

User Guide Module 11: Document Tagging and Publishing, Export, and Saving to a Repository

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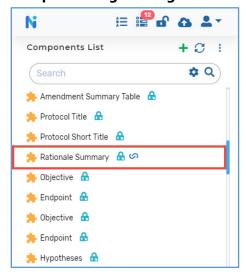


1. DOCUMENT TAGGING AND PUBLISHING

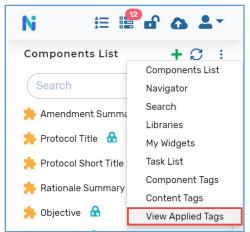
Applying component and content tags allow a user to redact specific information in a document, as per policies such as in European Medicines Agency (EMA) Policy 70.

A template can be preconfigured to already have selected components and/or content tagged. After a document is generated from a template and opened for editing (refer to Module 4, Section 1 for details on generating a document), any preconfigured tags can be viewed as follows.

1. In the *InteliNotion Word App* **Components List**, any components that have already been tagged will display the **Component tag binding** con next to its name.



2. In addition, any component *or* content tags already applied can be viewed by clicking the **vertical ellipsis** on the top of the *InteliNotion Word App*, then selecting **View Applied Tags**.



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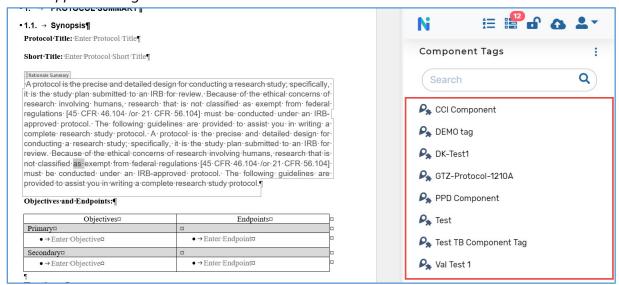


1.1 APPLYING TAGS IN A DOCUMENT

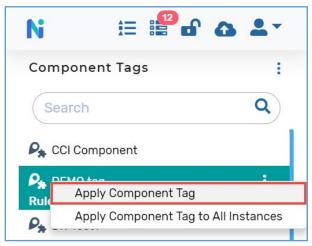
To apply tags in a document, follow the steps listed in the sections below.

1.1.1 Component Tag

Right-click in the applicable component. Click on the *InteliNotion* menu and select **View** Available Component Tags. The Component Tags view will open in the *InteliNotion Word* App on the right.



2. Click on the ellipses for the tag that needs to be applied and select **Apply Component Tag**.



Note: The second option can be selected if all identical instances of the selected component should be tagged.

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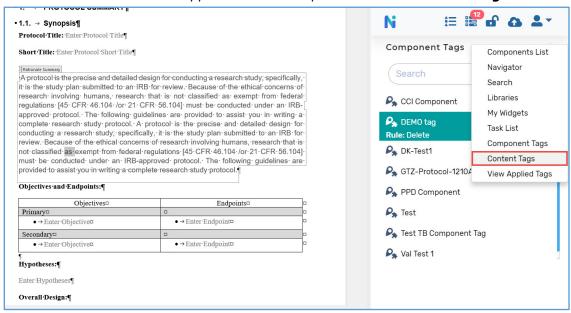


3. A Tag applied successfully dialog box will display.

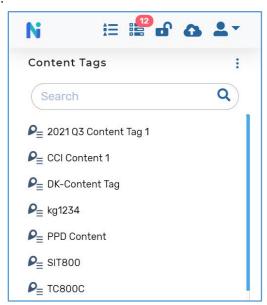


1.1.2 Content Tag

1. In the *InteliNotion Word App*, click on the ellipses, and select **Content Tags**.



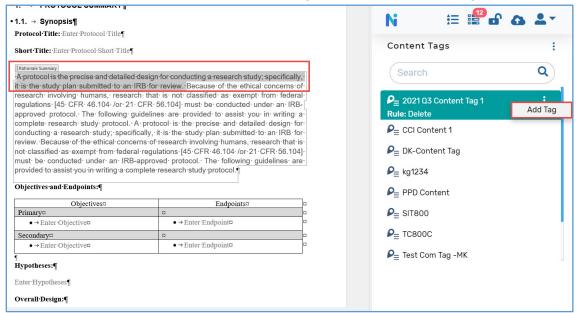
2. The tags will display.



