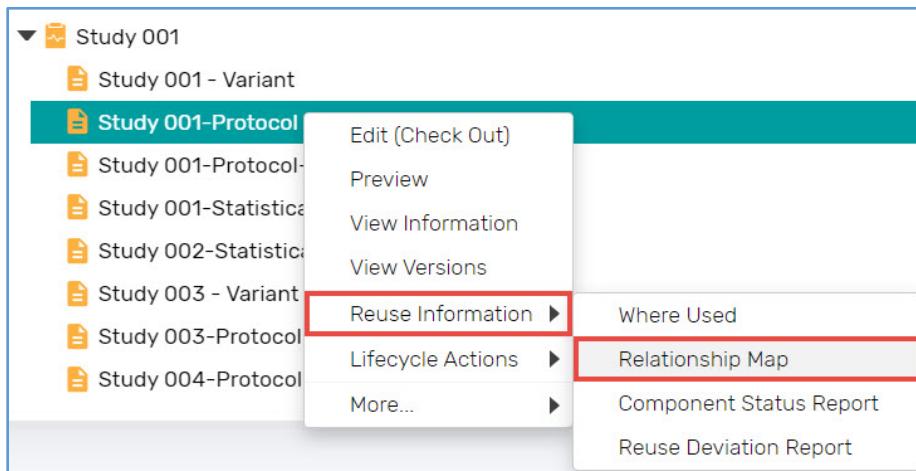
Please note that this component is being removed.

## 1.2 VIEWING THE RELATIONSHIP MAP

The **Relationship Map** provides details about any parent-sibling relationships for a business object (eg, document, component).

**Note:** This function is available in the *Web Console* **only**.

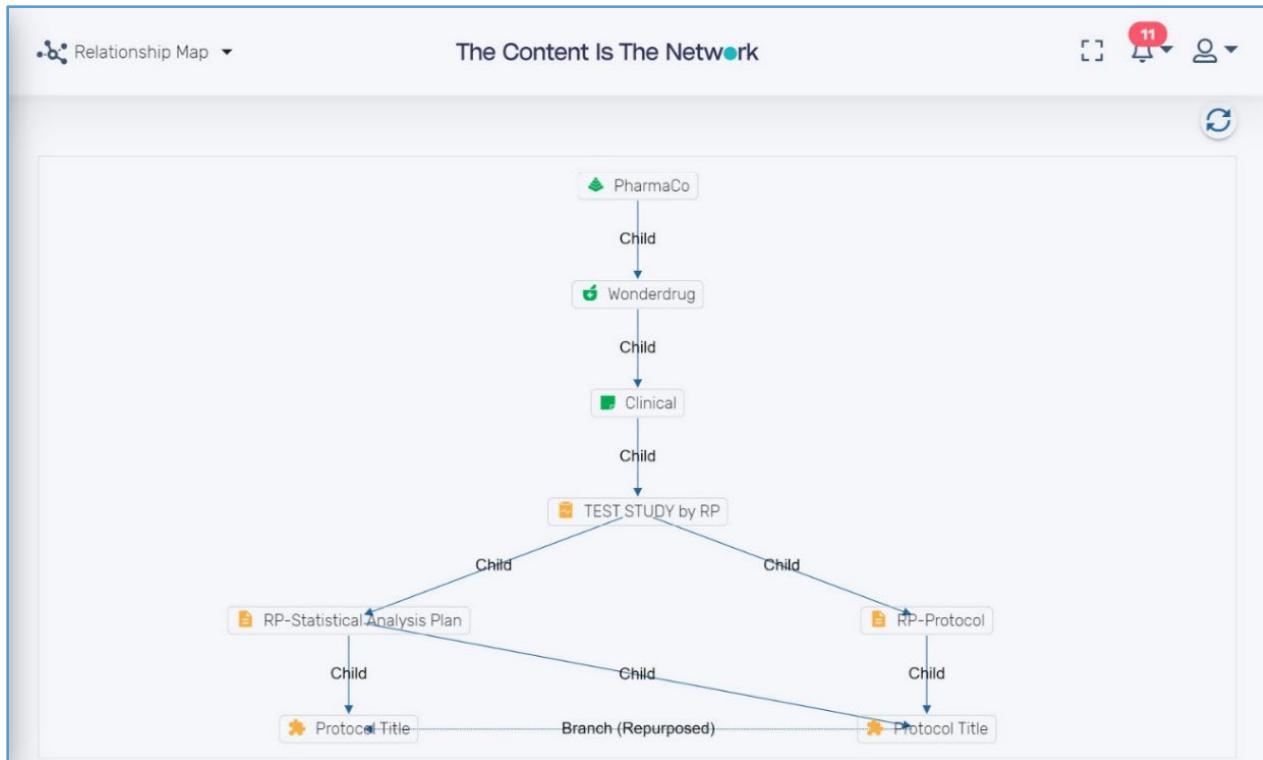
1. Navigate to the business object of interest (eg, document, component) in the **Navigator** and right-click on it. Under **Reuse Information**, click **Relationship Map**.



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2. A map showing the parent-sibling relationships for the selected business object will display:



**Notes:**

- Scroll in and out to zoom in and zoom out of the map, as needed.
- Click on the map to reposition the view.

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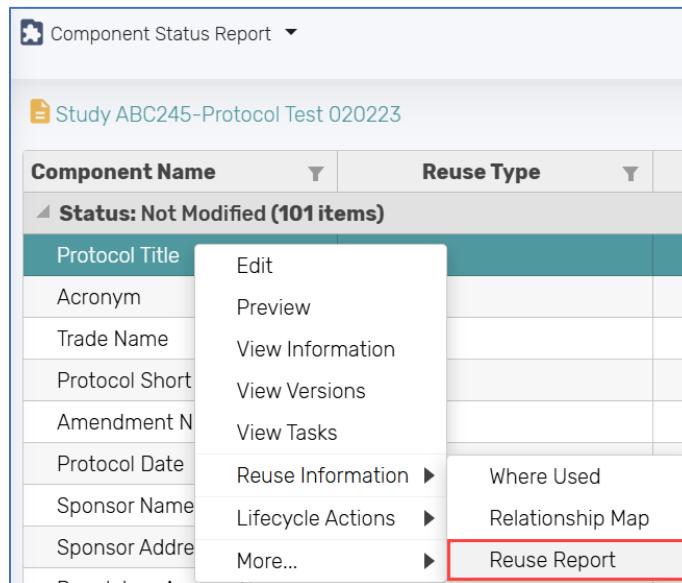
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## 1.3 VIEWING THE REUSE REPORT

The **Reuse Report** provides information about the lineage of a component in terms of its 'parent' or source as well as its child or children components, if applicable, along with associated reuse policy.

**Note:** The reuse report for a component can be viewed wherever a component object is found in the system, whether through the console view or the *Word app* view.

1. Double-click on a document in the Navigator (via *Web Console* or *InteliNotion Word App*) to launch its **Component Status Report**. Navigate to the component of a document in the **Component Status Report** and right-click on it. Under **Reuse Information**, click **Reuse Report**.



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2. A report with all relevant details and reuse information of that component will be displayed. The report will consist of three sections:

- a. **Immediate Parent Component:** This section displays the parent/source location information in relevance to the current component, if available.

**REUSE REPORT: AE GRADING SCALE**

Immediate Parent Component:				
Component Name	Associated Library	State	Last Modified	
AE Grading Scale	AI Standard Clinical Components	Approved	2024-09-11 11:53 PM	<a href="#">Close</a>

Current Component:				
Component Name	Associated Document	Reuse Policy from Parent	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-Protocol-01	Repurpose	Draft	2024-05-17 12:46 PM

Immediate Child Component(s):				
Component Name	Associated Document	Reuse Policy to Child	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-02-Multiple-...	Repurpose	Draft	2024-05-17 12:56 PM

- b. **Current Component:** This section displays information relevant to the current component. The current component section will always be displayed in the reuse report regardless of whether any reuse exists.

**REUSE REPORT: AE GRADING SCALE**

Immediate Parent Component:				
Component Name	Associated Library	State	Last Modified	
AE Grading Scale	AI Standard Clinical Components	Approved	2024-09-11 11:53 PM	<a href="#">Close</a>

Current Component:				
Component Name	Associated Document	Reuse Policy from Parent	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-Protocol-01	Repurpose	Draft	2024-05-17 12:46 PM

Immediate Child Component(s):				
Component Name	Associated Document	Reuse Policy to Child	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-02-Multiple-...	Repurpose	Draft	2024-05-17 12:56 PM

- c. **Immediate Child Component(s):** This section displays information of components that may be reused into downstream document(s), if available.

**REUSE REPORT: AE GRADING SCALE**

Immediate Parent Component:				
Component Name	Associated Library	State	Last Modified	
AE Grading Scale	AI Standard Clinical Components	Approved	2024-09-11 11:53 PM	<a href="#">Close</a>

Current Component:				
Component Name	Associated Document	Reuse Policy from Parent	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-Protocol-01	Repurpose	Draft	2024-05-17 12:46 PM

Immediate Child Component(s):				
Component Name	Associated Document	Reuse Policy to Child	State	Last Modified
AE Grading Scale	RP-Authoring-Demo-02-Multiple-...	Repurpose	Draft	2024-05-17 12:56 PM

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3. Available right-click actions:
  - a. **Edit:** To check out the component for editing.

**Note:**

    - Users will not be allowed to check out the component if it is checked out.
    - Users will not be allowed to check out the component if its source document is checked out.
    - Users will not be allowed to check out the component if it is an approved state.
    - Users will not be allowed to check out the component if it is a library component.
  - b. **Preview:** To view the latest component latest content.
  - c. **View Information:** To view the information of the selected component.
  - d. **View Versions:** To view version of the component
  - e. **View Tasks:** To view any tasks related to the selected component.
  - f. **Reuse Information:**
    - i. **Where Used:** To open the Where Used Report for selected component.
    - ii. **Relationship Map** (Web Console Only): A graphical representation showing relationships
    - iii. **Reuse Report:** The reuse report of the immediate parent and child component information will be displayed.
  - g. **Lifecycle Actions:** To send the component through configured lifecycle actions tasks.
  - h. **More** (Available if the component is not checked out):
    - i. **Locate Source Document in Navigator:** To open the component source document in navigator view. This applies to Word app and the console view for the Child and Parent component.
    - ii. **View Audit Logs:** To view audit logs for the selected component.
    - iii. **Edit Information:** To edit information (such as properties, name, state, etc.) for the selected component.

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#### 4. Manage Notifications: To subscribe to selected actions performed on the component

REUSE REPORT: ANALYSES ADVERSE EVENTS

Immediate Parent Component:				
Component Name	Associated Library	State		Last Modified
Analyses Adverse Events	AI Standard Clinical Components	Approved		2024-08-13 8:28 AM

Current Component:				
Component Name	Associated Document	Reuse Policy from Parent	State	Last Modified
Analyses Adverse Events	RP-Authoring-Demo-Protocol-01	Repurpose	Draft	2024-05-17 12:46 PM

Immediate Child Component(s):				
Component Name	Associated Document	Reuse Policy to Child	State	Last Modified
Analyses Adverse Events	Analyses Adverse Events	Multiple... Repurpose	Draft	2024-05-17 12:56 PM

Edit  
 Preview  
 View Information  
 View Versions  
 View Tasks  
 Reuse Information ► 0.5 2024-05-17 12:46 PM  
 Lifecycle Actions ► 0.5 2024-05-17 12:46 PM  
 More... ► Locate Source Document in Navigator  
 View Audit Logs  
 Edit Information  
 Manage Notifications

[Close](#)

## 1.4 VIEWING THE REUSE DEVIATION REPORT

A user will be able to view a **Reuse Deviation Report** for a specified document. The report will include the following types of information for each of the document's components:

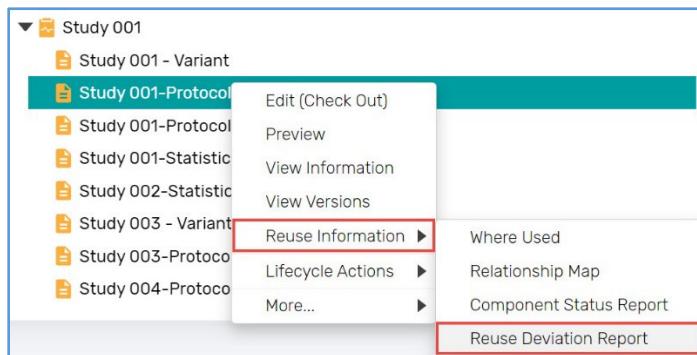
- Component's name and version
- Component's reuse information, if applicable, such as:
  - Reuse source (eg, upstream document or library) and parent component's version information
  - Planned and actual reuse policies
  - Change rationale if actual reuse policy differs from the planned one
  - Change comparison for repurpose reused components

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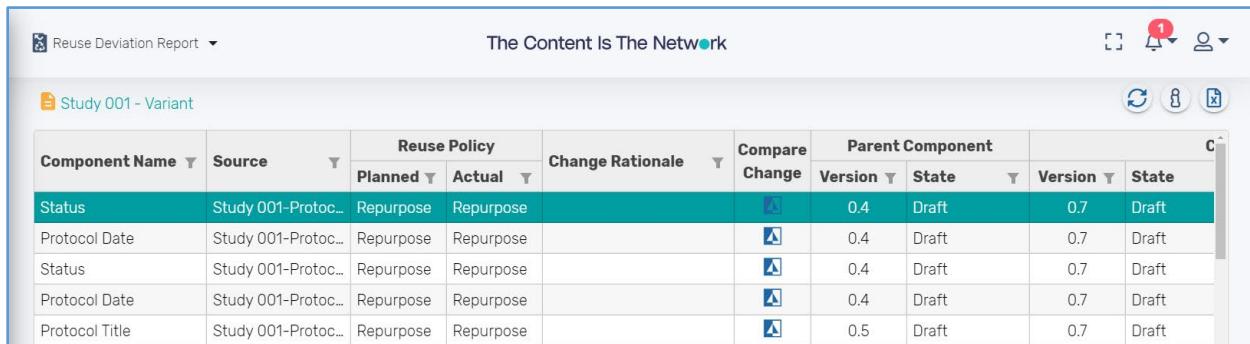
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Follow the steps listed below to view the Reuse Deviation Report.

1. Navigate to the document in the **Navigator** (via *Web Console* or *InteliNotion Word App*) and right-click on it. Under **Reuse Information**, click **Reuse Deviation Report**.

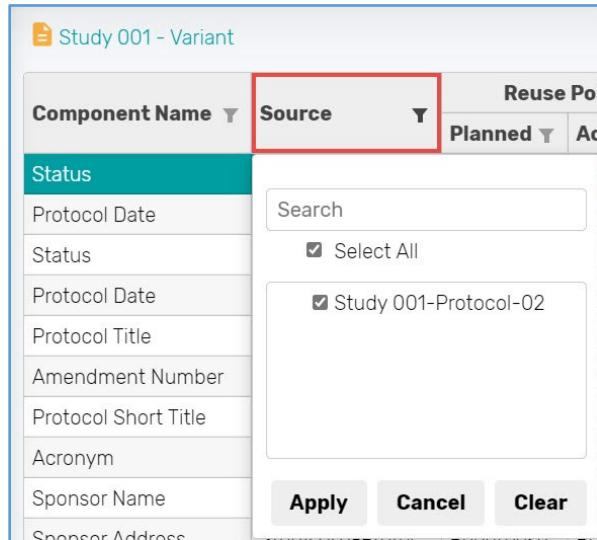


2. The Reuse Deviation Report will display.



Component Name	Source	Reuse Policy		Change Rationale	Compare Change	Parent Component		C	
		Planned	Actual			Version	State		
Status	Study 001-Protocol-02	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Date	Study 001-Protocol-02	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Status	Study 001-Protocol-02	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Date	Study 001-Protocol-02	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Title	Study 001-Protocol-02	Repurpose	Repurpose			0.5	Draft	0.7	Draft

3. Users will have the ability to filter options such as **Source**, **Reuse Policy**, **Parent Component**, etc.



Component Name	Source	Reuse Pol
Status	Protocol Date	Planned
Status	Protocol Date	Actual
Protocol Date	Protocol Title	Planned
Protocol Title	Amendment Number	Actual
Protocol Short Title	Protocol Short Title	Planned
Acronym	Protocol Short Title	Actual
Sponsor Name	Protocol Short Title	Planned
Sponsor Address	Protocol Short Title	Actual

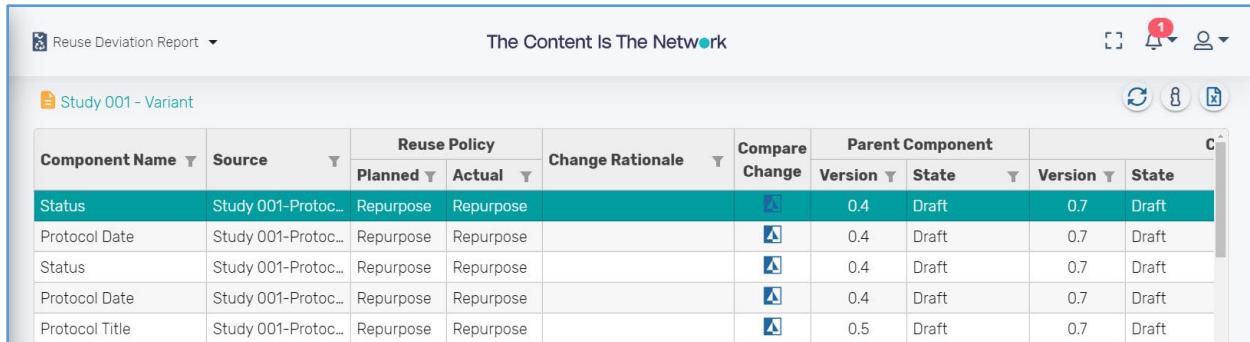
Search:   
 Select All  
 Study 001-Protocol-02  
 Apply    Cancel    Clear

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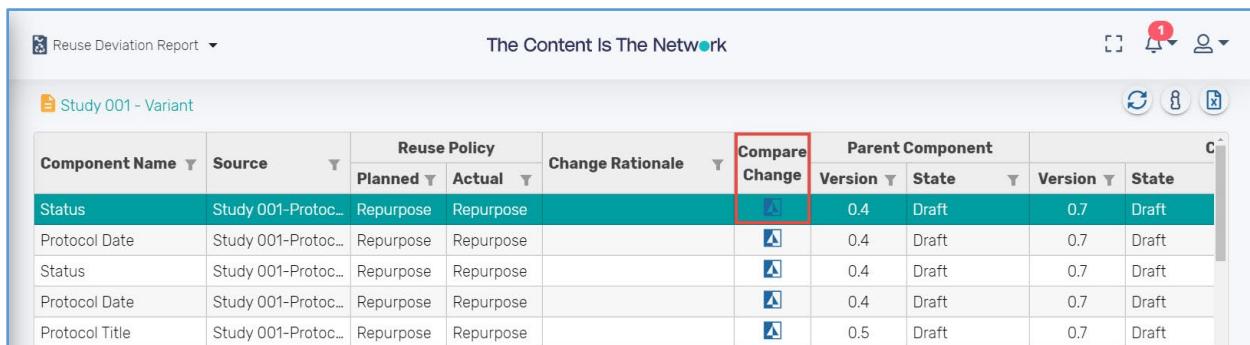
4. Click **Apply** and the filtered options will display.



