InteliNotion

User Guide Module 10: Amending a Document

For InteliNotion Version: 2024.GR2.0
Last Modified: November 2024

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1. AMENDING A DOCUMENT

A document may be amended by editing an **Approved** version, which results in a new **Draft** version being created.

In the *InteliNotion Word App* (shown below) or *Web Console*, right-click on an **Approved** document (version X.0) and click **Edit (Check Out)**.
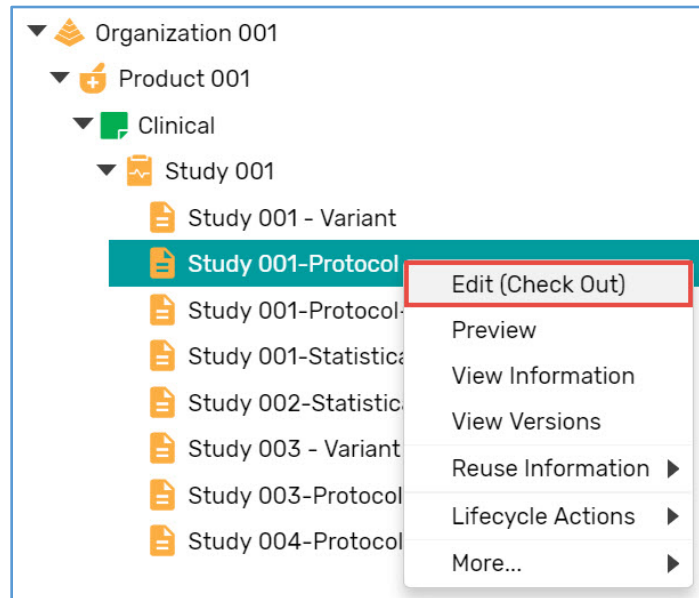
Update the document following the steps outlined in Module 5, then save and check in the document (becomes version X.1) following the steps outlined in Module 5 Section 2.

The amended document may be considered final once it enters an **Approved** state again.

2. GENERATING A SUMMARY OF CHANGES

A **Summary of Changes** (SOC) table can be generated for the comparison of 2 versions of the same document, or for 2 different documents.

2.1 COMPARING TWO VERSIONS OF A DOCUMENT

When comparing 2 versions of the same document to render the SOC table, the user can select any prior version to compare with the current/latest version.