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3. Highlight the relevant content within a component or the document itself, click on the **vertical ellipsis** of the relevant content tag name, and click **Add Tag**.

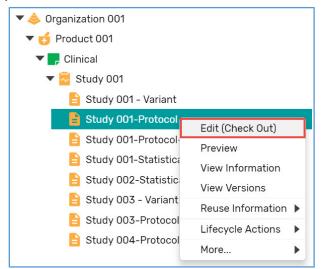


4. A Tag applied successfully dialog box will display.



1.2 VIEWING TAGS APPLIED IN DOCUMENT

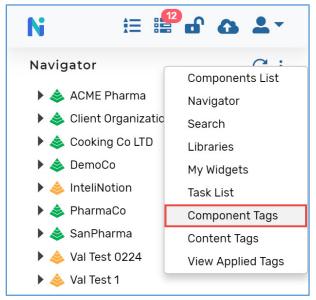
1. **Edit (Check Out)** the document used in Section 1.1.



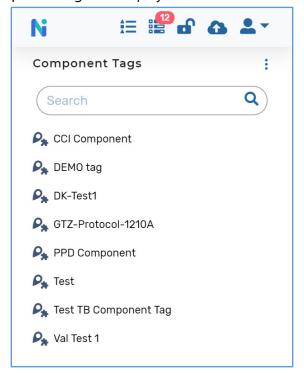
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a. To only view the component tags, click the **vertical ellipsis** in the *InteliNotion Word App* and click **Component Tags**.



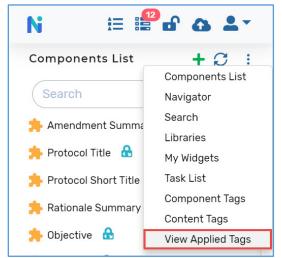
b. A list of component tags will display.



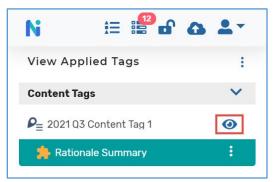
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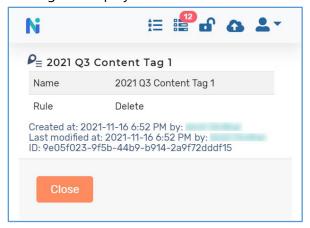
2. To view only component tags that exist in the open document, click the **vertical ellipsis** in the *InteliNotion Word App* and click **View Applied Tags**.



3. The existing tags in the document will display. Click the **eye ! icon** on the tag to view its information.



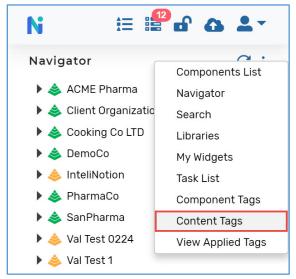
4. Further details for the tag will display.



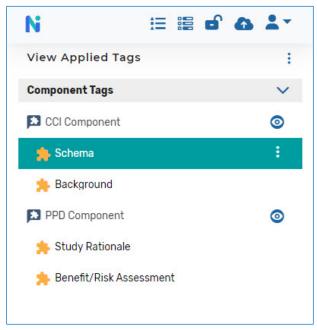
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5. To locate the applied content tags in the document, click the **vertical ellipsis** in the *InteliNotion Word App* and click **View Applied Tags**.



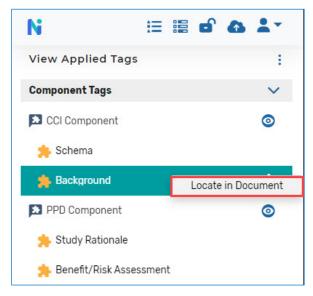
6. Click on the arrow next to **Content Tags**, and a list of content tags used in the document will display.