The screenshot shows a table titled "Study 001 - Variant" under the "Reuse Deviation Report" tab. The table has columns for Component Name, Source, Reuse Policy (Planned vs Actual), Change Rationale, Compare Change (with a blue icon), Parent Component (Version and State), and a column for the current component (Version and State). The "Compare Change" column for the first row is highlighted with a blue icon.

Component Name	Source	Reuse Policy		Change Rationale	Compare Change	Parent Component		C
		Planned	Actual			Version	State	
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Title	Study 001-Protocol	Repurpose	Repurpose			0.5	Draft	0.7 Draft

5. For repurpose reused components only, click the **Compare Change** icon to view a comparison of the latest current component version (ie, the component in the document) vs the latest parent component version.



The screenshot shows the same table as above, but the "Compare Change" column for the first row is highlighted with a red box around the blue icon.

Component Name	Source	Reuse Policy		Change Rationale	Compare Change	Parent Component		C
		Planned	Actual			Version	State	
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7 Draft
Protocol Title	Study 001-Protocol	Repurpose	Repurpose			0.5	Draft	0.7 Draft

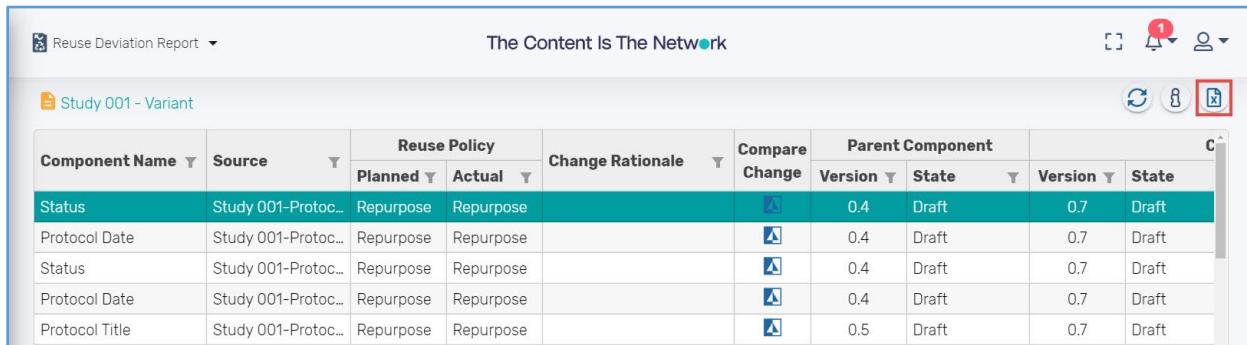
#### COMPARE PARENT COMPONENT 'TITLE (0.6)' WITH CURRENT COMPONENT 'TITLE (0.2)'

A(n) [intervention model] [primary purpose], [study phase], [blinding], [number]-arm study to investigate [health measurement/outcome] with [study intervention] [intervention form] compared with [study intervention] [intervention form] in [male and/or female] participants [aged X to X years of age] with [condition/disease]

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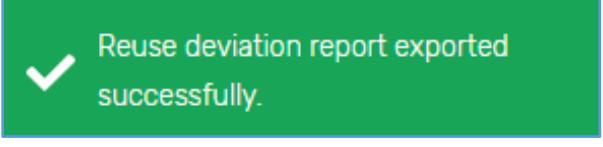
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6. When viewing the report in the *Web Console* only, export the report by clicking on the **Export report as excel file**  icon.



Component Name	Source	Reuse Policy		Change Rationale	Compare Change	Parent Component		C	
		Planned	Actual			Version	State		
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Status	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Date	Study 001-Protocol	Repurpose	Repurpose			0.4	Draft	0.7	Draft
Protocol Title	Study 001-Protocol	Repurpose	Repurpose			0.5	Draft	0.7	Draft

7. After the report is exported, a confirmation message will display, and a copy of the file is downloaded locally.



 Reuse deviation report exported successfully.

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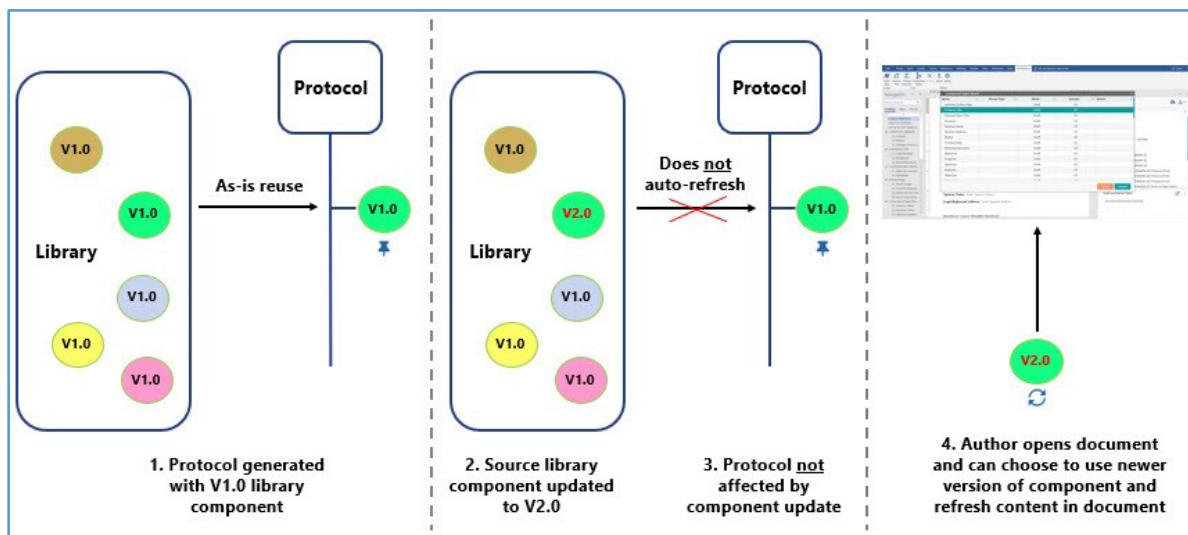
## 2. COMPONENT VERSION BINDING AND THE COMPONENT STATUS REPORT

### 2.1 OVERVIEW

A specific version of a component is bound/pinned to the document based on predefined, configurable rules by the admin, for example:

- If an **Approved** component is reused **As Is**
- If a **Draft** component is **Approved**
- If a **Draft** document is **Approved**

After the user edits/checks out a document in single authoring **and** if there were changes made to at least one component since the last document save, the user will be alerted of these changes via pop-up message and will be given the option there to open the **Component Status Report**. All components of the document are listed in the report, grouped under a relevant section such as **Modified** or **Not Modified**. Some components are auto refreshed based on rules and are identified accordingly.



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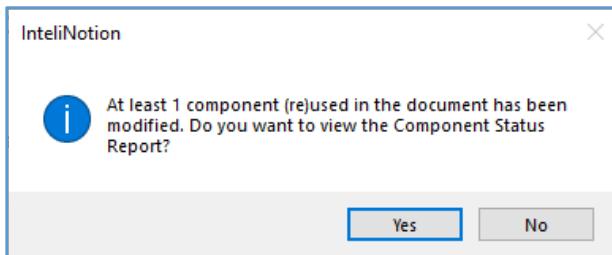
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## 2.2 HOW IT WORKS

See the information listed below for steps to use the Component Status Report.

**Note** The system admin should have enabled **Component Version Binding** by configuring the appropriate version binding rules for documents.

1. When a document is checked out for editing by a single user (see [Module 5](#)), if at least 1 of its reused components was updated, or 1 of its current components was updated outside of the document, the user is notified when he/she opens the document. Note that this notification is only displayed if the updated version of the reused component is available for use (eg, the latest version of a library component must be in an 'approved' state).



2. Click **Yes**. The **Component Status Report** will be displayed on the screen. All components included in the document are listed. The components can be filtered and sorted by clicking on the column heading. Icons are included next to the component name to indicate the following:
  - a. **Version Binding** (lock icon) – indicates that the component is version bound (ie, locked) to the document; its content will not be auto-refreshed if there is a new version available.
  - b. **Checkout Status** (padlock icon) – indicates that the component is checked out to a user.
  - c. **Edit Restriction Applied** (key icon) – indicates that the component's content cannot be edited due to either the info model's or template's policy.
  - d. **Auto Refresh** (refresh icon) – The current component in the document was auto-refreshed with updates made to the parent/source component based on the version binding rules (eg, the component was in a draft state when it was first as-is reused).
  - e. **Source/Parent Component** (person icon) – indicates that the information displayed in the 'State', 'Version', and 'Modified On' columns is of the source/parent component.

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3. The updated components are listed under a relevant section if the source reused component was updated, or the current document's component was updated outside of the document (ie, individually). See [Section 3.2](#) for details of the different sections.

**Notes:**

- If the component's owner or property value (excluding its state) is changed, this will not be shown as a change on the component status report.
- The current version of the source component is displayed in parenthesis in the Version column. The version outside the parenthesis is the version of the component currently (re)used in that document. For components listed in the 'Modified' section, the information displayed in the 'State', 'Version' and 'Modified On' columns will be of the parent/source component.
- The user can click on the filter icon next to the column and sort label the component's list as per the condition listed below:
  - **Component Name** – sort by specific component via checkbox or search all components
  - **Reuse Type** – sort by reuse type via checkbox selection (Use As Is, Repurpose, DeNovo)
  - **State** – sort by state via checkbox selection (Draft, Approved)
  - **Version** – sort by version via checkbox or ascending/descending order
  - **Modified On** – sort by date/time listed in each cell for the components. The user can enter a date range and click on Apply to filter the components based on the date range they have entered
  - **Change Type** – sort by change type via checkbox (types listed below)
    - **Component** - the component was replaced in the parent document
    - **Content** - the current component's content was modified (eg, outside of the document)
    - **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
    - **New Repeating Instance** - a new repeating instance of the reused component was added in the parent document
    - **New Repeating Set** - a new repeating component set or table set instance was added in the parent document
    - **Deleted Repeating Instance** - a previously reused repeating instance of the component was deleted from the parent document

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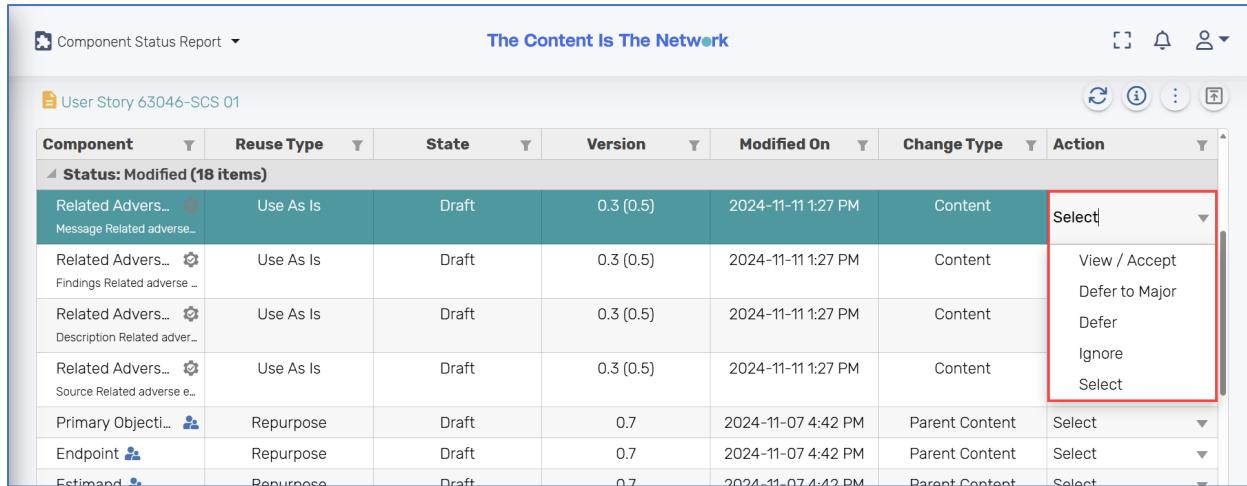
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- **Deleted Repeating Set** - a previously reused repeating component set or table set instance was deleted from the parent document
  - **Deleted** - a previously reused (non-repeating) component was deleted from the parent document
  - **Action** – sort by action taken via checkbox (View/Accept, Defer to Major, Defer, Ignore)
  - The user can click on the filter icon in the **Modified On** cell and will see a date range option. The user can enter a date range and click on Apply to filter the components based on the date range they have entered.
  - The **Modified On** date will not be populated for components with change type **New Repeating Instance** and **Deleted Repeating Instance**.
4. When a document is checked out, all its associated, editable components are also checked out (ie, de novo or repurpose reused components). Similarly, when a document is checked in and up versioned, all its associated, editable components are also checked in and up versioned. As a result of this, some of the as-is reused components listed in the **Component Status Report** are included under the **Not Modified** section with 2 versions displayed in the Version column. In this case, there was no content or formatting change made to the as-is reused component, which is why it is listed under **Not Modified**. However, the following types of content changes may result in a false negative (ie, the component is listed under **Not Modified**, but a change was still made):
- Insert → Tables → Quick Table
  - Insert → Illustrations → Shapes → Callouts
  - Table Layout → Properties → Title / Description
  - Layout → Bring Forward, Send Backward, Selection Pane
  - Review → Comments → Comment Resolve / Reopen / Reply
  - Review → Tracking → Reviewing Pane Vertical or Horizontal (all edits made using the pane)
  - Right-click → Number or Bullet List Paragraph → Adjust List Indents
  - Developer → Controls → Properties

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5. The following actions can be performed on the components listed in the Modified section, unless they were auto refreshed when the document was edited/checked out:



Component	Reuse Type	State	Version	Modified On	Action Type	Action
<b>▲ Status: Modified (18 items)</b>						
Related Advers...	Use As Is	Draft	0.3 (0.5)	2024-11-11 1:27 PM	Content	Select
Message Related adverse...						
Related Advers...	Use As Is	Draft	0.3 (0.5)	2024-11-11 1:27 PM	Content	View / Accept
Findings Related adverse ...						
Related Advers...	Use As Is	Draft	0.3 (0.5)	2024-11-11 1:27 PM	Content	Defer to Major
Description Related adver...						
Related Advers...	Use As Is	Draft	0.3 (0.5)	2024-11-11 1:27 PM	Content	Defer
Source Related adverse e...						
Primary Objecti...	Repurpose	Draft	0.7	2024-11-07 4:42 PM	Parent Content	Select
Endpoint	Repurpose	Draft	0.7	2024-11-07 4:42 PM	Parent Content	Select
Estimand	Repurpose	Draft	0.7	2024-11-07 4:42 PM	Parent Content	Select

- **View / Accept** – view all versions of the reused component, compare 2 versions, and select a new version to use (see [Section 2.4](#) for details).

**Note:** When accepting components via the component status report that have had their reuse changed to different policies in separate upstream documents, eg **Repurpose** in Doc A and **Use As Is** in Doc B, users must follow the steps listed below depending on the conditions:

- If the document is open for editing:
  - The user must view/accept the Parent Content change and then click Update in the Component Status Report.
  - Component change will not show the view/accept drop-down.
  - Then, the user can reopen the Component Status Report and view/accept the component change and then click Update in the Component Status Report.
  - The user does NOT have to save the document in between the operations.
- If the document is closed for editing:
  - The user must view/accept the Parent Content change and then click Update in the Component Status Report.
  - Component change will not show the view/accept drop-down.
  - The user must save the document.
  - Then, the user can reopen the Component Status Report and view/accept the component change.

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- Finally, the user must save the document again.
  - **Defer to Major** – take no action and the user is not notified again until a major version (eg, 1.0, 2.0) of the reused component is available. After the **Defer to Major** option is selected for a component, it will remain in the **Modified** section with the selection displayed, so that it can be changed later, if needed (see [Section 2.4.2](#) for details).
  - **Defer** – take no action and the user is not notified until the next minor version (eg, 0.2, 1.1) of the component is available (see [Section 2.4.2](#) for details).
- Note:** This action is not available for approved library components.
- **Ignore** – marking a component as **Ignore** will suppress the component status report pop-up notifications received for any/all updates made to the parent/source component. Refer to [Section 2.4.3](#) for more information related to ignoring changes.

**Notes:** The **Defer to Major** and **Defer** actions can also be applied to multiple components at once as follows:

- For individual components – click on 1 component in the **Modified** section of the **Component Status Report**. While pressing the **Ctrl** key on the keyboard, 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 1 component in the **Modified** section of the **Component Status Report**. While pressing the **Shift** key on the keyboard, click on 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.

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Additional information regarding the Component Status Report can be found by clicking on the information icon :

**COMPONENT STATUS REPORT HELP**

X

1. The latest state and version for the component is displayed in parentheses, if applicable.
2. A component may be listed in the 'Modified' section even though no content change was made during co-authoring.
3. A component with a 'Repurpose' Reuse Type included in the 'Modified' section may also appear in the 'Not Modified' section, based on the status of the current component in the document.
4. After a component is moved to the 'Ignored' section, the system will not alert the user about the component being modified again until this action is changed later, if needed.
5. A repeating component or component set included in the 'Ignored' section may have either:
  - a. Already existed when the document was first generated but was not selected for reuse at that time. OR
  - b. Been previously reused in the document but was subsequently deleted from it.
6. If the Action is reverted back to 'Select', the component will be moved to the relevant modified section after saving.
7. For Change Type:
  - a. Component = The component was replaced in the parent document.
  - b. Content = The current component's content was modified (eg, outside of the document).
  - c. Parent Content = The parent component's content was modified.
  - d. Content and Parent Content = The current component's content, as well as the parent component's content, was modified.
  - e. New Repeating Instance = A new repeating instance of the reused component was added in the parent document.
  - f. New Repeating Set = A new repeating component set or table set instance was added in the parent document.
  - g. Deleted Repeating Instance = A previously reused repeating instance of the component was deleted from the parent document.
  - h. Deleted Repeating Set = A previously reused repeating component set or table set instance was deleted from the parent document.
  - i. Deleted = A previously reused (non-repeating) component was deleted from the parent document.
8. Components that are part of either a component set or table set will be displayed in a group under a respective set row in the 'Not Modified' section only. If any single component from a set is listed in another section (eg, 'Modified'), it will be shown individually.
9. A component set can be reused from the 'Not Modified' section only.
10. Use Ctrl+Click to select multiple individual items or Shift+Click to select a range of items.