1. To open the document, right-click on the document name and click **Edit (Checkout)**.
2. Click on **Change Summary** in the InteliNotion ribbon.
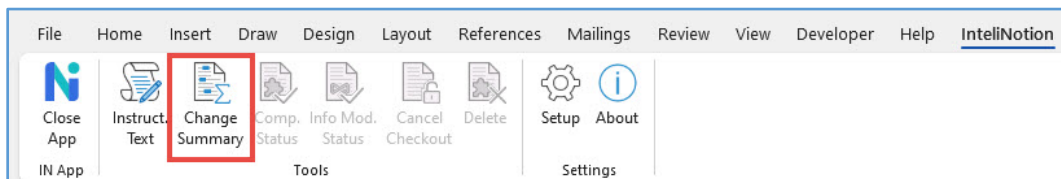
3. The following pop-up window will appear with the **Versions** radio button selected by default. Choose the appropriate version to **Compare With** and click **Compare**.
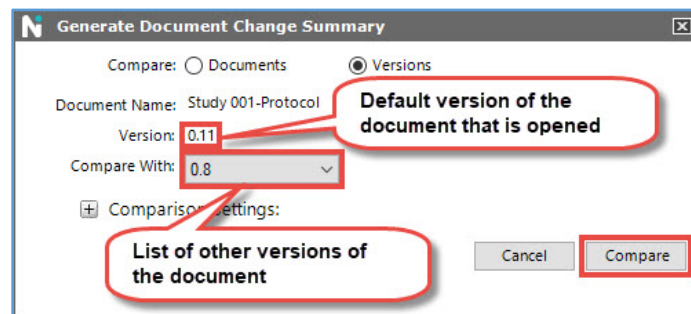
> **Note:** To include formatting changes in the comparison, expand the **Comparison Settings** by clicking the **plus sign icon** ＋ and then selecting the appropriate checkbox.
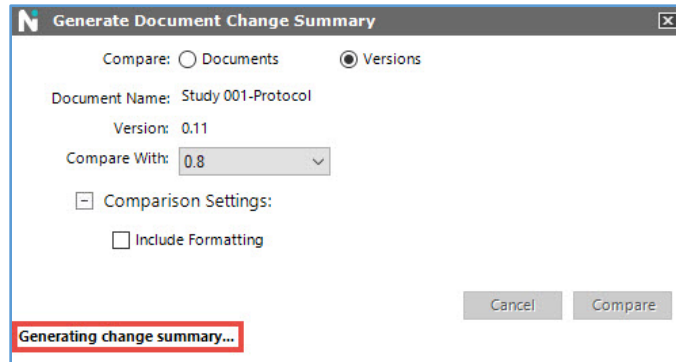>
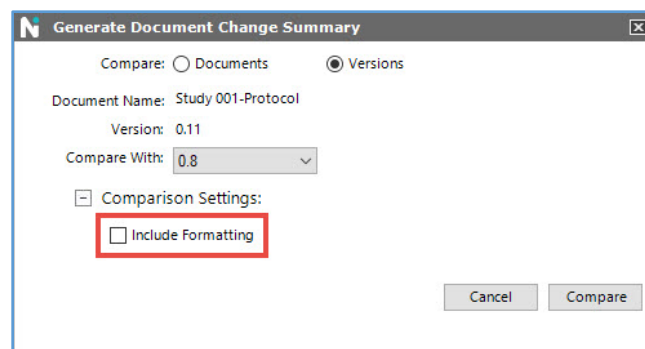
4. The following message will display in the window while the system opens the document versions in the background for processing.

5. Once the comparison is finished, the associated SOC table will open in a new *MS Word* document. The SOC table can be edited, as needed, then saved to the user's local system or in an appropriate shared area; it cannot be saved/uploaded to the InteliNotion system.

Section	Document Name: Study 2018WON-01-Protocol Version: 0.3	Document Name: Study 2018WON-01-Protocol Version: 0.6	Rationale
Section: CLINICAL PROTOCOL, Protocol Title, Paragraph 1	**Replace:** **Protocol Title:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus testinib for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy	**With:** **Protocol Title:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus ~~testinib~~Wonderiganum for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy	
Section: CLINICAL PROTOCOL, Protocol Short Title, Paragraph 1	**Replace:** **Short Title:** A Study of Testestium vs testinib to Treat Advanced Non-Small Cell Lung Cancer	**With:** **Short Title:** A Study of Testestium vs ~~testinib~~Wonderiganum to Treat Advanced Non-Small Cell Lung Cancer	
Section: 1.1 Synopsis, Protocol Title, Paragraph 1	**Replace:** **Protocol Title:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus testinib for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy	**With:** **Protocol Title:** A randomized double-blind phase 3 efficacy and safety study of pf 00299804 (Testestium) versus ~~testinib~~Wonderiganum for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy	
Section: 1.1 Synopsis, Protocol Short Title, Paragraph 1	**Replace:** **Short Title:** A Study of Testestium vs testinib to Treat Advanced Non-Small Cell Lung Cancer	**With:** **Short Title:** A Study of Testestium vs ~~testinib~~Wonderiganum to Treat Advanced Non-Small Cell Lung Cancer	
Section: 1.1 Synopsis, Hypotheses, Paragraph 1	**Replace:** Enter Hypotheses	**With:** ~~Enter Hypotheses~~Based upon the clinical efficacy, safety, and pharmacokinetics data for WON-5539 from the Phase 1 study (2016WON-03) and Phase 2 study (2017WON-09) in subjects with multiple myeloma, 5 WON-5539 dose regimens have been chosen for evaluation in this Phase 3 study, including 5 mg q12w	

> **Note:** It may take a few minutes for the SOC table to be rendered.