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7. To locate a content tag, click on the ellipses next to the content tag and select **Locate in Document**.

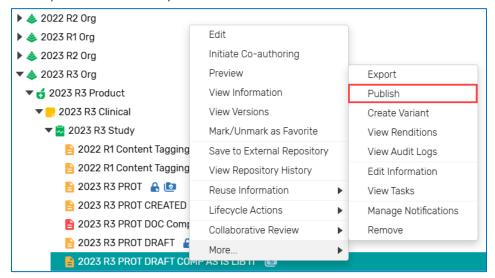


8. The document view will switch to the closest instance of the applicable component tag.

Note: If the content tag's name is updated in the *InteliNotion* system, locating the tag in the document will still take the user to the instances where content tags were applied with the old name.

1.3 PUBLISHING A DOCUMENT – REDACTION WITH DELETE ACTION

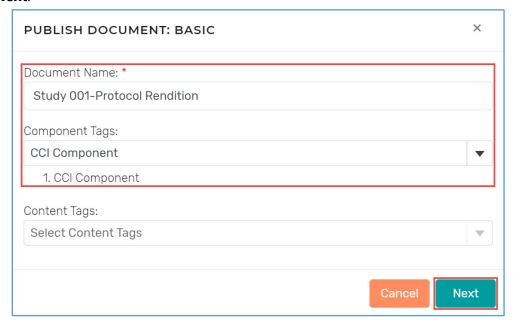
1. Locate the document used in the steps above within the **Navigator**. Right-click on the document, hover over **More**, and click **Publish**.



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2. The **Publish Document** form will open. The document name is prefilled with the word 'Rendition' added at the end; edit it if needed. In the available tags drop-down, select the relevant component tag(s) and/or content tag(s) to perform the redaction action, and click **Next**.



Note: At least one selection for each type of tag must be made if they are present in the document being published.

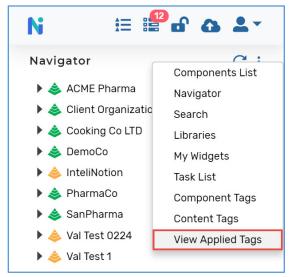
3. The **Selection Location to Publish Document** page will display. Select the location for the document to be published and click **Save**.



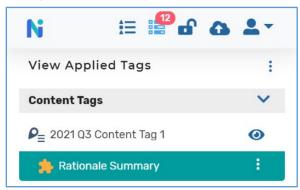
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- 4. The document is saved in the selected location. Click on the published document (eg, the one with 'Rendition' in the document name) and select **Edit (Check Out).**
- 5. Click on the **vertical ellipsis** in the *InteliNotion Word App* and choose **View Applied Tags**.



6. In the **View Applied Tags** display, the tags selected for redaction during the Publish step will no longer be listed, while the tags that were <u>not</u> selected are still listed, because the tagged component and/or content remain in the document.



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2. EXPORTING AND IMPORTING A DOCUMENT

This section describes document export and import functionality in *InteliNotion*. Documents can be exported out of *InteliNotion* in various formats depending on the purpose of export. For example, a non-*InteliNotion* format may be required for loading documents in a GxP repository. Note that exporting a document is different than publishing a document. Publishing is used to create a rendition of the document wherein some action was taken against prespecified content within it (eq., it was removed); refer to Section 1 above for more details.

InteliNotion provides very limited functionality for importing documents in *InteliNotion* as described in Section 2.2 below. Note that importing a document is different than document ingestion; refer to the **InteliNotion Application Admin Guide Section 10** for more details.

2.1 EXPORTING A DOCUMENT

Any user with R-E-A-D or higher permission can export a document out of *InteliNotion* and save it locally for a variety of needs. A document's content may be modified in the exported copy by specifying the format and other options as follows:

• InteliNotion Document (.docx) – The document will be exported in the as-is condition. It will be in *InteliNotion* format that contains content controls and intelligence in the form of XML data. Note that this document cannot be edited with *InteliNotion app* and cannot be imported back into *InteliNotion* even if it was exported in *InteliNotion* format.