**Close**

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## 2.3 ACCESSING THE COMPONENT STATUS REPORT

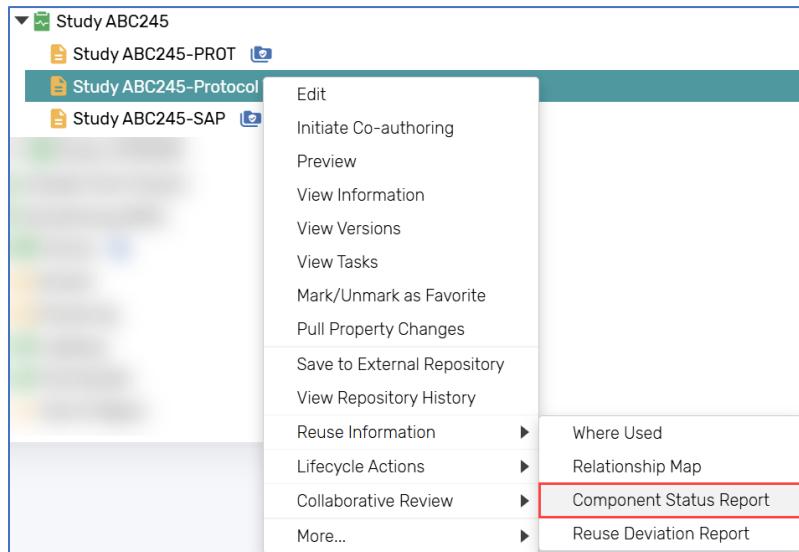
As mentioned in [Section 2.2](#) above, the **Component Status Report** may be launched after electing to do so from the initial change notification pop-up message displayed when the document is first edit/checked out for authoring.

The **Component Status Report** also can be opened on demand via the *InteliNotion Ribbon* for the edit/checked out document:

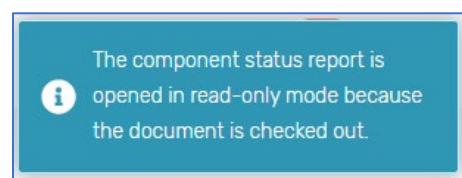


In addition, the **Component Status Report** for any document, either opened or closed, can be accessed in **one** of the following two ways:

- Double click on the document name in the Navigator via the *Web Console* or the *InteliNotion Word App*.
- Right-click on a document name and under **Reuse Information**, select **Component Status Report** option.



**Note:** If a document is currently checked out by a user and another user attempts to access the component status report, the following message will display:



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## 2.4 USING THE COMPONENT STATUS REPORT IN AN OPEN DOCUMENT

See the sections listed below for instructions on how to use the Component Status Report, such as accepting, deferring, or ignoring changes to components.

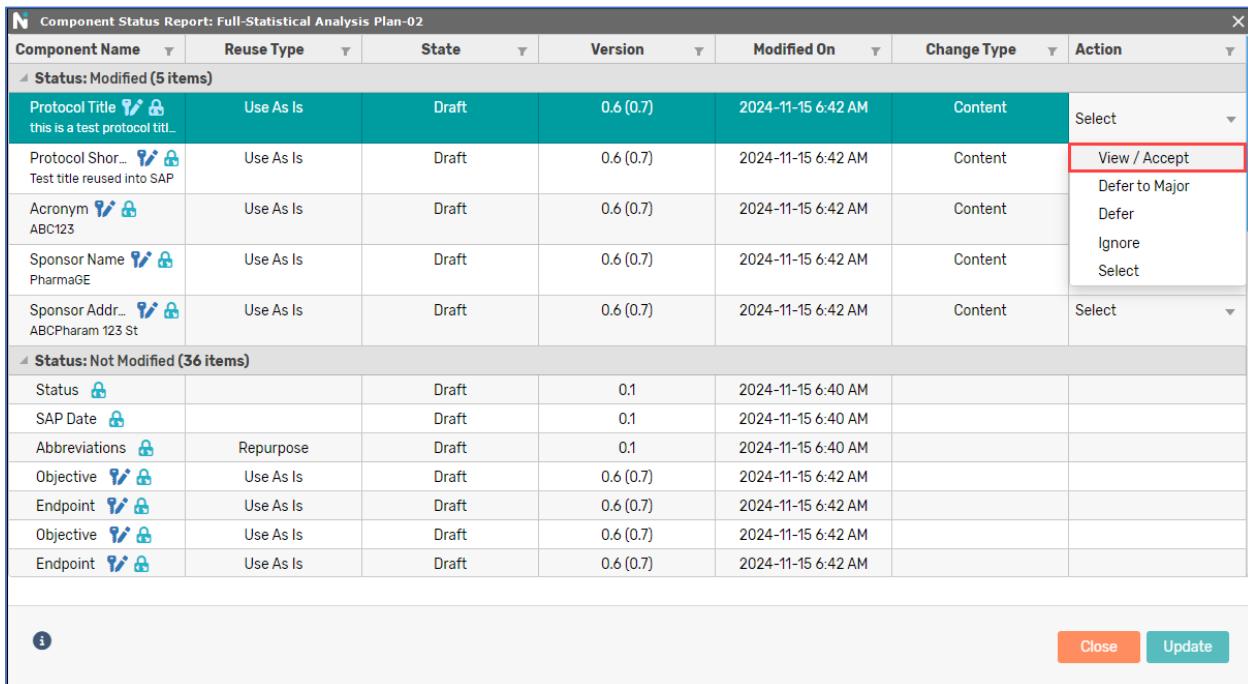
### 2.4.1 Accepting Changes

See the sections below for instructions on accepting changes to components.

#### 2.4.1.1 As-Is Reused Component (Content Change Type)

If a component was as-is reused, its version was not bound or locked to the document (eg, because the component was in a draft state), and the **Change Type** is 'Content,' use the steps below to view and accept the update made to the parent/source component. If a component was as-is reused and the **Change Type** is 'Component,' see [Section 2.4.1.3](#) for details on how to accept the update.

1. Select the **View / Accept** action.



The screenshot shows a 'Component Status Report' dialog box with the title 'Component Status Report: Full-Statistical Analysis Plan-02'. The table has columns: Component Name, Reuse Type, State, Version, Modified On, Change Type, and Action. There are two sections: 'Status: Modified (5 items)' and 'Status: Not Modified (36 items)'. In the 'Action' column for the first item ('Protocol Title'), a context menu is open with options: View / Accept (highlighted in red), Defer to Major, Defer, Ignore, and Select. At the bottom right of the dialog are 'Close' and 'Update' buttons.

**Note:**

- The current state and version for the component are displayed in parentheses, if applicable.
- Adding repeating components through the component status report is not currently enabled for users.

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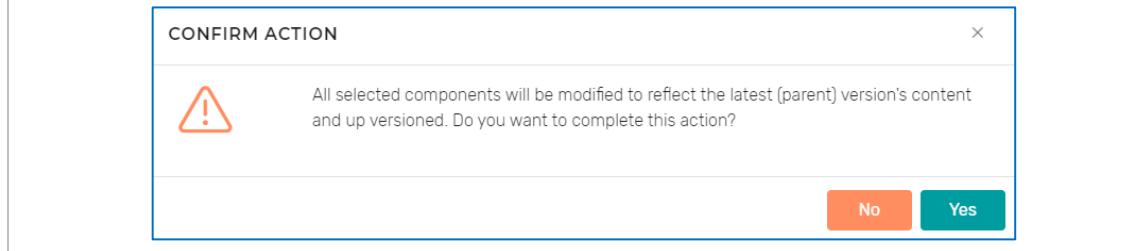
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- If bulk selecting components to update, right click and choose the applicable action.

Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>▲ Status: Modified (5 items)</b>						
Protocol Title  	Use As Is	View / Accept	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
this is a test protocol titl...		Defer	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
Protocol Shor...  	Use As Is	Defer to Major	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
Acronym  	Use As Is	Ignore	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
Sponsor Name  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
PharmaGE						
Sponsor Addr...  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	Select
ABCPharam 123 St						
<b>▲ Status: Not Modified (36 items)</b>						
Status 		Draft	0.1	2024-11-15 6:40 AM		
SAP Date 		Draft	0.1	2024-11-15 6:40 AM		
Abbreviations 	Repurpose	Draft	0.1	2024-11-15 6:40 AM		
Objective  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Endpoint  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Objective  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Endpoint  	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
					<b>Close</b>	<b>Update</b>

**Note:** If **View/Accept** is the action taken, all the selected components that have a **Use As Is** reuse policy AND any change type (ie, **Content** OR **Component**) will be modified and up versioned. The component content will be updated as per the latest available version of each source component.



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2. A **Select Version** pane will display on the screen.

SELECT VERSION: PROTOCOL TITLE				
<input type="checkbox"/>	Version	Modified On	Size	State
<input type="checkbox"/>	0.7	2024-11-15 6:42 AM	6.34 KB	Draft
<input checked="" type="checkbox"/>	0.6	2024-02-28 1:34 PM	3 Bytes	Draft
<input type="checkbox"/>	0.5	2024-02-28 1:33 PM	3 Bytes	Draft
<input type="checkbox"/>	0.4	2024-02-28 1:32 PM	3 Bytes	Draft
<input type="checkbox"/>	0.3	2023-11-10 12:55 AM	3 Bytes	Draft
<input type="checkbox"/>	0.2	2023-10-27 7:05 PM	3 Bytes	Draft
<input type="checkbox"/>	0.1	2023-10-27 6:33 PM	0Kb	Draft

■ Indicates the component version cu...

**Close**   **Compare Versions**   **Use Version**

**Note:** The component version currently being used in the document is highlighted in green.

3. If desired, compare 2 versions of the source component by clicking the checkbox next to each version, and clicking **Compare Versions**. A new **Compare Versions** pane will display to show the differences between versions in track changes; click the **X** at the top-right corner of the pane to close it.

SELECT VERSION: PROTOCOL TITLE				
<input type="checkbox"/>	Version	Modified On	Size	State
<input checked="" type="checkbox"/>	0.7	2024-11-15 6:42 AM	6.34 KB	Draft
<input checked="" type="checkbox"/>	0.6	2024-02-28 1:34 PM	3 Bytes	Draft
<input type="checkbox"/>	0.5	2024-02-28 1:33 PM	3 Bytes	Draft
<input type="checkbox"/>	0.4	2024-02-28 1:32 PM	3 Bytes	Draft
<input type="checkbox"/>	0.3	2023-11-10 12:55 AM	3 Bytes	Draft
<input type="checkbox"/>	0.2	2023-10-27 7:05 PM	3 Bytes	Draft
<input type="checkbox"/>	0.1	2023-10-27 6:33 PM	0Kb	Draft

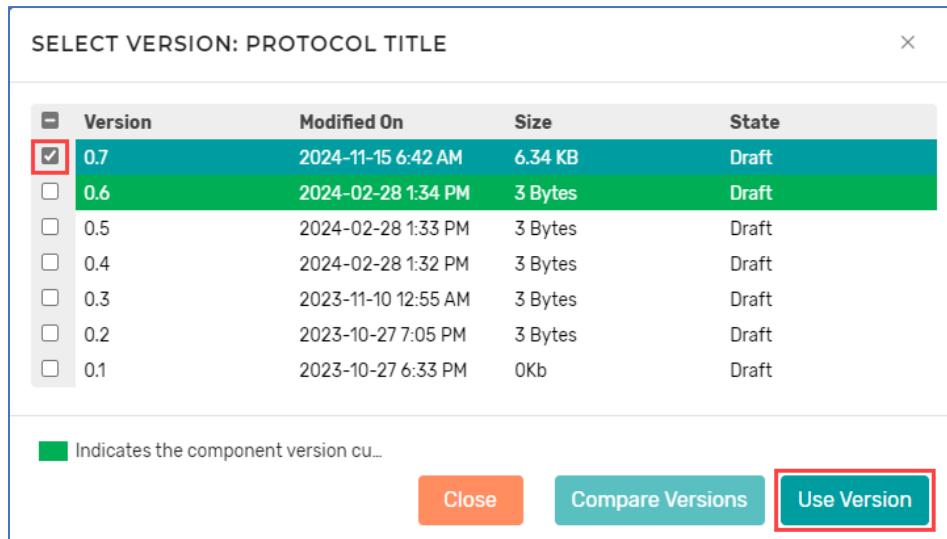
■ Indicates the component version cu...

**Close**   **Compare Versions**   **Use Version**

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4. If an updated version is to be used in the document, select the appropriate version by clicking the checkbox next to it, and click **Use Version**.



5. Click **Update** to refresh the selected version's content into the document.

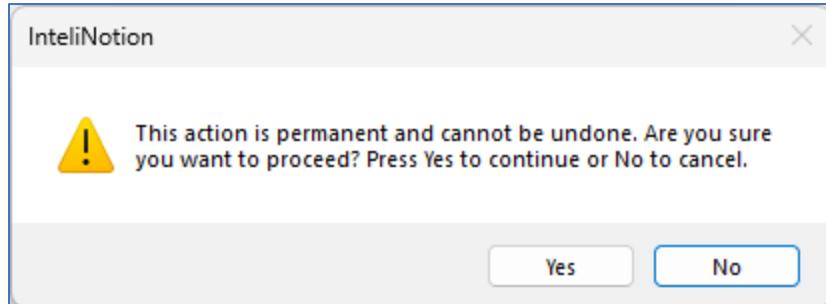
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
Protocol Title   this is a test protocol title...	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	<b>Select</b>
Protocol Short Name   Test title reused into SAP	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	<b>Select</b>
Acronym   ABC123	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	<b>Select</b>
Sponsor Name   PharmaGE	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	<b>Select</b>
Sponsor Address   ABCPharam 123 St	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM	Content	<b>Select</b>
Status		Draft	0.1	2024-11-15 6:40 AM		
SAP Date		Draft	0.1	2024-11-15 6:40 AM		
Abbreviations	Repurpose	Draft	0.1	2024-11-15 6:40 AM		
Objective	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Endpoint	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Objective	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		
Endpoint	Use As Is	Draft	0.6 (0.7)	2024-11-15 6:42 AM		

**Close** **Update**

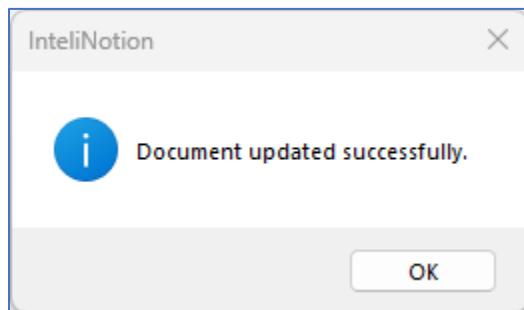
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6. The following confirmation message will display. Click **Yes**:



7. The following confirmation message will display:



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8. After the update completes, the content of the component in the document is refreshed to reflect the new version, as shown below in this example:

Before update
<p><b>AE Grading Scale</b></p> <p>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:</p> <ul style="list-style-type: none"><li>• Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.</li><li>• Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental activities of daily living (ADL)*.</li><li>• Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**.</li><li>• Grade 4: Life-threatening consequences; urgent intervention indicated.</li><li>• Grade 5: Death related to AE.</li></ul> <p>*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.</p> <p>**Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.</p> <p>More edits made to the component</p>
After update
<p><b>AE Grading Scale</b></p> <p>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:</p> <ul style="list-style-type: none"><li>• Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.</li><li>• Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental activities of daily living (ADL)*.</li><li>• Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**.</li><li>• Grade 4: Life-threatening consequences; urgent intervention indicated.</li><li>• Grade 5: Death related to AE.</li></ul> <p>*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.</p> <p>**Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.</p> <p>Last sentence was removed</p>

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#### 2.4.1.2 Repurpose Reused Component (Parent Content or Content and Parent Content)

If a component was repurpose reused and the **Change Type** is 'Parent Content,' use the steps below to view and accept the update made to the parent/source component. If a component was repurpose reused and the **Change Type** is 'Component,' see [Sections 2.4.1.3](#) for details on how to accept the update.

1. Select the **View / Accept** action.

Component Name	Reuse Type	State	Version	Modified On	Action	
<b>▲ Status: Modified (7 items)</b>						
Acronym	Use As Is	Draft	0.6 (0.8)	2024-11-15 4:43 PM	Content	Select
Sponsor Name	Use As Is	Draft	0.6 (0.8)	2024-11-15 4:43 PM	Content	Select
Sponsor Addr...	Use As Is	Draft	0.6 (0.8)	2024-11-15 4:43 PM	Content	Select
Abbreviations	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Hypotheses	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Sample Size D...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	<b>View / Accept</b>
Randomizatio...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Defer to Major Defer Ignore Select
<b>▲ Status: Not Modified (38 items)</b>						
Protocol Title	Use As Is	Draft	0.7 (0.8)	2024-11-15 4:43 PM		
Protocol Sh...	Use As Is	Draft	0.7 (0.8)	2024-11-15 4:43 PM		
						<b>Close</b> <b>Update</b>

**Note:** When a user views a document's **Component Status Report**, the 'State', 'Version' and the 'Modified On' column will display information of the parent component.

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- If bulk selecting components to update, right click and choose the applicable action.

Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
Status: Modified (7 items)						
Acronym	Use As Is	Draft	0.8	2024-11-15 4:43 PM	Content	
Sponsor N...	Use As Is	Draft	0.8	2024-11-15 4:43 PM	Content	
Sponsor A...	Use As Is	Draft	0.8	2024-11-15 4:43 PM	Content	
Abbreviations	Repurpose	Draft	<span style="border: 1px solid red; padding: 2px;">View / Accept</span>	2024-11-15 4:43 PM	Parent Content	Select
Lorem ipsum dolor sit a...			Defer	2024-11-15 4:43 PM	Parent Content	Select
Hypotheses	Repurpose	Draft	Defer to Major	2024-11-15 4:43 PM	Parent Content	Select
Video provides a powerf...			Ignore	2024-11-15 4:43 PM	Parent Content	Select
Sample Size D...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Randomizatio...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Lorem ipsum dolor sit a...						
Status: Not Modified (38 items)						
Protocol Title	Use As Is	Draft	0.8	2024-11-15 4:43 PM		
this is a test protocol t...						
Protocol Sh...	Use As Is	Draft	0.8	2024-11-15 4:43 PM		
Test title reused into S...						

Close    Update

**Note:** If **View/Accept** is the action taken, all the selected components that have a **Repurpose** reuse policy AND the change type is listed as **Component** will be modified. The component content will be updated as per the latest available parent component version for each component.

2. A **Select Version** pane will appear on the screen. The pane has 2 tabs:
  - a. **Current Component** - The version history of the current component (ie, child) in the document is displayed.

