



User Guide Module 10: Amending a Document

For InteliNotion Version: 2024.GR2.0

Last Modified: November 2024

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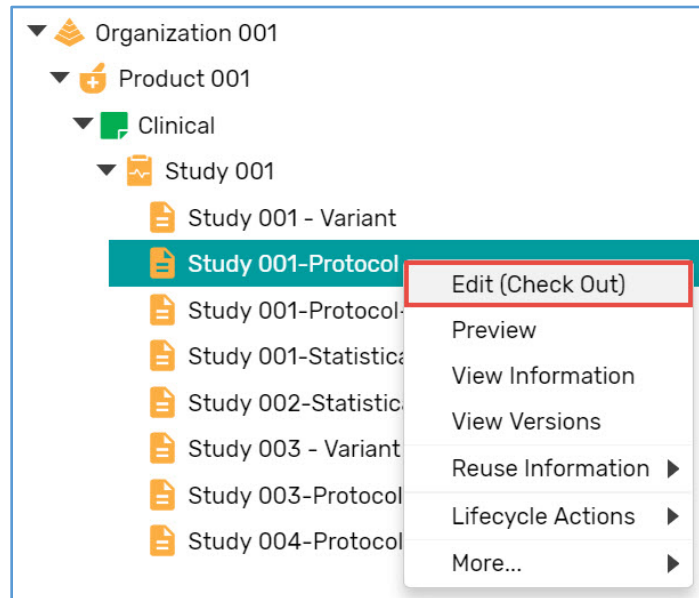
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1. AMENDING A DOCUMENT

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.

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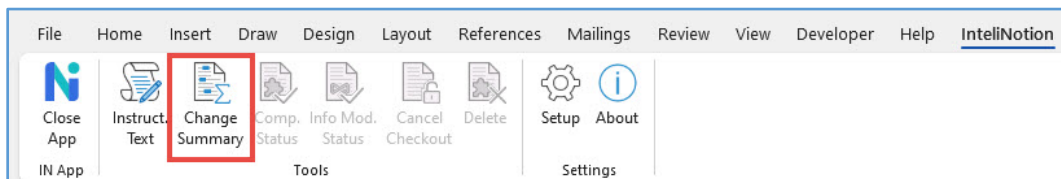
2. GENERATING A SUMMARY OF CHANGES

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

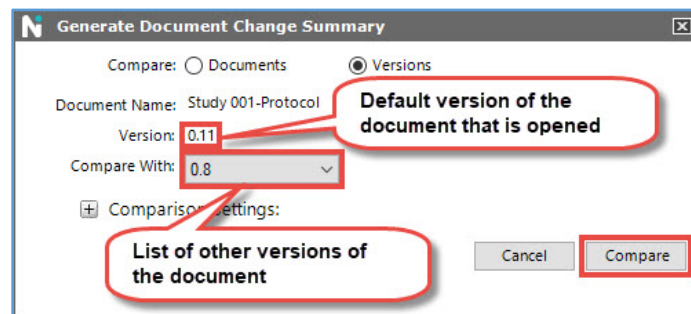
2.1 COMPARING TWO VERSIONS OF A DOCUMENT


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.

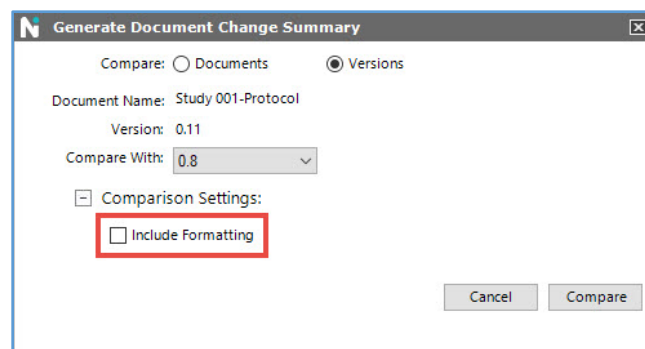
1. To open the document, right-click on the document name and click **Edit (Checkout)**.
2. Click on **Change Summary** in the InteliNotion ribbon.



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.

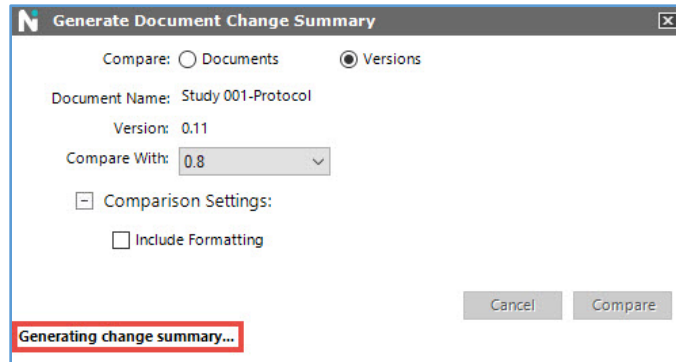


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- The following message will display in the window while the system opens the document versions in the background for processing.