2.2 COMPARING TWO DIFFERENT DOCUMENTS

When comparing 2 different documents to render the SOC table, both files must be available on the user's local system for selection. The steps below are for documents available in InteliNotion; however, any 2 documents may be used.

1. Download a previous version of a document to the local system by right-clicking on the document name and clicking **View Versions**.
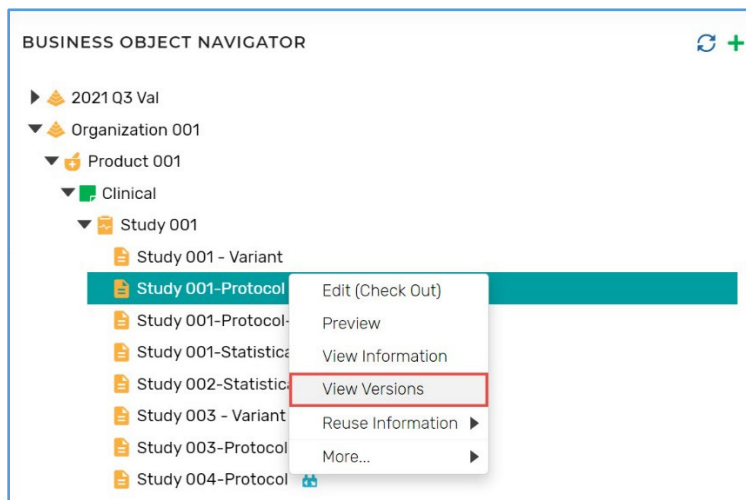
2. Click on the ellipses to export the relevant version to the local system. The user can change the default save location if needed.