**SELECT VERSION: HYPOTHESES**

Current Component	Parent Component												
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Version</th> <th style="width: 15%;">Modified On</th> <th style="width: 15%;">Size</th> <th style="width: 15%;">State</th> </tr> </thead> <tbody> <tr> <td style="background-color: #009640; color: white; text-align: center;">0.2</td> <td style="text-align: center;">2024-11-15 4:37 PM</td> <td style="text-align: center;">10.19 KB</td> <td style="text-align: center;">Draft</td> </tr> <tr> <td style="text-align: center;">0.1</td> <td style="text-align: center;">2024-11-15 6:40 AM</td> <td style="text-align: center;">3 Bytes</td> <td style="text-align: center;">Draft</td> </tr> </tbody> </table>		Version	Modified On	Size	State	0.2	2024-11-15 4:37 PM	10.19 KB	Draft	0.1	2024-11-15 6:40 AM	3 Bytes	Draft
Version	Modified On	Size	State										
0.2	2024-11-15 4:37 PM	10.19 KB	Draft										
0.1	2024-11-15 6:40 AM	3 Bytes	Draft										
<span style="color: #009640;">█</span> Indicates the component version cu...													
<span style="border: 1px solid #ccc; padding: 2px 10px; background-color: #ff9933; color: white; font-weight: bold;">Close</span> <span style="border: 1px solid #ccc; padding: 2px 10px; background-color: #009640; color: white; font-weight: bold;">Compare Versions</span> <span style="border: 1px solid #ccc; padding: 2px 10px; background-color: #009640; color: white; font-weight: bold;">Use Version</span>													

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- b. **Parent Component** - The version history of the parent component (from the source document) is displayed.

SELECT VERSION: HYPOTHESES

<input type="checkbox"/> Version	Modified On	Size	State
<input type="checkbox"/> 0.8	2024-11-15 4:43 PM	10.03 KB	Draft
<input type="checkbox"/> 0.7	2024-11-15 6:42 AM	3 Bytes	Draft
<input checked="" type="checkbox"/> 0.6	2024-02-28 1:34 PM	3 Bytes	Draft
<input type="checkbox"/> 0.5	2024-02-28 1:33 PM	3 Bytes	Draft
<input type="checkbox"/> 0.4	2024-02-28 1:32 PM	3 Bytes	Draft
<input type="checkbox"/> 0.3	2023-11-10 12:55 AM	3 Bytes	Draft
<input type="checkbox"/> 0.2	2023-10-27 7:05 PM	3 Bytes	Draft
<input type="checkbox"/> 0.1	2023-10-27 6:33 PM	0Kb	Draft

█ Indicates the parent component ver...

[Close](#) [Compare Versions](#) [Use Version](#)

**Note:** The component version currently used in the document is highlighted in green.

- c. IF a comparison between two versions of the component is needed, check the check box next to the version to be compared against the version used in the document on the **Parent Component** tab, and click **Compare Versions**.

SELECT VERSION: HYPOTHESES

<input type="checkbox"/> Version	Modified On	Size	State
<input checked="" type="checkbox"/> 0.8	2024-11-15 4:43 PM	10.03 KB	Draft
<input type="checkbox"/> 0.7	2024-11-15 6:42 AM	3 Bytes	Draft
<input checked="" type="checkbox"/> 0.6	2024-02-28 1:34 PM	3 Bytes	Draft
<input type="checkbox"/> 0.5	2024-02-28 1:33 PM	3 Bytes	Draft
<input type="checkbox"/> 0.4	2024-02-28 1:32 PM	3 Bytes	Draft
<input type="checkbox"/> 0.3	2023-11-10 12:55 AM	3 Bytes	Draft
<input type="checkbox"/> 0.2	2023-10-27 7:05 PM	3 Bytes	Draft
<input type="checkbox"/> 0.1	2023-10-27 6:33 PM	0Kb	Draft

█ Indicates the parent component ver...

[Close](#) [Compare Versions](#) [Use Version](#)

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**Note:** If the previous version that is being compared to the version used in the document has been deleted, the highlight color will show as red.

- If an updated version of the parent component is to be used, select the appropriate version by clicking the checkbox next to it, and click **Use Version**.

SELECT VERSION: HYPOTHESES

Current Component
Parent Component

#	Version	Modified On	Size	State
<input checked="" type="checkbox"/>	0.8	2024-11-15 4:43 PM	10.03 KB	Draft
<input type="checkbox"/>	0.7	2024-11-15 6:42 AM	3 Bytes	Draft
<input type="checkbox"/>	0.6	2024-02-28 1:34 PM	3 Bytes	Draft
<input type="checkbox"/>	0.5	2024-02-28 1:33 PM	3 Bytes	Draft
<input type="checkbox"/>	0.4	2024-02-28 1:32 PM	3 Bytes	Draft
<input type="checkbox"/>	0.3	2023-11-10 12:55 AM	3 Bytes	Draft
<input type="checkbox"/>	0.2	2023-10-27 7:05 PM	3 Bytes	Draft
<input type="checkbox"/>	0.1	2023-10-27 6:33 PM	0KB	Draft

■ Indicates the parent component ver...

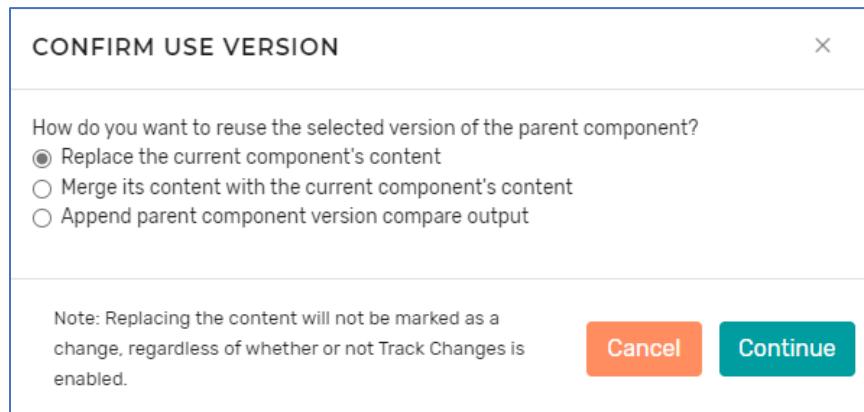
Close
Compare Versions
Use Version

- A pop-up message will display and provide 3 options:
  - Replace the current component's content** – this option replaces the content of the current component (child) with that of the parent component; any edits made to the current component since it was initially reused from the parent will be lost.
  - Merge its content with the current component** – this option merges the content of the current component (child) with that of the parent component; the merged content is added into the component in track changes, so the user can accept/reject individual edits, as needed.

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- **Append parent version compare output** – this option performs a comparison of the version used in the document and the user selected version and appends the compare result at end of the child component. Once this comparison is complete, there is the option to append just these changes into the downstream document's component. The existing content of the downstream document will not be affected.



5. Choose one of the above options, as appropriate, and click **Continue**.
6. Click **Update** icon to either merge in the selected parent version's content or replace the existing content in the document.

Component Status Report: Full-Statistical Analysis Plan-02						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Modified (7 items)</b>						
Acronym	Use As Is	Draft	0.6 (0.8)	2024-11-15 4:43 PM	Content	Select
ABC123						
Sponsor Name	Use As Is	Draft	0.6 (0.8)	2024-11-15 4:43 PM	Content	Select
PharmadE						
Sponsor Addr...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
ABCPharam 123 St						
Abbreviations	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Video provides a power...						
Hypotheses	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	View / Accept
Video provides a power...						
Sample Size D...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Video provides a power...						
Randomizatio...	Repurpose	Draft	0.8	2024-11-15 4:43 PM	Parent Content	Select
Lorem ipsum dolor sit a...						
<b>Status: Not Modified (36 items)</b>						
Protocol Title	Use As Is	Draft	0.7 (0.8)	2024-11-15 4:43 PM		
this is a test protocol f...						
Protocol Sh...	Use As Is	Draft	0.7 (0.8)	2024-11-15 4:43 PM		
Test title reused into S...						

**Note:** Multiple components can have actions selected for them individually before clicking **Update** so that they are all refreshed into the document at 1 time.

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7. After the update completes, the content of the component in the document is refreshed to reflect the new version, as follows:

- a. If the **Replace the current component's content** option is selected, the component's content is replaced entirely; this change is not tracked.

Before

**2.2 Sample Size Justification**  
Sample Size Determination

Approximately 90 participants will be enrolled in the study and approximately 30 participants will be assigned to treatment with WON-5539.

This is a single-arm estimation study. It is assumed that an MRD-negative rate of 10% could be observed by chance in this study. Therefore, if the assumed rate of MRD negativity is at least 30%, then the sample size for this study ( $N = 30$ ) is sufficient to demonstrate that, with 95% confidence, the rate of achieving MRD negativity is greater than 10%. This would also be sufficient to demonstrate evidence of clinical activity.

After

**2.2 Sample Size Justification**  
Sample Size Determination

Approximately 90 participants will be enrolled in the study and approximately 30 participants will be assigned to treatment with WON-5539.

A table showing the CI for different assumed rates of MRD negativity with a sample size of  $N = 30$  is presented below:

Assumed rate of MRD negativity, n (%)	Lower 95% Confidence Limit (%)	Upper 95% Confidence Limit (%)
8 (26.7)	12.3	45.9
9 (30)	14.7	49.4
11 (36.7)	19.9	56.1
12 (40)	22.7	59.4
14 (46.7)	28.3	65.7

The study will enroll approximately 90 participants to achieve the desired sample size of 30 participants who are MRD-positive at the time of enrollment or during the run-in period. As part of the run-in period participants will be followed by clinic visits at 3, 5, 7, 9 and 12 months and thereafter every 3 months up to 24 months for monitoring of MRD status, it is therefore expected that there could be more than 30 participants who at some point become MRD-positive before the study ends. Any participant who becomes MRD-positive after the 30 participants required are treated will still be eligible for treatment with WON-5539, therefore the final sample size may be higher than 30 participants.

- b. If **Merge the parent component's and child component's content** option is selected, the content of the parent component is merged with that of the child component, with the differences between the 2 displayed in track changes as follows:
- Difference from parent content – tracked as an insertion

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## ii. Difference from child content – tracked as a deletion

**Before**

**2.2 Sample Size Justification**  
[Sample Size Determination]

Approximately 90 participants will be enrolled in the study and approximately **40** participants will be assigned to treatment with WON-5539.

This is a single-arm estimation study. It is assumed that an MRD-negative rate of 10% could be observed by chance in this study. Therefore, if the assumed rate of MRD negativity is at least 30%, then the sample size for this study ( $N = 30$ ) is sufficient to demonstrate that, with 95% confidence, the rate of achieving MRD negativity is greater than 10%. This would also be sufficient to demonstrate evidence of clinical activity. **New sample content inserted in SAP.**

A table showing the CI for different assumed rates of MRD negativity with a sample size of  $N = 30$  is presented below:

Assumed rate of MRD negativity, n (%)	Lower 95% Confidence Limit (%)	Upper 95% Confidence Limit (%)
8 (26.7)	12.3	45.9
9 (30)	14.7	49.4
11 (36.7)	19.9	56.1
12 (40)	22.7	59.4
14 (46.7)	28.3	65.7

The study will enroll approximately 90 participants to achieve the desired sample size of 30 participants who are MRD-positive at the time of enrollment or during the run-in period. As part of the run-in period participants will be followed by clinic visits at 3, 5, 7, 9 and 12 months and thereafter every 3 months up to 24 months for monitoring of MRD status, it is therefore expected that there could be more than 30 participants who at some point become MRD-positive before the study ends. Any participant who becomes MRD-positive after the 30 participants required are treated will still be eligible for treatment with WON-5539, therefore the final sample size may be higher than 30 participants.

**After**

**2.2 Sample Size Justification**  
[Sample Size Determination]

Approximately 90 participants will be enrolled in the study and approximately **40****30** participants will be assigned to treatment with WON-5539. **Sample content.**

This is a single-arm estimation study. It is assumed that an MRD-negative rate of 10% could be observed by chance in this study. Therefore, if the assumed rate of MRD negativity is at least 30%, then the sample size for this study ( $N = 30$ ) is sufficient to demonstrate that, with 95% confidence, the rate of achieving MRD negativity is greater than 10%. This would also be sufficient to demonstrate evidence of clinical activity. **New sampleAdditional edits to content inserted in SAP.**

A table showing the CI for different assumed rates of MRD negativity with a sample size of  $N = 30$  is presented below:

Assumed rate of MRD negativity, n (%)	Lower 95% Confidence Limit (%)	Upper 95% Confidence Limit (%)
8 (26.7)	12.3	45.9
9 (30)	14.7	49.4
11 (36.7)	19.9	56.1
12 (40)	22.7	59.4
14 (46.7)	28.3	65.7

The study will enroll approximately 90 participants to achieve the desired sample size of 30 participants who are MRD-positive at the time of enrollment or during the run-in period. As part of the run-in period participants will be followed by clinic visits at 3, 5, 7, 9 and 12 months and thereafter every 3 months up to 24 months for monitoring of MRD status, it is therefore expected that there could be more than 30 participants who at some point become MRD-positive before the study ends. Any participant who becomes MRD-positive after the 30 participants required are treated will still be eligible for treatment with WON-5539, therefore the final sample size may be higher than 30 participants.

**Note:** The user should have **All Markup** selected under the Review Tab's Tracking section to view all track changes after merging content.



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#### 2.4.1.3 Component Replaced in Parent Document (Component Change Type)

If a component was updated in the parent document by being replaced (ie, component was reused from a library, search, or another document), the **Change Type** for the reused component in a downstream document will show as 'Component' in its **Component Status Report**. Follow the steps below to view and accept these types of updates made to the parent/source component.

1. Select the **View / Accept** action.

Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Modified (7 items)</b>						
Acronym    ABC123	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Sponsor N...    PharmaGE	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Sponsor A...    ABCPharam 123 St	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Abbreviations   Lorem ipsum dolor sit a...	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	Select
Hypotheses   Video provides a powerf...	Repurpose	Draft	0.1	2024-11-15 4:59 PM	Component	Select
Sample Size D...   Video provides a powerf...	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	<b>View / Accept</b>
Randomizatio...   Lorem ipsum dolor sit a...	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	Ignore Select
<b>Status: Not Modified (38 items)</b>						
Protocol Title   this is a test protocol t...	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM		
Protocol Sh...   Test title reused into S...	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM		
?				Close	Update	

2. A **Select Version** pane will display on the screen.

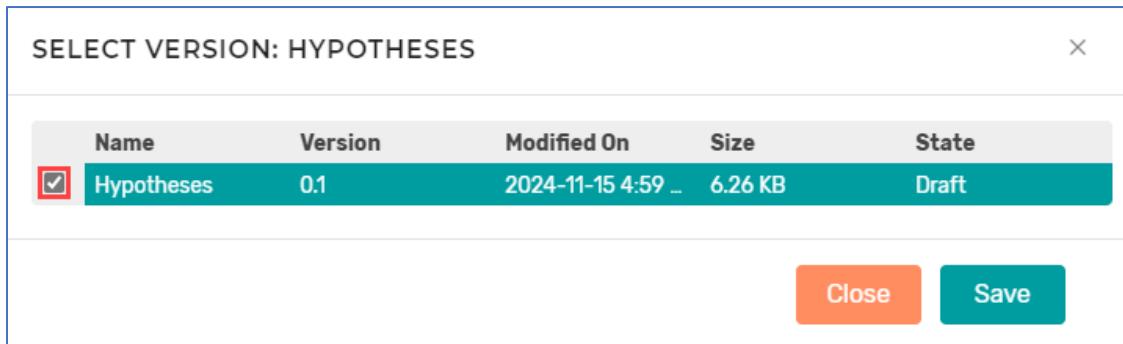
SELECT VERSION: HYPOTHESES					
Name	Version	Modified On	Size	State	
<input type="checkbox"/> Hypotheses	0.1	2024-11-15 4:59 ...	6.26 KB	Draft	
					Close
					Save

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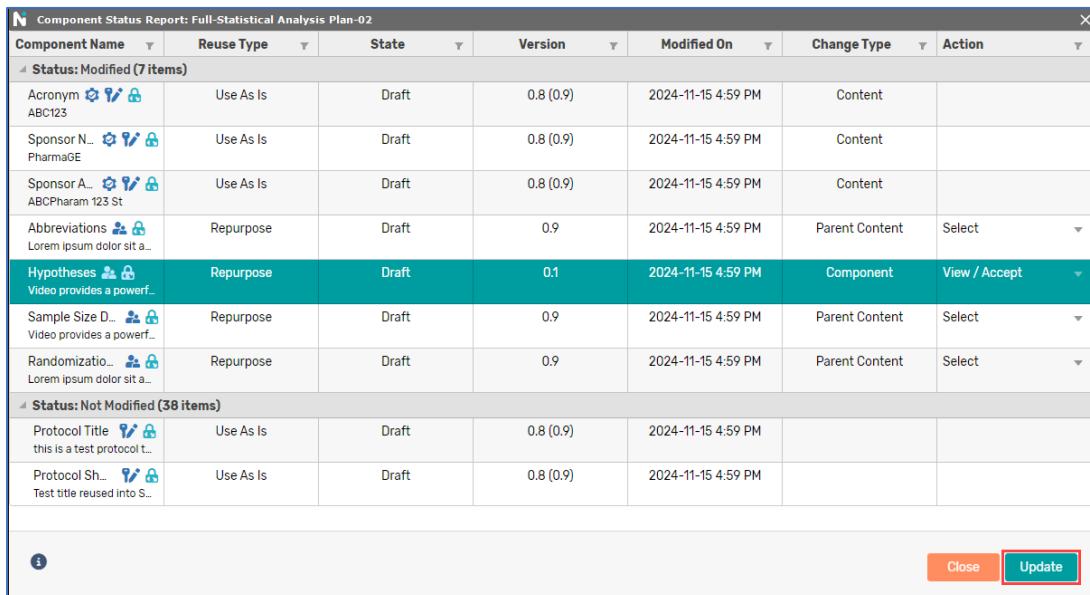
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3. If the new parent version is to be used in the current document, select it by clicking the checkbox next to it, then click **Save**.



4. Click **Update** to refresh the selected version's content into the document.



Component Name	Reuse Type	State	Version	Modified On	Action	
Acronym ABC123	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Sponsor N... PharmaGE	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Sponsor A... ABCPharm 123 St	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM	Content	
Abbreviations	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	Select
Hypotheses	Repurpose	Draft	0.1	2024-11-15 4:59 PM	Component	View / Accept
Sample Size D...	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	Select
Randomizatio...	Repurpose	Draft	0.9	2024-11-15 4:59 PM	Parent Content	Select
<b>Status: Not Modified (38 items)</b>						
Protocol Title	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM		
Protocol Sh...	Use As Is	Draft	0.8 (0.9)	2024-11-15 4:59 PM		

**Note:** Multiple components can have actions selected for them individually before clicking **Update** so that they are all refreshed into the document at 1 time.