Generate Document Change Summary

Compare: ☐ Documents ☒ Versions

Document Name: Study 001-Protocol

Version: 0.11

Compare With: 0.8

☐ Comparison Settings:

☐ Include Formatting

Cancel Compare

Generating change summary...

- 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 (<u>Testestium</u>) versus <u>testinib</u> 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 (<u>Testestium</u>) versus <u>testinibWonderiganum</u> for the treatment of advanced non-small cell lung cancer following progression after, or intolerance to, at least one prior chemotherapy	
Section: PROTOCOL, Protocol Short Title, Paragraph 1	Replace: Short Title: A Study of <u>Testestium</u> vs <u>testinib</u> to Treat Advanced Non-Small Cell Lung Cancer	With: Short Title: A Study of <u>Testestium</u> vs <u>testinibWonderiganum</u> 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 (<u>Testestium</u>) versus <u>testinib</u> 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 (<u>Testestium</u>) versus <u>testinibWonderiganum</u> 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 <u>Testestium</u> vs <u>testinib</u> to Treat Advanced Non-Small Cell Lung Cancer	With: Short Title: A Study of <u>Testestium</u> vs <u>testinibWonderiganum</u> to Treat Advanced Non-Small Cell Lung Cancer	
Section: 1.1 Synopsis, Hypotheses, Paragraph 1	Replace: Enter Hypotheses	With: <u>Enter Hypotheses</u> 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.

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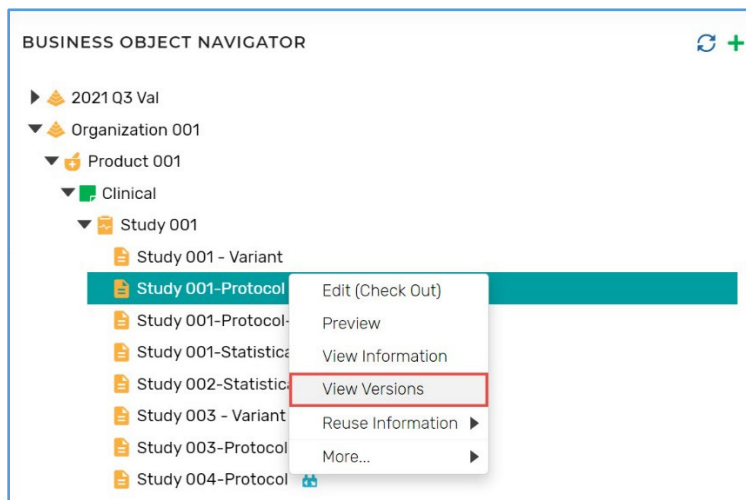
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2.2 COMPARING TWO DIFFERENT DOCUMENTS

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.

	Version	Modified On	Modified By	Comment	Size	
<input checked="" type="checkbox"/>	0.2	2022-02-22 12:12 PM		Test	193.12 KB	:
<input type="checkbox"/>	0.1	2022-02-11 12:58 PM			193.87 ...	:

Owner:

Name: Amber Test-Protocol

Compound Number: WON-5539

Country:

Established Name: wondercept

EudraCT Number:

Generic Name: wonderiganum

Indication: Prostate Cancer

IND Number: 123,456

INN: wonderigan

Preview

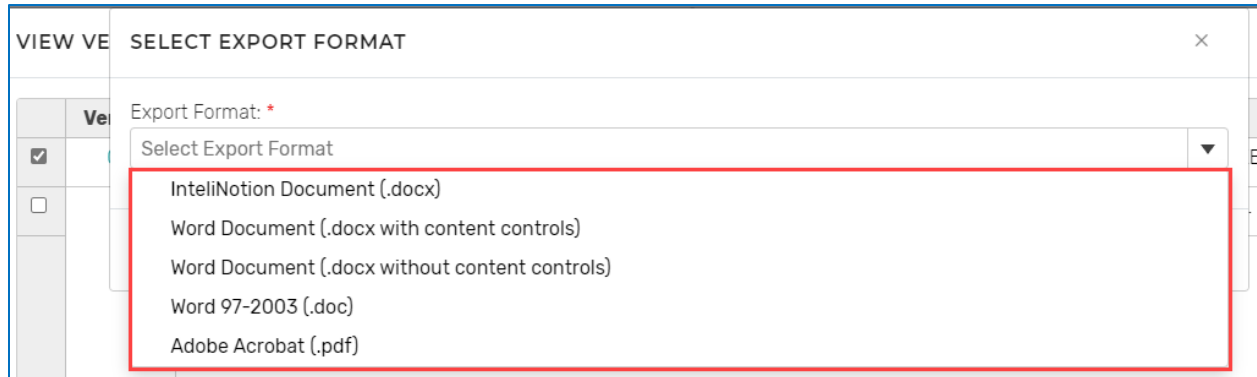
Export

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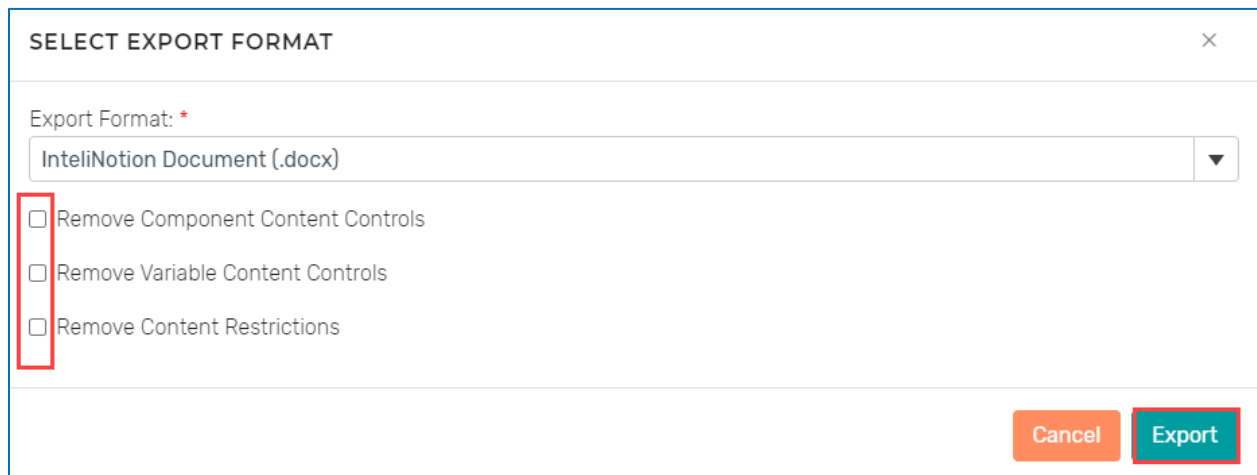
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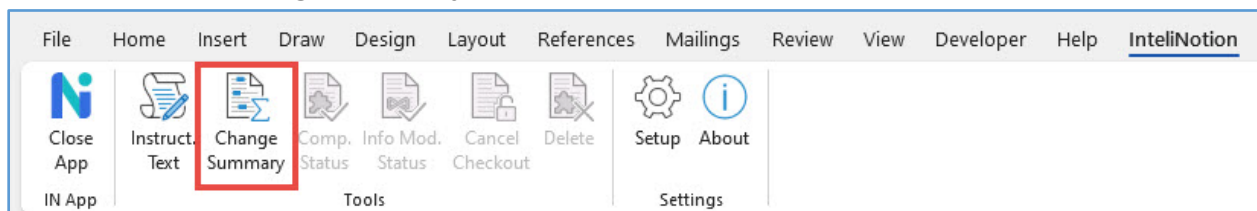
3. A pop-up will display. Choose the desired format from the drop-down menu.



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.

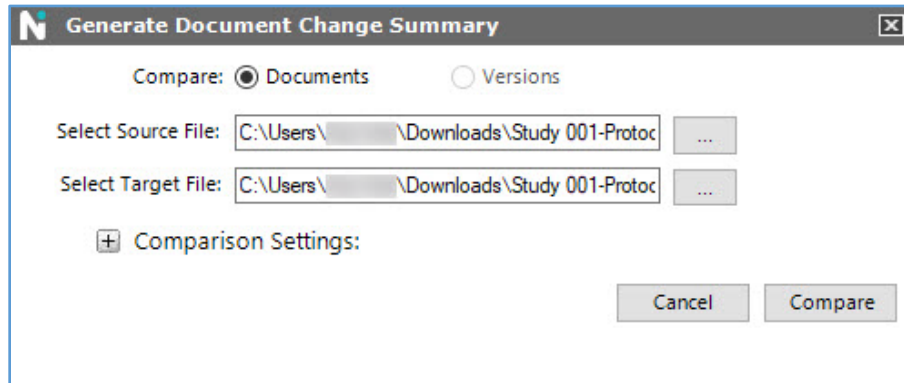


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- The following pop-up window will appear with the **Documents** radio button selected by default (unless an InteliNotion document is currently open); if not selected, check it. Click on the **vertical ellipsis** (ie, browse) to select the appropriate 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.

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