Note: Documents exported in this format cannot be edited with *InteliNotion app* and cannot be imported back into InteliNotion even if it was exported in *InteliNotion* format.

- Word Document (.docx with content controls) The document will be exported in DOCX format with content controls, but without any intelligence in the form of XML data. Editing and deletion restrictions are preserved.
- Word Document (.docx without content control boxes) The document will be exported in DOCX format without content controls and related XML data. All content restrictions will be removed.
- Word Document (.docx with the ability to import) The document will be exported in DOCX format without content controls and associated restrictions. The exported document will contain additional information that will allow for importing it back into InteliNotion after it was edited offline outside of *InteliNotion*. This capability is intended to allow for offline review/revision by external users (eg, health authorities).

<u>Note:</u> In order to view the option **Word Document (.docx with the ability to import)** from the right click menu in the *Web Console*, authorized users must have **Document Ingestion Management** permissions configured. Users with the proper

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permissions can also access this option through the **Export** function when in the **View Versions** screen.

- **Word 97-2003 (.doc)** The document will be exported in legacy .doc format. This option is not recommended and is available only for backward compatibility.
- Adobe Acrobat (.pdf) The document will be exported PDF format.

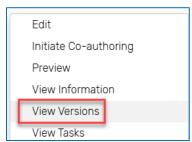
To export a document, follow the series of steps listed below as applicable.

- Use the direct **Export** option to export the latest version of the document.
 - Right-click on the document, hover over More and click Export.

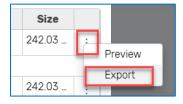


<u>OR</u>

- Use **View Versions** to export a selected version of the document.
 - o Right-click on the document and select **View Versions**.



o Click on the ellipses next to the desired document version and select **Export**.

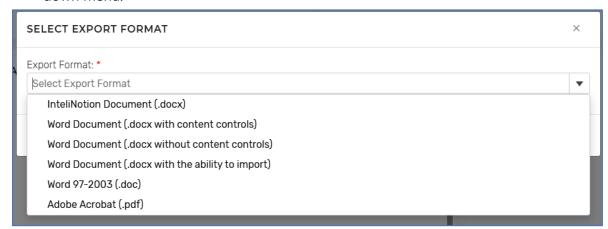


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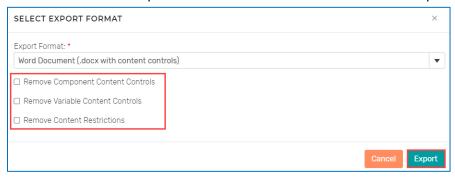


Once the export option method has been chosen, follow the steps listed below to complete the export process.

1. The **Select Export Format** window will display. Choose the desired format from the drop-down menu.



 If the InteliNotion Document (.docx) or Word Document (.docx with content controls) option is selected, the following additional options are available to further tailor the contents of exported document. Select 1 or more of the options, as desired.



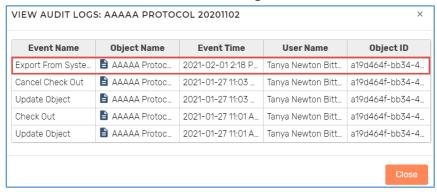
- **Remove Component Content Controls** If checked, all component content controls and related XML data will be removed.
 - Remove Variable Content Controls If checked, all variable content controls and related XML data will be removed.
 - Remove Content Restrictions If checked, all content restriction controls will be removed.

Note: The export process will not remove any content controls other than those listed above.

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- 2. Click **Export**. The exported file will be generated and downloaded locally. Depending on your selections, it may take several moments to prepare and download the document. Also note that the filename includes the version number if an older version is exported.
- 3. An export event will be shown in the **Audit Log**, if enabled.



<u>Note:</u> Documents exported in **Word Document (.docx with the ability to import)** format will contain hidden bookmarks to retain content control boundaries. These bookmarks and other information embedded in the document are vital to it being imported back in *InteliNotion* and must not be removed.