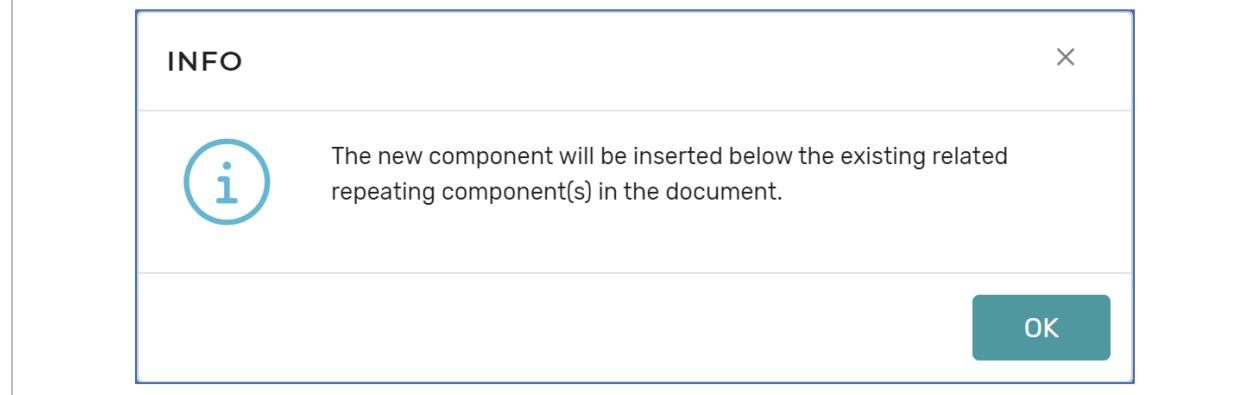
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#### 2.4.1.4 New Repeating Components

When new repeating instances are created in a parent document, they will be displayed in the **New** section of the Component Status Report. The user can choose to either **Accept** (or **Ignore**) this change into the child document.

**Note:** After accepting a new repeating instance, the user will be notified that the new component will be inserted below the existing related repeating component(s) in the document.



Components can be bulk selected by clicking on a component, pressing Ctrl + clicking on additional components. Use the right-click menu to select relevant **Accept** or **Ignore** action against the selected components.

The behavior for each type of repeating component is as follows:

1. Standalone Repeating Instance: A newly created standalone repeating instance in parent document will be displayed in the **New** section of the component status report with its 'Change Type' listed as 'New Repeating Instance'. Users have the option to **Accept** or **Ignore** this change via the 'Action' drop-down menu.

Component Status Report: Repeating Components Reuse Behavior						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
↳ Status: New (1 items)						
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 12:20 PM	New Repeating Instance	Select
↳ Status: Not Modified (13 items)						
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 12:19 PM		Accept
O&E Table						Ignore
						Select

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2. Component Set: A new instance of a component set in parent document will be displayed in the **New** section of the Component Status Report with its 'Change Type' listed as 'New Repeating Set'. The 'Action' menu drop-down will provide user option to **View/Accept** or **Ignore** this change.

Component Status Report: Repeating Components Reuse Behavior - 02						
Component Name	Reuse Type	State	Version	Modified On	Action	Change Type
<b>New</b> (1 items)						
Related Adverse Events 2						
<b>New</b> (13 items)						
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 12:19 PM		New Repeating Set
O&E Table						
Primary Objec...	Repurpose	Draft	0.1	2024-11-08 12:19 PM		

3. After selecting **View/Accept**, the **Insert Set** window will pop-up for user to review the list of components (with their relevant latest information) that will be created as part of the new component set. Click **Accept** to confirm the insertion of the new component set into the current document.

**INSERT SET: RELATED ADVERSE EVENTS 2**

Note: The following component(s) will be inserted as a new component set in the document.

Name	Version	Modified On	Size	State
Related Adverse Events Message	0.1	2024-11-08 12:3...	3 Bytes	Draft
Related Adverse Events Findings	0.1	2024-11-08 12:3...	3 Bytes	Draft
Related Adverse Events Description	0.1	2024-11-08 12:3...	3 Bytes	Draft
Related Adverse Events Source	0.1	2024-11-08 12:3...	3 Bytes	Draft

**Accept**

4. Table Set: A newly created table set will be displayed in the 'New' section of the Component Status Report with its 'Change Type' listed as 'New Repeating Set'. The 'Action' menu drop-down will provide user option to **View/Accept** or **Ignore** the change.

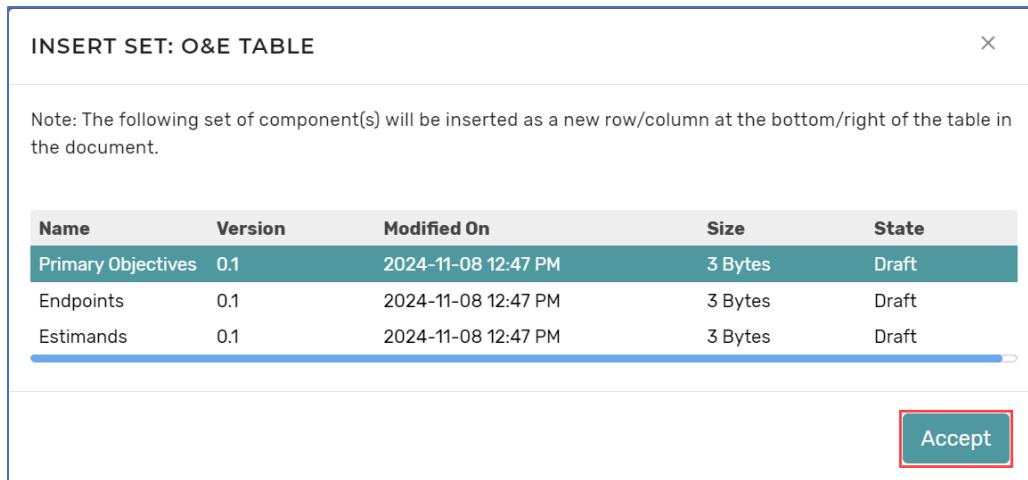
Component Status Report: Repeating Components Reuse Behavior - 02						
Component Name	Reuse Type	State	Version	Modified On	Action	Change Type
<b>New</b> (1 items)						
O&E Table						
<b>New</b> (13 items)						
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 12:19 PM		New Repeating Set
O&E Table						
Primary Objec...	Repurpose	Draft	0.1	2024-11-08 12:19 PM		

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5. After selecting **View/Accept**, the 'Insert Set' window will pop-up for user to review the list of components (with their relevant latest information) that will be created as part of the new table set. Click **Accept** to confirm the insertion of the new table set into the current document.



#### 2.4.1.5 Deleted Repeating Components

When a repeating instance of a component that was previously reused into the child document is deleted in a parent document, this change will be displayed in the 'Deleted' section of the Component Status Report. The user can choose to either **Accept** (or **Ignore**) this deletion into the child document.

**Note:** Components can be bulk selected by clicking on a component, pressing Ctrl + clicking on additional components. Use the right-click menu to select relevant **Accept** or **Ignore** action against the selected components.

1. Standalone Repeating Instance: A deleted standalone repeating instance in parent document will be displayed in the 'Deleted' section of the Component Status Report with its 'Change Type' listed as 'New Repeating Instance'. Users have the option to **Accept** (or **Ignore**) this deletion via the 'Action' drop-down menu.

Component Status Report: Repeating Components Reuse Behavior - 02						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>↳ Status: Deleted (1 items)</b>						
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 1:00 PM	Deleted Repeating Instance	Select
<b>↳ Status: Not Modified (22 items)</b>						
Inclusion Criteria	Repurpose	Draft	0.2	2024-11-08 1:00 PM		Accept
Inclusion Criteria	Repurpose	Draft	0.1	2024-11-08 1:00 PM		Ignore
						Select

2. Component Set: A deleted component set in parent document will be displayed in the 'Deleted' section of the Component Status Report with its 'Change Type' listed as 'Deleted'

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Repeating Set. The 'Action' menu drop-down will provide user option to **View/Accept** or **Ignore** this deletion.

Component Status Report: Repeating Components Reuse Behavior - 02						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>▲ Status: Deleted (1 items)</b>						
Related Adverse Eve...					Deleted Repeating Set	Select
<b>▲ Status: Not Modified (21 items)</b>						
Inclusion Criteria 	Repurpose	Draft	0.2	2024-11-08 1:00 PM		
O&E Table						
Primary Objec... 	Repurpose	Draft	0.2	2024-11-08 1:00 PM		

- After selecting **View/Accept**, the **Delete Set** window will pop-up for user to review the list of components (with their relevant latest information) that will be removed from the current document as part of this deletion. Click **Accept** to confirm the deletion of the component set from the current document.

**DELETE SET: RELATED ADVERSE EVENTS 2** X

Note: The following set of component(s) will be deleted from the document.

Name	Version	Modified On	Size	State
Related Adverse...	0.1	2024-11-08 1:00 PM	3 Bytes	Draft
Related Adverse...	0.1	2024-11-08 1:00 PM	3 Bytes	Draft
Related Adverse...	0.1	2024-11-08 1:00 PM	3 Bytes	Draft
Related Adverse...	0.1	2024-11-08 1:00 PM	3 Bytes	Draft

**Accept**

- Table Set: A deleted table set in parent document will be displayed in the 'Deleted' section of the Component Status Report with its 'Change Type' listed as 'Deleted Repeating Set'. The 'Action' menu drop-down will provide user option to **View/Accept** or **Ignore** this deletion.

Component Status Report: Repeating Components Reuse Behavior - 02						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>▲ Status: Deleted (1 items)</b>						
O&E Table					Deleted Repeating Set	Select
<b>▲ Status: Not Modified (16 items)</b>						
Inclusion Criteria 	Repurpose	Draft	0.3	2024-11-08 1:56 PM		
O&E Table						
Primary Objec... 	Repurpose	Draft	0.3	2024-11-08 1:56 PM		

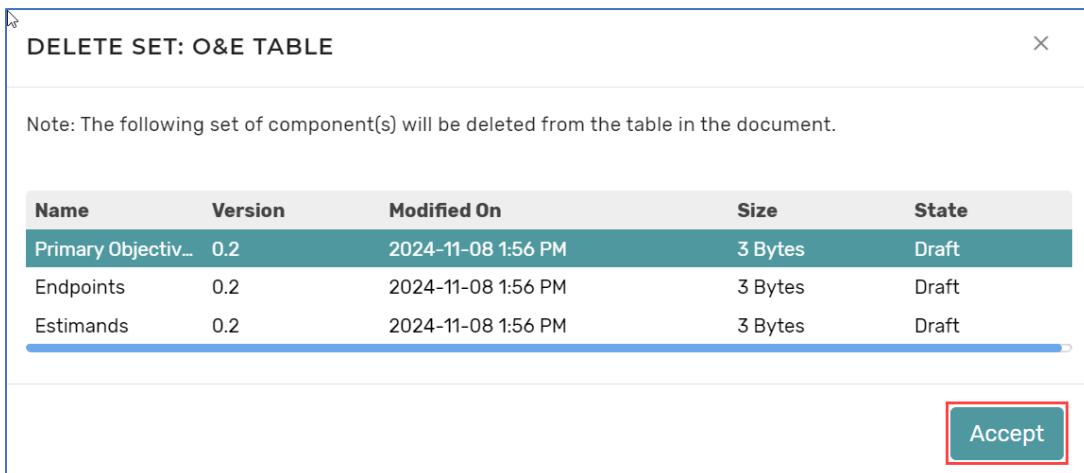
- After selecting **View/Accept**, the 'Delete Set' window will pop-up for user to review the list of components (with their relevant latest information) that will be removed from the

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current document as part of this deletion. Click **Accept** to confirm the deletion of the component set from the current document.



#### 2.4.1.6 Deleted Non-Repeating Components

If a non-repeating reused component has been deleted in a parent document, the user will have the option to either **Accept** or **Ignore** the deletion into the child document. The deleted components will be listed in the 'Deleted' section of the component status report and with the Change Type as **Deleted**.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Deleted (1 items)</b>						
Overall Design	Repurpose	Draft	0.5	2024-11-08 2:10 PM	Deleted	Select
<b>Status: Not Modified (41 items)</b>						
Protocol Title	Use As Is	Draft	0.5	2024-11-05 2:38 PM		Accept
this is a test protocol t...						Ignore
Protocol Sh	Use As Is	Draft	0.5	2024-11-05 2:38 PM		Select

#### Note:

- Deleted components can also be accepted via a closed document's component status report.
- If a component is not allowed for deletion per the info model policy, user will be presented with a warning message that the component cannot be deleted because it is restricted from deletion.
- If user does not have the sufficient permissions to delete a component, they will still be able to accept the deletion of a component from the component status report but will be presented with a warning message when saving the document informing them that the component cannot be deleted because it is restricted from deletion.
- If a reused component that is inserted in multiple locations of the document is deleted from the parent document or source library, then accepting the deletion via the child document's component status report will remove all instances of the component in the document.

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## 2.4.2 Deferring Changes

Users can choose to defer the latest changes from the parent document to a later version for reused components that are present in the modified section of the Component Status Report. The action to defer will be available for components with change type listed as 'Content', 'Parent Content', and 'Content and Parent Content'. Deferring components to a later version suppresses the "At least 1 component (re)used in the document has been modified. Do you want to view the Component Status Report?" pop-up notification, typically received for modified components upon opening the document.

**Note:** To bulk Defer/Defer to Major modified components, use Ctrl + click to select the desired component, right click and choose the applicable defer action.

Status: Modified (7 items)		
Protocol Title	Use As Is	Draft
Test title		
Inclusion Criteria Age	Repurpose	Draft
New CSR Age inclusion criteria		
Inclusion Criteria Type	Repurpose	Draft
Inclusion Criteria Weight	Repurpose	Draft
Inclusion Criterion Info	View / Accept	Draft
Exclusion Criteria Medi...	Defer	Draft
Even more CSR med condition More re...	Defer to Major	Draft
Exclusion Criteria Prior...	Ignore	Draft
Status: Not Modified (62 items)		
Status	Create Task/Lifecycle Transition	Draft
	Edit Information	Approved
CSR Data		

The following two defer options are available for modified components in the action menu:

- **Defer to Major** – select this option to defer the change notification to the next major version available for the source component.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Deferred (1 items)</b>						
Hypotheses	Repurpose	Draft	0.8	2024-11-09 10:31 AM	Parent Content	Select
Video provides a power...						
<b>Status: Not Modified (40 items)</b>						
Protocol Title	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		
this is a test protocol...						
Protocol Sh...	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		
New updates in upstr...						
Acronym	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		

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- **Defer** – select this option to defer the change notification to the next minor version available for the source component.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Deferred (1 items)</b>						
Hypotheses  	Repurpose	Draft	0.8	2024-11-09 10:31 AM	Parent Content	Select
<b>Status: Not Modified (40 items)</b>						
Protocol Title  	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		<span>View / Accept</span>
Protocol Sh...  	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		<span>Defer to Major</span>
Acronym  	Use As Is	Draft	0.7 (0.8)	2024-11-09 10:31 AM		<span>Defer</span>

Modified components with either of the defer options selected will be listed in the 'Deferred' section of the component status report.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Deferred (5 items)</b>						
Protocol Title  	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM	Content	Defer
this is a test protocol title new update to...						
Protocol Short Title  	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM	Content	Defer
New updates in upstream document. Mo...						
Hypotheses  	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Defer to Major
Video provides a powerful way to help y...						
Sample Size Determination  	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Defer to Major
For purposes of analysis, the following p...						
Populations for Analyses  	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Defer to Major
For purposes of analysis, the following p...						
<b>Status: Not Modified (38 items)</b>						
Acronym  	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM		
ABC123						

### Notes:

- Once the **Defer** or **Defer to Major** criteria are met, ie the parent component up-versions to a new minor or major version, then the relevant component(s) will be re-listed in the **Modified** section of the Component Status Report. This will also trigger the "At least 1 component (re)used in the document has been modified. Do you want to view the Component Status Report?" notification to be displayed upon opening the document.

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- Deferred components selection can be change to **View/Accept**, **Defer/Defer to Major**, or **Ignore**.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Deferred (5 items)</b>						
Protocol T...	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM	Content	Defer
Protocol S...	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM	Content	<b>View / Accept</b> Defer to Major Defer Ignore Select Defer to Major
Hypotheses	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	
Sample Size D...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	
Populations fo...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	
<b>Status: Not Modified (38 items)</b>						
Acronym	Use As Is	Draft	0.7 (0.9)	2024-11-09 10:39 AM		
ABC123						

- To defer components in bulk, select multiple components by using the 'Ctrl +' action in the modified section, and via the right-click menu select the relevant defer action:

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Modified (5 items)</b>						
Protocol Ti...	Use As Is	Draft	0.9	2024-11-09 10:39 AM	Content	
Protocol S...	Use As Is	Draft	0.9	2024-11-09 10:39 AM	Content	
Hypotheses	Repurpose	<b>View / Accept</b>	0.9	2024-11-09 10:39 AM	Parent Content	Select
Video provides a power...						
Sample Size D...	Repurpose	<b>Defer</b>	0.9	2024-11-09 10:39 AM	Parent Content	Select
Populations fo...	Repurpose	<b>Defer to Major</b>	0.9	2024-11-09 10:39 AM	Parent Content	Select
For purposes of analysis...						
<b>Status: Not Modified (38 items)</b>						

### 2.4.3 Ignoring Changes

Users can choose to **Ignore** the latest changes for reused components that are present in the modified section of the Component Status Report. The action to 'Ignore' will be available for components of all change types. Marking components as **Ignore** will suppress the "At least 1 component (re)used in the document has been modified. Do you want to view the Component Status Report?" pop-up notification, typically received for modified components upon opening.

Component Status Report: User Story 46537-Statistical Analysis Plan						
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action
<b>Status: Modified (3 items)</b>						
Hypotheses	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Select
Video provides a power...						
Sample Size D...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	<b>View / Accept</b> Defer to Major Defer
Populations fo...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	
For purposes of analysis...						
<b>Status: Not Modified (40 items)</b>						
Protocol Title	Use As Is	Draft	0.9	2024-11-09 10:39 AM		<b>Ignore</b> Select
this is a test protocol ...						

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Behavior after **Ignore** action:

- When the **Ignore** action for any modified components is chosen for an open document, and then the Component Status Report is updated and reopened manually, the 'Ignore' action will be set for the components and they will be displayed in the "Ignored" section.

Component Status Report: User Story 46537-Statistical Analysis Plan							
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action	
<b>△ Status: Ignored (3 items)</b>							
Hypotheses  Video provides a power...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Ignore	
Sample Size D...  For...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Ignore	
Populations fo...  For purposes of analysis...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Ignore	
<b>△ Status: Not Modified (40 items)</b>							

- When the **Ignore** action for any modified components is chosen for a closed document, and saved, when it gets reopened, the 'Ignore' action will be set for the components and they will be displayed in the 'Ignored' section.
- Content will not auto-refresh for components that are as-is reused in 'Draft' state, 'De novo', or repurpose reused into the document.
- If the component is editable and has 'Content' or 'Content and Parent Content' change type, then clicking inside component will result in a warning notifying the user that 'Ignore' action was taken against the component. In this scenario,
  - User can proceed with editing the component which will automatically refresh the latest version (if applicable) and subsequently check out the component. This action will move the component out of the 'Ignored' section and no longer display the pin icon next to the name of the component. The component will be moved to the **Not Modified** section if component is auto-refreshed or to the **Modified** section if a newer version of the parent component action is still pending.