3. A pop-up will display. Choose the desired format from the drop-down menu.
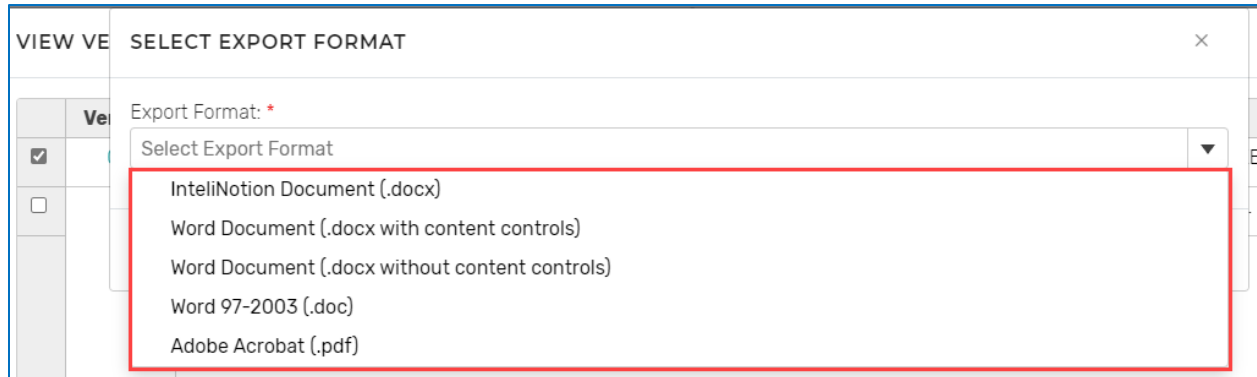
4. *IF* a format with content controls was chosen, click the applicable checkbox to choose which content controls will be retained, and click **Export**.
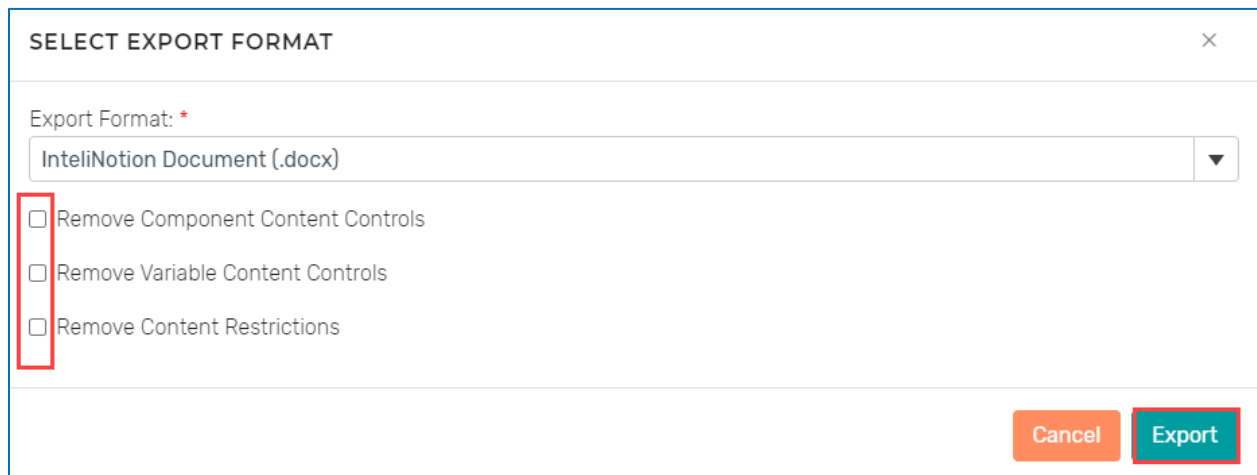
5. The document is exported to the designated location.
6. Repeat steps 1-3 for the second document to be compared.
7. Click on **Change Summary** in the InteliNotion ribbon.
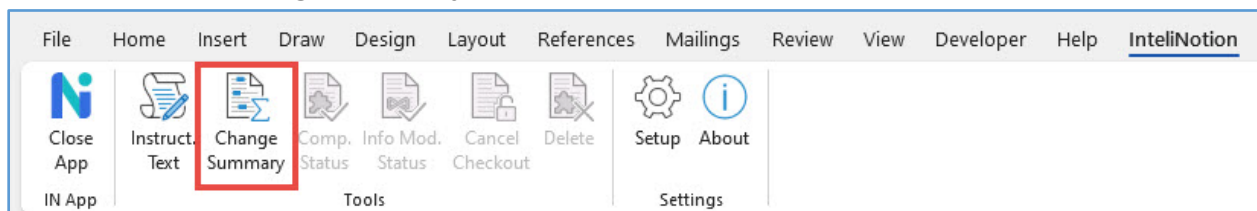
8. The following pop-up window will appear with the **Documents** radio button selected by default (unless an InteliNotion document is currently open); if not selected, check it. Click on the **vertical ellipsis** ⋮ (ie, browse) to select the appropriate downloaded document for both the **Source File** and **Target File**, and then click **Compare**. The SOC table will generate as shown in the section above.
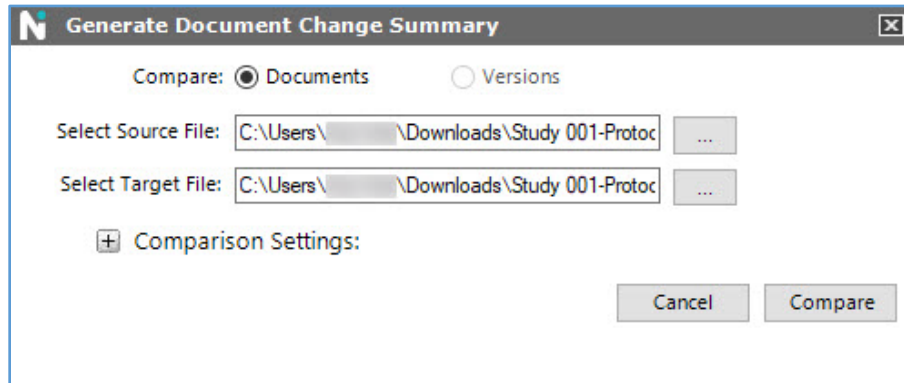
> **Note:** When there is no InteliNotion document open in *MS Word*, the **Versions** option is disabled.