2.2 IMPORTING A DOCUMENT

As covered in Section 2.1, InteliNotion supports limited functionality to export a document and edit it outside of InteliNotion. Any document that was exported in the **Word Document (.docx with the ability to import)** format can be imported back into InteliNotion. Importing a document into InteliNotion will replace all existing content (inside the document and its components) with the content in the document being imported. Therefore, this function should be used carefully; refer to the latest product release notes for more information on known issues.

Any user with **Document Ingestion Management** functional permission can import the document. Import process works in multiple stages as described below:

- The input document is verified to be the one that was exported from *InteliNotion* in the relevant format.
- The input document is checked for errors such as missing markers for components, variables, and content restrictions. The findings are presented in a validation report.
- The input document is then converted to *InteliNotion* format and compared against the original/target document in *InteliNotion*. All discrepancies (eg, component was added/
- removed after exporting the document for external review) are presented in the import report.

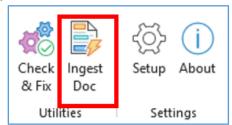
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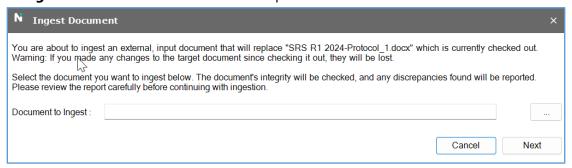
• If the user decides to proceed with the import/ingestion and then either saves or saves and checks in the document to *InteliNotion*, a new version will be created using the imported content.

To import a document, follow the steps listed below.

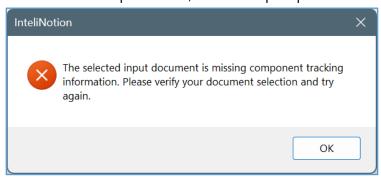
- 1. Right-click and select **Edit** on the target document to check it out.
- 2. Click the **Ingest Doc** option on the *InteliNotion* ribbon.



3. The **Ingest Document** screen will display. Click the **ellipses** next to the **Document to Ingest** field to browse and select the input document.

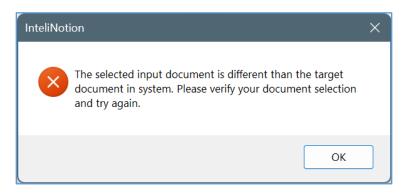


4. The **input document** is checked by the system to make sure it is in correct format and its ID matches with the target document. If these validation checks fail, an error message will display, as shown in the examples below, and the import process will be terminated.

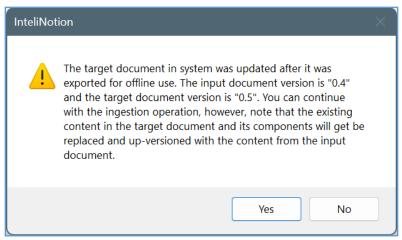


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5. After the format and document ID have been checked, the document versions of the input and target documents are compared, and the following warning is displayed to alert the user of changes made to the target document in *InteliNotion* after it was exported for the external review activity. If needed, review the message carefully, as some content loss may occur. Click **Yes** to continue.



<u>Warning:</u> *InteliNotion* does not prevent editing a document while its exported copy is being reviewed externally. Due to this fact, this practice it is strongly recommended against, as most of these changes will be lost from the document and will require manual reconciliation.

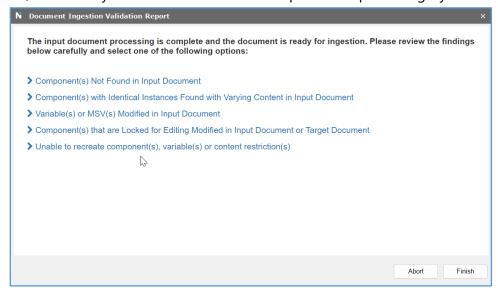
6. The **input document's** contents are verified for accuracy and completeness. This may take a few minutes depending on the number of components and content controls in the input document.