OR

  - User can choose not to edit the component in which case no action will be taken against the component and the cursor will be moved out of the component to prevent any edits.
- Ignored components selection can be changed to **View/Accept**, **Defer/Defer to Major**, or **Select**, which will move the component back to modified section.

Component Status Report: User Story 46537-Statistical Analysis Plan							
Component Name	Reuse Type	State	Version	Modified On	Change Type	Action	
<b>△ Status: Ignored (3 items)</b>							
Hypotheses  Video provides a power...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content	Ignore	
Sample Size D...  For...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content		
Populations fo...  For purposes of analysis...	Repurpose	Draft	0.9	2024-11-09 10:39 AM	Parent Content		
<b>△ Status: Not Modified (40 items)</b>							
Protocol Title  this is a test protocol ...	Use As Is	Draft	0.9	2024-11-09 10:39 AM		 <ul style="list-style-type: none"> <li><a href="#">View / Accept</a></li> <li><a href="#">Defer to Major</a></li> <li><a href="#">Defer</a></li> <li><a href="#">Ignore</a></li> <li><a href="#">Select</a></li> </ul>	

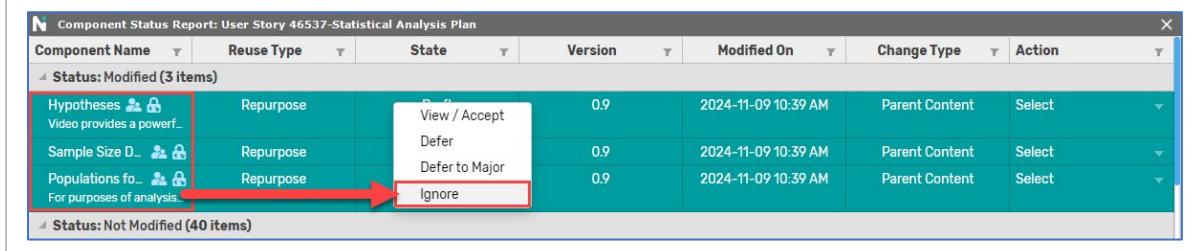
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6. If, for reused repeating components that are currently 'Ignored', a new repeating instance is added in the parent document, then this new instance will be displayed in the **New** section of the Component Status Report and user will be notified of this change when opening a document.
7. If, for reused repeating components that are currently 'Ignored', a repeating instance is deleted in the parent document, then this instance will be displayed in the 'Deleted' section of the Component Status Report and user will be notified of this change when opening a document.

**Note:** To ignore components in bulk, select multiple components by using the 'Ctrl +' action in the modified section, and via the right-click menu select the ignore action:



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## 2.5 USING THE COMPONENT STATUS REPORT IN A CLOSED DOCUMENT

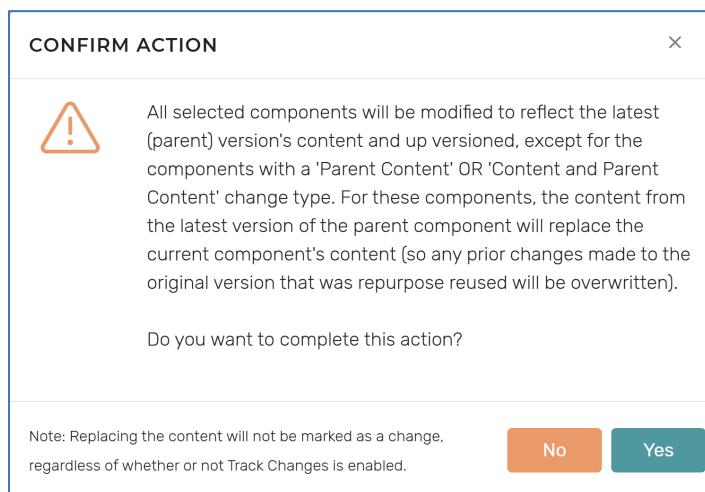
As mentioned in [Section 2.3](#), the **Component Status Report** can be launched separate from the document itself. If the document is not currently checked out when its **Component Status Report** is launched, a user can view and accept the updates made to the reused components and save those changes without having to open the document itself.

Viewing and accepting changes to the reused components is generally the same when performed via the **Component Status Report** of a closed document. However, the following differences must be noted:

1. For a repurpose reused component, after selecting a new version to use, only the replace functionality is supported.



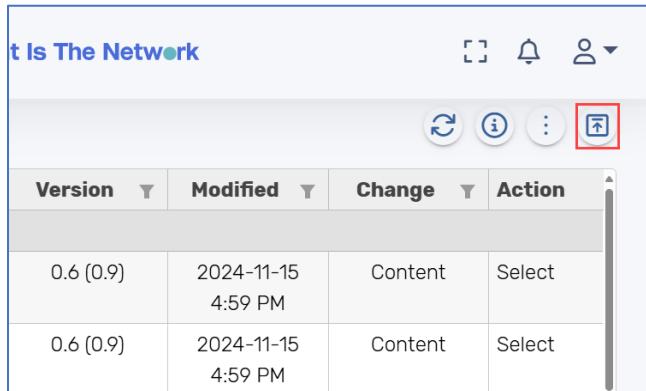
2. For bulk selected updates, all selected components will be modified to reflect the latest (parent) version's content and up versioned, except for the components with a **Parent Content OR Content and Parent Content** Change Type. For these components, the content from the latest version of the parent component will replace the current component's content (any prior changes made to the original version that was repurposed will be overwritten).



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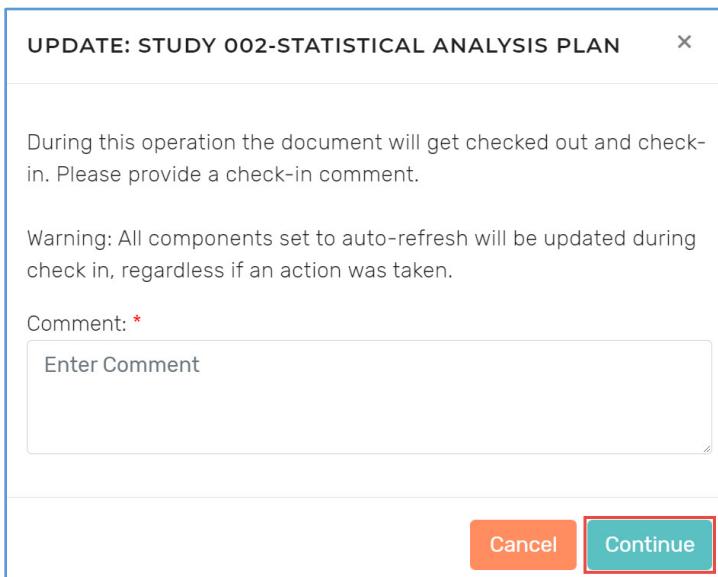
3. After making the relevant selections using the **Action** column, the user must click the **Save** icon  to update the document (ie, create a new version).



Version	Modified	Change	Action
0.6 (0.9)	2024-11-15 4:59 PM	Content	Select
0.6 (0.9)	2024-11-15 4:59 PM	Content	Select

**Note:** Any components that are set to auto-refresh into the document (eg, modified draft as-is reused component, current component modified outside of its document) will do so during this process and will be indicated with the auto-refresh icon , regardless of whether the user accepted the newer version or left **Select** in the **Action** column. Components edited outside of the document do not auto refresh.

4. Click Continue.



During this operation the document will get checked out and check-in. Please provide a check-in comment.

Warning: All components set to auto-refresh will be updated during check in, regardless if an action was taken.

Comment: \*

Enter Comment

Cancel Continue

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### 3. ACCEPTING UPDATES IN AN OPEN DOCUMENT VIA CHILD DOCS REUSED COMPONENT REPORT

This section covers the ability to accept updates made to a child document's component(s) within its respective parent document's Child Document(s) Report, which is separate from the general Component Status Report covered in [Sections 1](#) and [2](#). The Child Document(s) Report can be accessed via the IN ribbon. This will display a list of child documents that were created with the current/open document selected as a parent/base. A Reused Component Report is available for each child document and provides a more detailed component level report that focuses on the components reused from the parent document into the child document, categorizing them into various sections. Users can access these reports to complete the following list of actions:

- View all child documents linked to the parent document in the Child Document(s) Report.
- View the Reused Component Report for all child documents.
- In the Reused Component Report, users can manage changes coming from child to parent components by performing actions like View/Accept, Defer, Defer to Major, or Ignore.
- An author can compare the child document's version of a modified component with the parent document's version in the Reused Component Report.

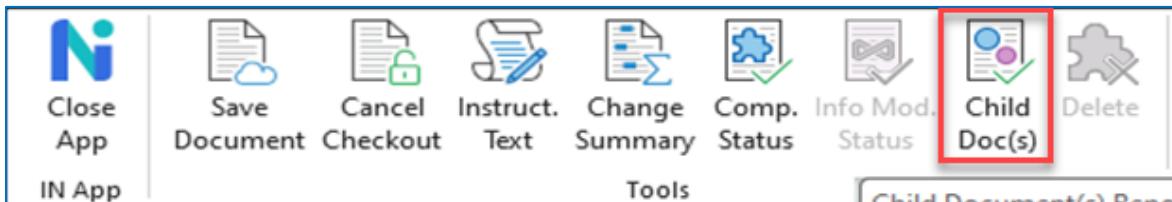
Instructions on how to access these reports and take relevant action are provided in the sections below.

#### 3.1 USING THE CHILD DOCUMENT(S) REPORT

All child documents that have reused components from the parent document can be viewed inside the Child Document(s) Report.

To open the **Child Document(s) Report**, follow the steps given below:

1. **Select and edit** the parent document to open it in Word desktop application.



2. Click on "**Child Docs Report**" button. All the child documents from which components are reused from child documents and variant documents along with child document's information get listed in a pop-up.
3. Child Document is divided into two sections:

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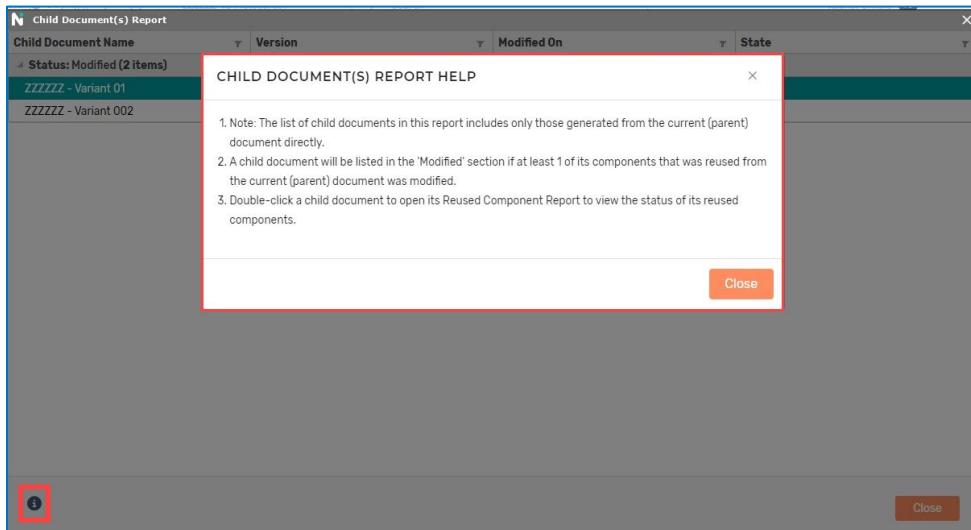
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- a. **Modified:** In a child document if the component(s) are **modified** (deleted, modified, ignored, deferred or new), the document will be listed under this section.
- b. **Not Modified:** In a child document if the components that are reused are **not modified**, that document will be listed in this section and if the report is opened, all the non-modified components will be listed.

**Notes:**

- The list of child documents in this report includes only those generated from the current (parent) document directly.
- A child document will be listed in the 'Modified' section if at least 1 of its components that was reused from the current (parent) document was modified.
- Double-click a child document to open its Reused Component Report to view the status of its reused components.
- An Info ('i') icon will be displayed at bottom on the left-hand side. When clicked it opens a separate window **Child Document(s) Report Help**.



## 3.2 USING THE REUSED COMPONENT REPORT

The Reused Component Report is used to update any changes made in a component version of a document or to update component(s) in upstream or downstream document(s). After the Child Document(s) Report is opened, double click to access this report.

The Reused Component Report consists of a list of all components present in the Child document and the components are listed under five different sections, depending upon their status:

- **Modified** – changes made to the child component will appear as a modified component with a new version number.

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- **New** – when a repeating component or component set is added in the child document, a new addition gets listed under this section.
- **Deleted** – when a repeating component or component set is deleted in the child document, a deletion gets listed under this section.
- **Ignored** – changes that were listed under modified when selecting Ignore pushes the content to this section after performing and Update and Save action on the parent document.
- **Not Modified** – when there are no changes between the parent and the child component, the components are listed under this section.

Component Name	Reuse Policy		Change Rationale	Compare Change	Child Component			Reuse Policy	Current..
	Planned	Actual			Version	State	Modified On		
<b>&gt;Status: Modified (1 items)</b>									
Component 81	Repurpose	Repurpose			0.5	Draft	27/02/2024 7:17 PM		0.6
<b>&gt;Status: Not Modified (60 items)</b>									
R Element	Repurpose	Repurpose							0.5
R Element 1	Use As Is	Use As Is							0.5
R Element 2	Repurpose	Repurpose							0.5
Component 41	Repurpose	Repurpose							0.5
Component 51	Use As Is	Use As Is							0.5
Component 61	Use As Is	Use As Is							0.5
Component 71	Use As Is	Use As Is							0.5
Library Compone...	Use As Is	Use As Is						Repurpose	0.5
Primary Objective	Use As Is	Use As Is							0.5
Primary Endpoint	Use As Is	Use As Is							0.5
Secondary Object...	Repurpose	Repurpose							0.5
Secondary Endpo...	Repurpose	Repurpose							0.5
Tertiary Objective	Use As Is	Use As Is							0.5
Endpoint 1	Use As Is	Use As Is							0.5

i Reused component report help
 Close
Update

To use the **Reused Component Report**, select a child document and double click on it to open. View the components of the parent document within a selected child document and follow the procedures listed in the sections below to complete the actions listed above.

**Note:** The different sections of the reuse report, ie **Ignore/Modified**, display according to the change actions taken on the components contained therein. However, as there is no **Deferred** section, components that have had their changes deferred will display in the **Modified** section.

### 3.2.1 Modified Section

If a component is modified (content updated) in a child document, it will appear as modified in the child doc report of the current (parent) document. If the child document's component(s) are edited, they will be listed in the **Modified** section of the parent document and provide the author

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with the option of performing actions with the components such as **View/Accept**, **Ignore**, **Defer** or **Defer to Major**.

Child Document(s) Report			
Child Document Name	Version	Modified On	State
IM 40785-SAP added content restriction	0.5	27/02/2024 7:17 PM	Draft
Status: Modified (1 items)			
IM 40785-SAP added content restriction	0.1	28/02/2024 6:07 PM	Draft
Status: Not Modified (1 items)			

Follow the steps listed below when a component is modified in the child document.

1. Select from the following actions in the drop-down:
  - **View/ Accept** – On selecting this option and selecting an appropriate version from the list provided, will move the component to not modified.
  - **Defer to Major** – On selecting this option the component remains in the Modified section.
  - **Defer** – On selecting this option the component remains in the Modified section.
  - **Ignore** – On selecting these options the component goes to Ignored section and it will remain there until the action on the component is changed from ignored.

Component	Current Component (Parent Document)						Change Type	Action
	Modified On	Reuse Policy	Current ...	Version ...	State	Modified On		
2024-04-24 8:23 PM		1.9	1.8	Draft	2024-04-24 7:51 PM	Child Content	Ignore	
		1.8		Draft	2024-04-13 3:07 AM			
		1.8		Draft	2024-04-13 3:07 AM			
		1.9		Draft	2024-04-24 7:51 PM			
		1.6		Draft	2024-01-25 1:37 AM			

**Note:** Refer to [Section 3.3](#) based on Change Type:

- **View/Accept** – Provide the list of version of parent and child component's version.
- **Defer to Major** – This would defer to the next major version.
- **Defer** – This would defer until the next version.
- **Ignore** – This would ignore the further changes to the component and push the component to the ignored section.
- **Select** - default value for all change types.

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2. Click **Update** to confirm actions selected in the Reused Component Report and save the document as needed.

N Reused Component Report: PROT1 Draft

Component	Current Component (Parent Document)						Change Type	Action
	Modified On	Reuse Policy	Current ...	Version ...	State	Modified On		
2024-04-24 8:23 PM		1.9	1.8	Draft	2024-04-24 7:51 PM		Child Content	View / Ac... ▾
		1.8		Draft	2024-04-13 3:07 AM			
		1.8		Draft	2024-04-13 3:07 AM			
		1.9		Draft	2024-04-24 7:51 PM			
		1.6		Draft	2024-01-25 1:37 AM			
		1.6		Draft	2024-01-25 1:37 AM			
		1.6		Draft	2024-01-25 1:37 AM			
		1.8		Draft	2024-04-13 3:10 AM			
		1.8		Draft	2024-04-13 3:10 AM			
		1.8		Draft	2024-04-13 3:10 AM			
		1.6		Draft	2024-01-25 1:37 AM			

**i** Close Update

3. After the Reused Component Report has been updated, the component row will be moved to the relevant section (see above).

**Note:** Ignore – On selecting these options the component goes to Ignored section and it will remain there until the action on the component is changed from ignored.

### 3.2.2 Deleted Section

The child document will be listed as **Modified** in the Child Docs Report when a reused component is deleted. Specifically, if a repeating component or a component set/ complex table is deleted in the child document, the child document will appear as modified in the child doc report of the parent document

When the Reuse component report of that child document is opened, the deleted component will be listed under the **Deleted** section with the applicable change type and provide the author with the option of ignoring the change.

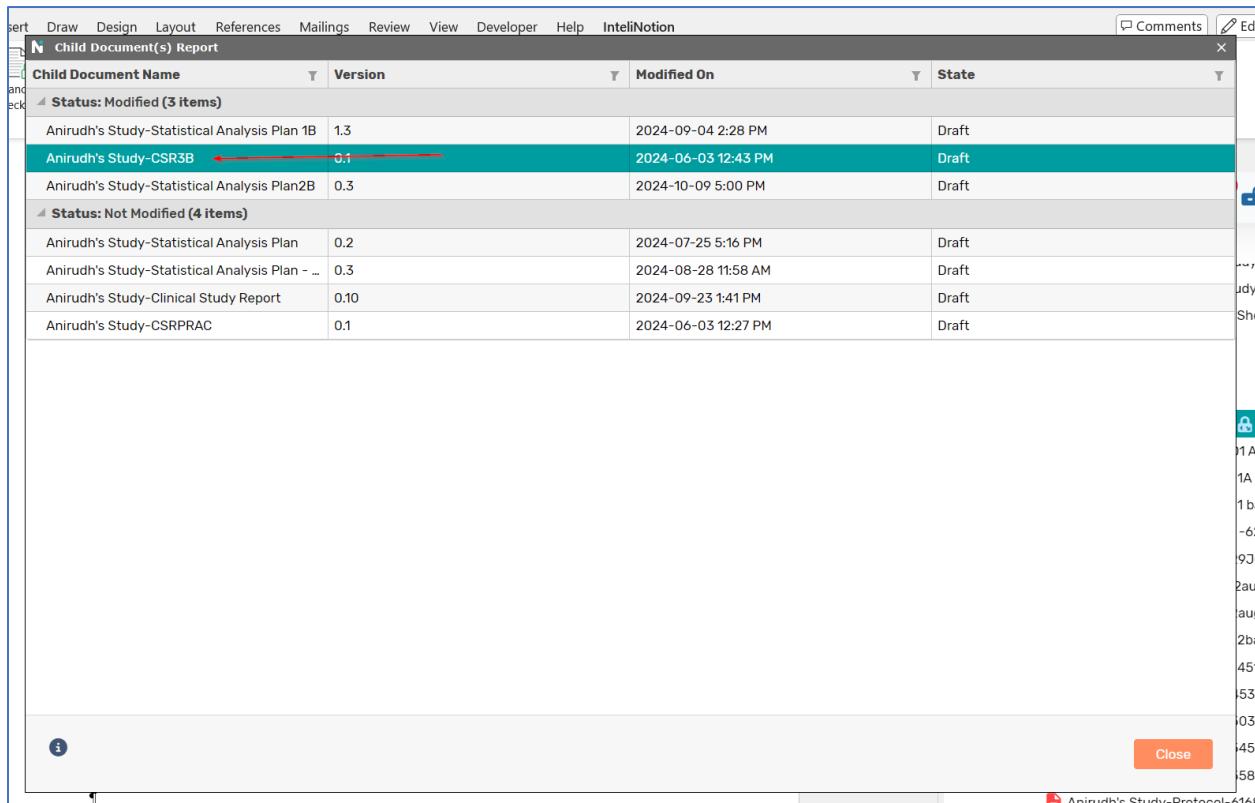
When a repeating component, component set or complex is deleted from the child document, follow the steps listed below:

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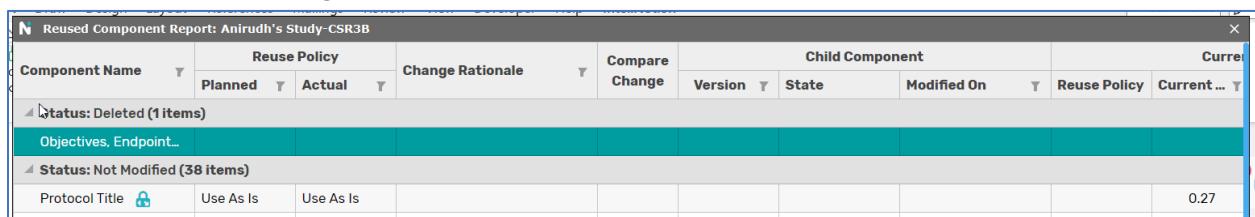
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- Select a child document and double click on it to open Reused Component Report. View the components of the parent document with a selected child document.



A screenshot of a Microsoft Word document titled "Child Document(s) Report". The table has columns for "Child Document Name", "Version", "Modified On", and "State". There are two sections: "Status: Modified (3 items)" and "Status: Not Modified (4 items)". The "Status: Modified" section contains three rows: "Anirudh's Study-Statistical Analysis Plan 1B" (Version 1.3, Modified 2024-09-04 2:28 PM, Draft), "Anirudh's Study-CSR3B" (Version 0.1, Modified 2024-06-03 12:43 PM, Draft), and "Anirudh's Study-Statistical Analysis Plan2B" (Version 0.3, Modified 2024-10-09 5:00 PM, Draft). The "Status: Not Modified" section contains four rows: "Anirudh's Study-Statistical Analysis Plan" (Version 0.2, Modified 2024-07-25 5:16 PM, Draft), "Anirudh's Study-Statistical Analysis Plan - ..." (Version 0.3, Modified 2024-08-28 11:58 AM, Draft), "Anirudh's Study-Clinical Study Report" (Version 0.10, Modified 2024-09-23 1:41 PM, Draft), and "Anirudh's Study-CSRPRAC" (Version 0.1, Modified 2024-06-03 12:27 PM, Draft).

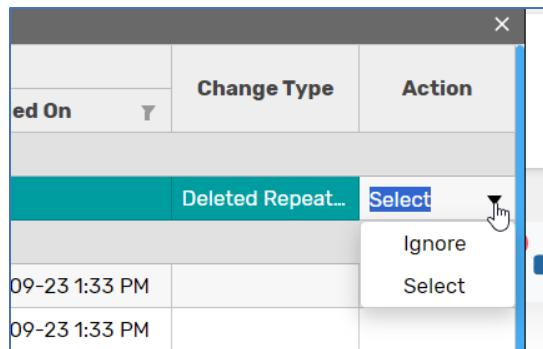
- In the actions dropdown menu, the only option available is to **Ignore** the deleted component change.



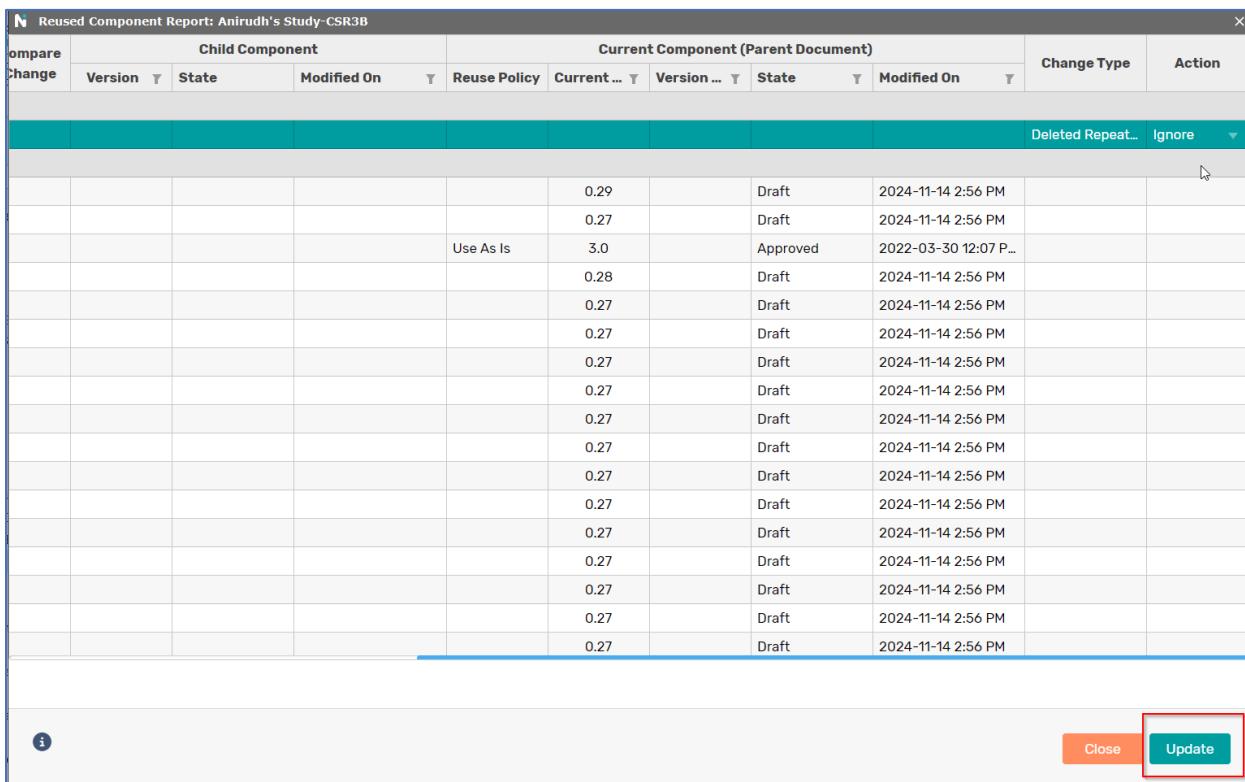
A screenshot of a Microsoft Word document titled "Reused Component Report: Anirudh's Study-CSR3B". The table has columns for "Component Name", "Reuse Policy", "Change Rationale", "Compare Change", "Child Component", and "Current". There are two sections: "Status: Deleted (1 items)" and "Status: Not Modified (38 items)". The "Status: Deleted" section contains one row: "Objectives, Endpoint...". The "Status: Not Modified" section contains 38 rows. At the bottom, there is a table for "Protocol Title" with columns for "Use As Is" and "0.27".

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- Click **Update** to confirm actions selected in the Reused Component Report and save the document as needed.



**Note:** Ignore – On selecting these options the component goes to Ignored section and it will remain there until the action on the component is changed from ignored.

- After the Reused Component Report has been updated, the component row will be moved to the relevant section

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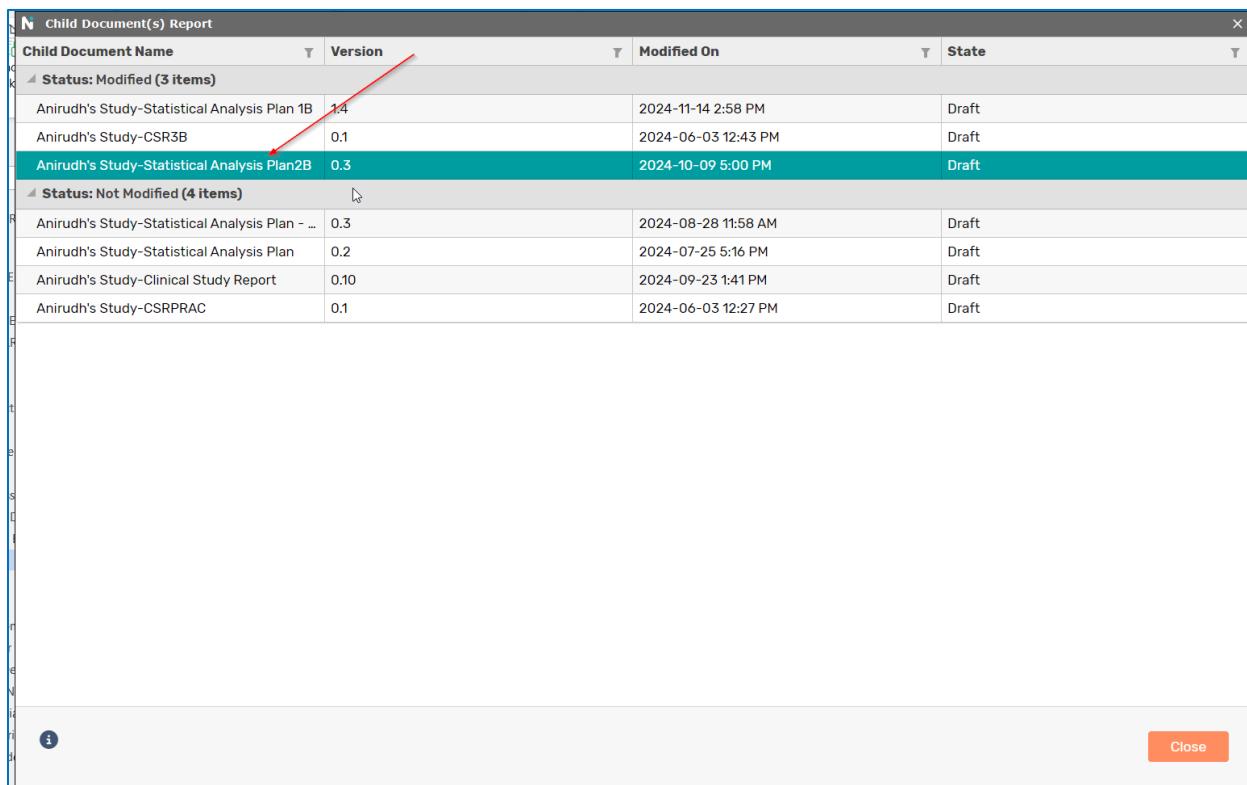
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### 3.2.3 New Section

The child document will be listed as **Modified** in the Child Docs Report when a new reused component is added. Specifically, if a new repeating component, component set, or complex table is added in the child document, it will appear as modified in the child doc report of the parent document. When the Reuse Component Report for that child document is opened, the new component will be listed under the **New** section with the applicable change type, giving the author the option to accept or ignore the change.

When a repeating component, component set or complex is added from the child document, follow the steps listed below:

1. Select a child document and double click on it to open Reused Component Report. View the components of the parent document with a selected child document.



A screenshot of a software dialog box titled "Child Document(s) Report". The table has columns: "Child Document Name", "Version", "Modified On", and "State". There are two sections: "Status: Modified (3 items)" and "Status: Not Modified (4 items)". A red arrow points to the row "Anirudh's Study-Statistical Analysis Plan2B" in the "Status: Modified" section, which is highlighted in teal. The row contains the document name, version 0.3, modification date 2024-10-09 5:00 PM, and state Draft. The "Close" button is visible at the bottom right.

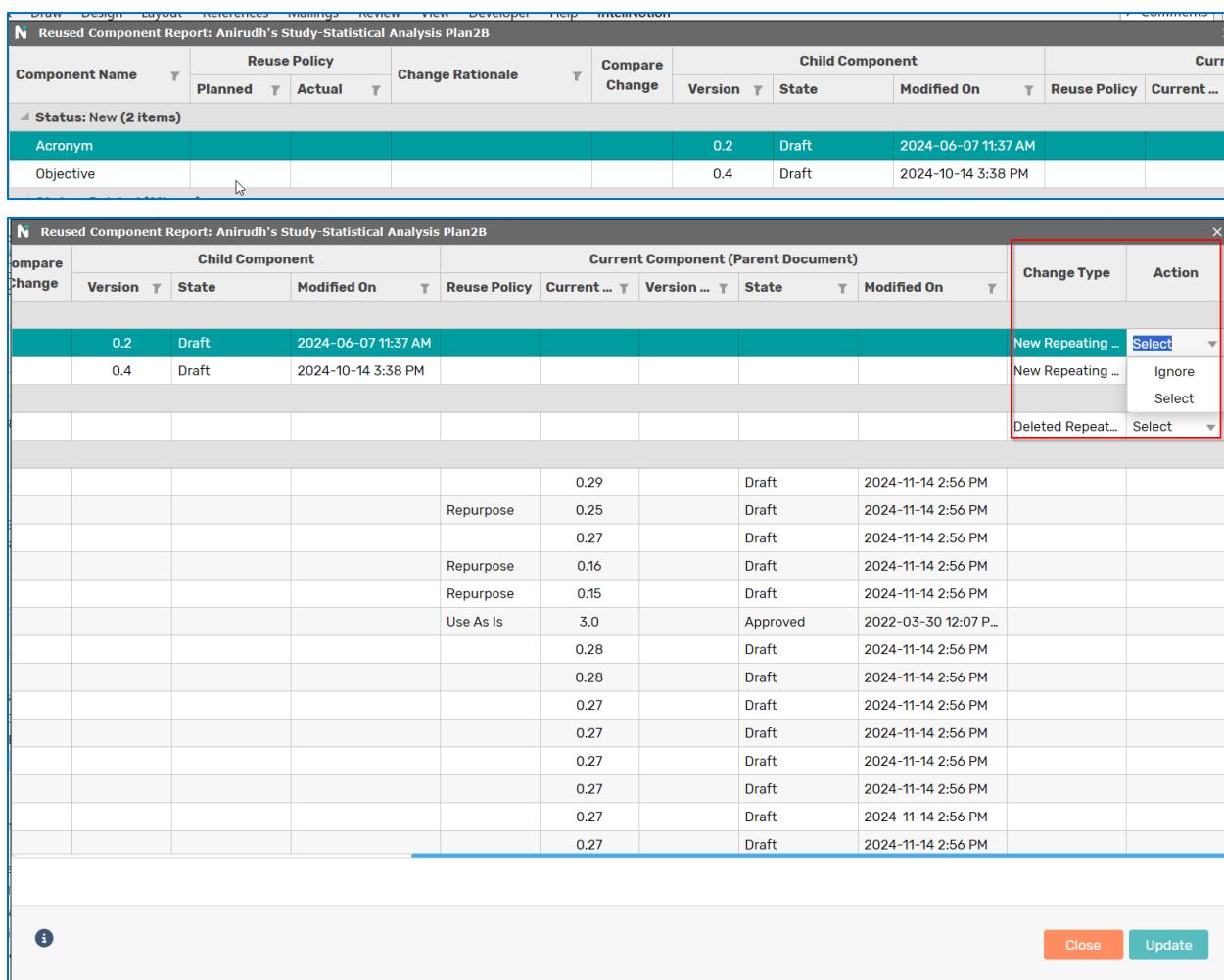
Child Document Name	Version	Modified On	State
<b>Status: Modified (3 items)</b>			
Anirudh's Study-Statistical Analysis Plan 1B	1.4	2024-11-14 2:58 PM	Draft
Anirudh's Study-CSR3B	0.1	2024-06-03 12:43 PM	Draft
<b>Anirudh's Study-Statistical Analysis Plan2B</b>	<b>0.3</b>	<b>2024-10-09 5:00 PM</b>	<b>Draft</b>
<b>Status: Not Modified (4 items)</b>			
Anirudh's Study-Statistical Analysis Plan - ...	0.3	2024-08-28 11:58 AM	Draft
Anirudh's Study-Statistical Analysis Plan	0.2	2024-07-25 5:16 PM	Draft
Anirudh's Study-Clinical Study Report	0.10	2024-09-23 1:41 PM	Draft
Anirudh's Study-CSRPRAC	0.1	2024-06-03 12:27 PM	Draft

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2. Select from the options in the dropdown, the options available are to ignore or perform no action.

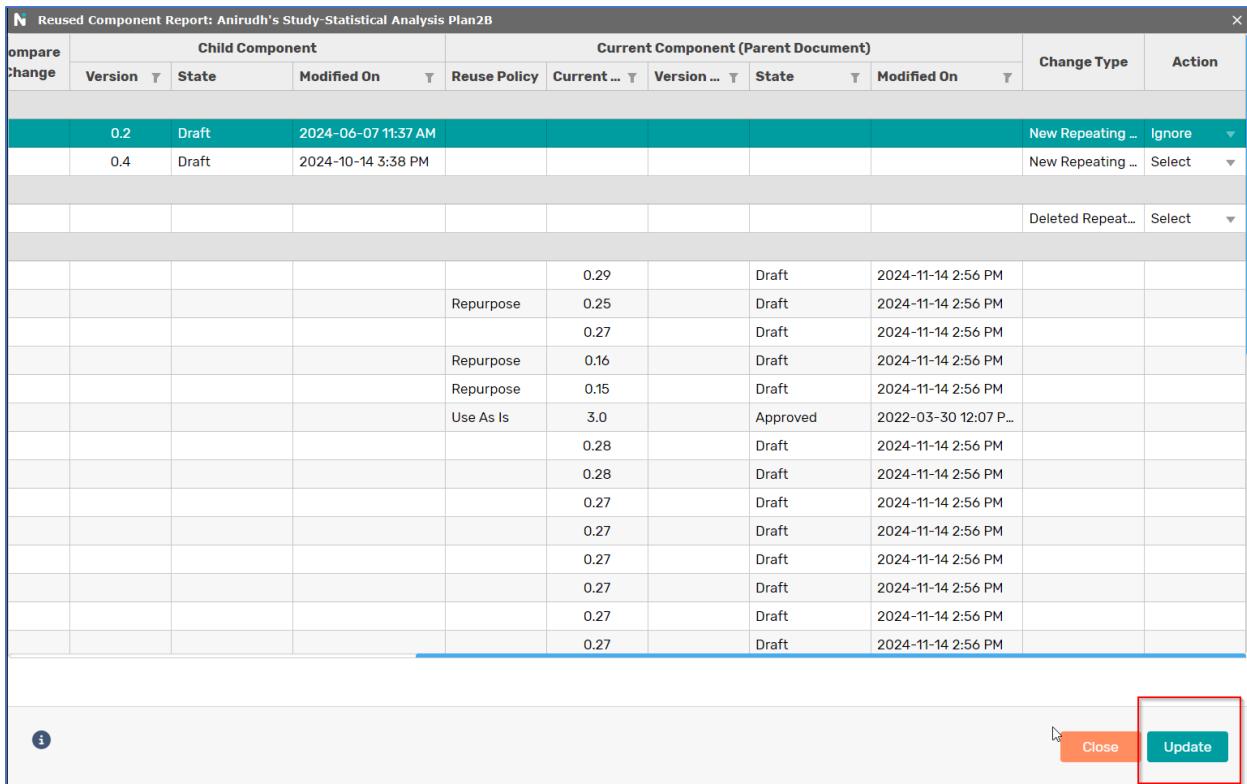


The screenshot shows the InteliNotion Reused Component Report interface. At the top, there's a navigation bar with 'DRAW', 'Design', 'Layout', 'References', 'Warnings', 'Review', 'View', 'Developer', 'Help', and 'InteliNotion'. Below the navigation bar is a title bar 'Reused Component Report: Anirudh's Study-Statistical Analysis Plan2B'. The main area contains two tables: 'Child Component' and 'Current Component (Parent Document)'. A red box highlights the 'Change Type' and 'Action' columns in the 'Current Component' table. The 'Change Type' column includes options like 'New Repeating...', 'Ignore', and 'Select'. The 'Action' column has a dropdown menu with 'Select' and 'Ignore' options. The 'Child Component' table has rows for 'Acronym' and 'Objective'. The 'Current Component' table has multiple rows with various values for columns like Version, State, and Modified On.

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3. Click **Update** to confirm actions selected in the Reused Component Report and save the document as needed.



The screenshot shows a table titled "Reused Component Report: Anirudh's Study-Statistical Analysis Plan2B". The table has columns for "Child Component" and "Current Component (Parent Document)". The "Change Type" column includes options like "New Repeating ..", "Ignore", "Select", and "Deleted Repeat...". The "Action" column contains buttons for "Close" and "Update". A red box highlights the "Update" button.

Child Component		Current Component (Parent Document)						Change Type	Action	
Component Change	Version	State	Modified On	Reuse Policy	Current ...	Version ...	State	Modified On		
	0.2	Draft	2024-06-07 11:37 AM						New Repeating ..	Ignore
	0.4	Draft	2024-10-14 3:38 PM						New Repeating ..	Select
									Deleted Repeat...	Select
				0.29		Draft	2024-11-14 2:56 PM			
				Repurpose	0.25	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
				Repurpose	0.16	Draft	2024-11-14 2:56 PM			
				Repurpose	0.15	Draft	2024-11-14 2:56 PM			
				Use As Is	3.0	Approved	2022-03-30 12:07 P...			
					0.28	Draft	2024-11-14 2:56 PM			
					0.28	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			
					0.27	Draft	2024-11-14 2:56 PM			

4. After the Reused Component Report has been updated, the component row will be moved to the relevant section

**Note:** Ignore – On selecting these options the component goes to Ignored section and it will remain there until the action on the component is changed from ignored.

### 3.2.4 Ignored Section

In the Reused Component Report, performing an Ignore action to a component when the component was previously in Modified, Deleted or New moves the component into the Ignored section. The component remains in this section irrespective of the changes made to the component in either the parent or child document until changed to one of the other options provided.

When the new section appears in the reused component report, follow the steps listed below:

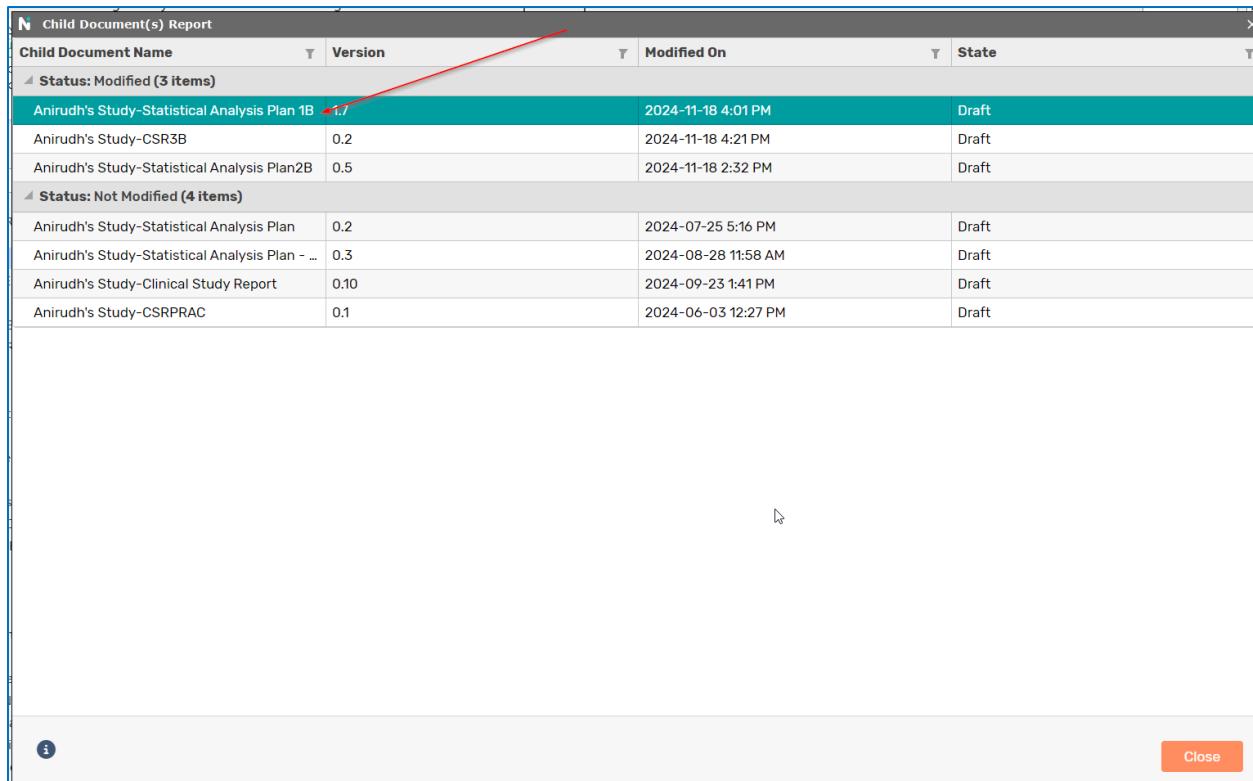
- Select a child document and double click on it to open Reused Component Report. View the components of the parent document with a selected child document.

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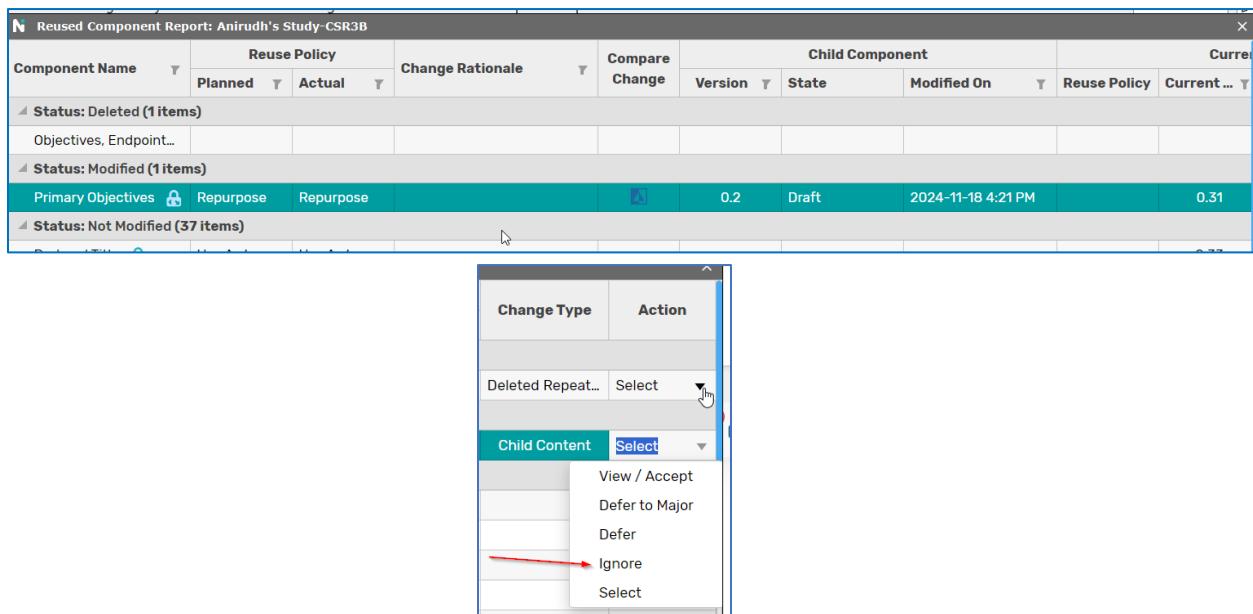
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2. Select from the options in the dropdown, the options available are to **View/Accept, Defer to Major, Defer, Ignore** or perform no action



Child Document Name	Version	Modified On	State
Anirudh's Study-Statistical Analysis Plan 1B	1.7	2024-11-18 4:01 PM	Draft
Anirudh's Study-CSR3B	0.2	2024-11-18 4:21 PM	Draft
Anirudh's Study-Statistical Analysis Plan2B	0.5	2024-11-18 2:32 PM	Draft
<b>Status: Not Modified (4 items)</b>			
Anirudh's Study-Statistical Analysis Plan	0.2	2024-07-25 5:16 PM	Draft
Anirudh's Study-Statistical Analysis Plan - ...	0.3	2024-08-28 11:58 AM	Draft
Anirudh's Study-Clinical Study Report	0.10	2024-09-23 1:41 PM	Draft
Anirudh's Study-CSPRPAC	0.1	2024-06-03 12:27 PM	Draft

3. Select **Ignore** from the Dropdown options.



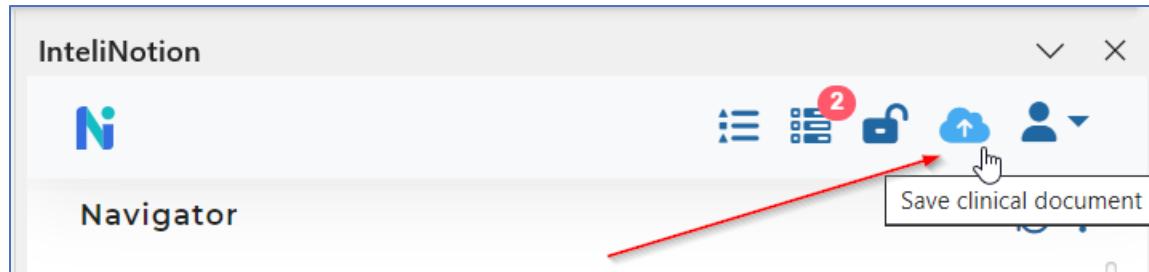
Component Name	Reuse Policy	Change Rationale	Compare Change	Child Component	Reuse Policy
Planned	Actual		Version	State	Current ...
<b>Status: Deleted (1 items)</b>					
Objectives, Endpoint...					
<b>Status: Modified (1 items)</b>					
Primary Objectives	Repurpose	Repurpose		0.2	Draft
<b>Status: Not Modified (37 items)</b>					

Change Type	Action
Deleted Repeat...	Select
Child Content	Select
	<b>View / Accept</b>
	Defer to Major
	Defer
	<b>Ignore</b>
	Select

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4. Save the document.



5. Reopen the Child Document(s) Report and open the Reused Component Report of the same child document.  
 6. The component is found in the ignored section.

Component Name	Reuse Policy		Change Rationale	Compare Change	Child Component			Current	
	Planned	Actual			Version	State	Modified On	Reuse Policy	Current ...
<b>Status: Ignored (1 items)</b>									
Hypotheses	Repurpose	Repurpose			1.2	Draft	2024-11-18 4:01 PM		0.31
<b>Status: Not Modified (32 items)</b>									
Protocol Title	Use As Is	Use As Is							0.33
Protocol Short Tit...	Use As Is	Use As Is							0.31
Acronym	Use As Is	Use As Is						Use As Is	3.0
Sponsor Name	Use As Is	Use As Is							0.32
Sponsor Address	Use As Is	Use As Is							0.32
Objective	Use As Is	Use As Is							0.31

7. After the Reused Component Report has been updated, the component row will be moved to the relevant section.

### 3.3 LIMITATIONS AND BEHAVIORS

See the items listed below for the known limitations and behaviors of the reused component report:

- Notifications in the Child Docs/Reused Component Report of the parent document will only occur when reused components, component sets, or complex table instances are present in the downstream child document. Modifications in reused repeating components in the child document will also trigger notifications in the Child Docs/Reused Component Report of the parent document.
- If a component is reused in a downstream child document with only a single instance in the child document and then replaced in the child document, the relationship with the upstream parent component will be broken. When the user opens the Child Docs/Reused Component Report, that component will not be displayed in the report. For example, if a user inserts (replaces) a component from a library in the child document or uses the search/related functionality to insert a component, that content change will not be

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displayed in the Child Docs/Reused Component Report and the component will no longer appear in the report.

- After a user accepts child content changes back into a component in the parent document, the user will be notified in the child document that the reused parent component has been modified via the child document Component Status Report. Best practice is to mark this change as **Ignore** in the child document Component Status Report.
- If all reused component instances are deleted from a child document, these changes will not trigger a notification to the parent document via the Child Docs/Reused Component Report as only reused components will be displayed in the report.
- The following are the available actions in the Child Docs/Reused Component Report based on change type in the initial instance of this functionality: select is the default option.

Change Type	Actions
Child content	View/Accept Defer to Major Defer Ignore
New Repeating Instance	Ignore
New Repeating Set	Ignore
Deleted Repeating Instance	Ignore
Deleted Repeating Set	Ignore

**Notes:**

- 'New/Deleted Repeating Instance' includes addition of a new repeating instance in a child document; deletion of a reused repeating instance from a child document; addition/deletion of a component set instance in a child document; addition/deletion of a set in a complex table in a child document.
- Change type 'Component' will not be included in the Reused Component Report (ie, only child content changes, or addition/deletion of repeating instances, will be included in the report).
- For parent and child documents created before the release of this new functionality, only the 'New Repeating Instance' and 'Deleted Repeating Instance' change types will be displayed as 'Modified' in the Child Docs/Reused Component Report. For parent documents created before this new functionality but child documents created after the new functionality, the 3 change types ('Child Content', 'New Repeating Instance', and 'Deleted Repeating Instance') will be displayed as 'Modified' in the Child Docs/Reused Component Report.

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- The **Ignore** action will apply at the component level and therefore, even if a component is ignored only for 1 child document, it will suppress future notifications for all other child documents as well. For example, if a parent document has 2 child documents that reuse the same 'Objective' component, and if the user selects 'Always Ignore' for the 'Objective' component in child document 1, then the 'Objective' component in child document 2 will also have the **Always Ignore** action set. Also, if another instance of a component (ie, a new repeating component instance) is added to a child document where the initial instance was set to **Ignore**, then the new instance will also be set to **Ignore**.
- If a new repeating instance of a component is added in a parent document (eg, Protocol) but not yet accepted into child documents, then all child documents (eg, SAP document, variant protocol document) will be displayed in the **Modified** section of the Child Docs report and the newly added instances will be displayed in the **Deleted** section of the Reused Component Report because the new instances have not been accepted via the Component Status Report in the child document yet.
- Similarly, if a new repeating instance of a component is deleted in a parent document (eg, Protocol) but not yet accepted into child documents, then all child documents (eg, SAP document, variant protocol document) will be displayed in the **Modified** section of the Child Docs report and deleted instances will be displayed in the **New** section of the Reused Component Report because the new instances have not been accepted via the Component Status Report in the child document yet.
- For a component with 2 instances that are repeating and reused in a child document, if either of the instances is replaced in the child document, then the Child Docs/Reused Component Report will display the previous/initially added component in the 'Deleted' section as 'Deleted Repeating Instance', and the replaced component in the **New** section as 'New Repeating Instance'.
- If a repeating instance of a component is added in a hierarchical complex table (eg, Objectives & Endpoints), it will not be displayed in the Child Docs/Reused Component Report. For example, if a new repeating instance of an endpoint component is added to an Objectives & Endpoints table, the newly added instance will not be displayed in the report.
- The replacement of a component within a complex table or component set will not trigger a notification in the Child Docs/Reused Component Report.
- Deleting an individual component from a complex table or component set will not trigger a notification in the Child Docs/Reused Component Report.
- Addition or deletion of an entire reused component set or a reused set in a complex table in a child document will trigger a notification in the Child Docs/Reused Component Report.

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- In a child document, if a user overrides an 'as is' reuse policy on a component, edits content in the component, and saves the document, the changes will be notified to the Child Docs/Reused Component Report in the parent document in 2 steps: first, the component's reuse policy change will be notified; second, the component's content changes will be notified when the user edits the child document for a second time, saves the document, and the component is up versioned.
- If a parent component is reused into the parent document from upstream with an 'as is' reuse policy, but a repurpose reuse policy in the child document, then the user cannot accept changes from the child component into the parent component.
- In manual mapping, if a child document is generated from 2 base documents, and a component set is mapped from each base document into the child document, then the Child Docs/Reused Component Report for both base documents will display an additional component set in the **New** section.

**Note:** If a new instance is added in upstream document and not yet accepted in child document or accepted and deleted from child document in both the cases it will show component in the **Deleted** section in the Reused Component Report.

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