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7. When document pre-processing is complete and if there are issues with the **input document**, these findings are presented in a validation report along with actions that will be taken by the import process should it continue. An example screenshot of a report is below, followed by a table that describes each possible report category:



Category*	Description	Processing Behavior after Import
Component(s) Not Found in Input Document	The component markers were deleted during external review, and they can no longer be located in the exported, input document.	These components will be removed from the imported document, however, they are not deleted from the system when the document is saved/checked in.
Component(s) Added in Target Document	The target document was edited in InteliNotion after exporting it for external review and one or more components were added to it that do not exist in the exported, input document.	These components are removed from the document but are not deleted from the system when the document is saved/checked in.
Component(s) Not Found in Target Document	The target document was edited in InteliNotion after exporting it for external review and one or more components were removed/replaced, but they still exist in the exported, input document.	These components are added back when the document is saved/checked in with the following behavior: If they exist in the Recycle Bin, they are restored/recovered.

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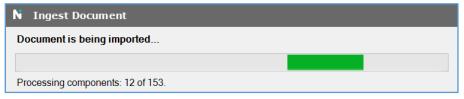
Category*	Description	Processing Behavior after Import
		If they do not exist at all, they are recreated in the system.
		In both these cases, contents of the component are populated from the input document.
Variable(s) Not Found in Input Document	The variable markers were deleted during external review, and they can no longer be located in the exported, input document.	These variables are removed from the document or component content in the target document.
Content Restriction(s) Not found in Input Document	The content restriction markers were deleted during external review, and it can no longer be located in the exported, input document.	These content restrictions are removed from the document or component content in the target document.
Component(s) with Identical Instances Found with Varying Content in Input Document	More than one identical instance of a component is present in the exported, input document, but their contents do not match because they were modified during external review.	Content from the first instance in the document will be used to populate the component and it will be synchronized with all other instances.
Variable(s) or MSV(s) Modified in Input Document	Variables and Metadata- sourced Variables (MSV) are read only in InteliNotion, but they were modified during external review in the exported, input document.	Any changes made to variables and MSVs are discarded. If a content change, comments or a tracked change is found within the variable content, it will be listed in the report as an error.
Component(s) that are Locked for Editing Modified in Input Document or Target Document	A component was locked for editing in InteliNotion (due to its reuse policy or approval status), but its contents were modified during external review in the exported, input document.	For an As Is reused component, its content will be imported from the input document and retained in the target document until the component is refreshed via Component Status Report. You must reconcile changes at source as soon as possible.

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Category*	Description	Processing Behavior after Import			
		Also, note that any changes made to such components in InteliNotion (via its source document/library) after exporting the document will also be lost.			
		Components that were locked due to approval status will be checked out, demoted to Draft state and contents will be imported.			
Unable to	The import process could not	The system is unable to recreate			
recreate component(s),	recreate content controls due to an unexpected/unspecified	content controls and application administrator support is required.			
variable(s) or	error.	These components, variables and			
content		content restrictions will be listed in			
restriction(s)		the report with additional			
		information such as component			
		name and page numbers.			
*Some of these categori	*Some of these categories will appear only after import processing is completed.				

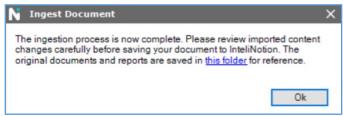
- 8. Review each finding carefully and click **Abort** to abandon the import process or **Finish** to continue.
- 9. After clicking **Finish**, the import processing will begin. This process may take a few to several minutes depending on the number of components and locked content (eg, as-is reused components, variables, and content restrictions). The progress bar displays the import/ingestion processing status as shown below:



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10. When import processing is complete, the checked-out target document currently open in *MS Word* will be closed. It will then be replaced in the user's **Data** folder with the imported content. The imported/replaced target document will open in *MS Word* and the confirmation message will be displayed.



- Click the link to access the import report as well as other files created as part of the import process. See table above for the possible report categories.
- 11. Click **Ok** to dismiss the message. This concludes the import operation, however, the document has not yet been saved to the system.
 - a. A copy of the documents used during import operation and the report files are saved temporarily in the **Data** folder. Each import operation will create one folder under which these files are saved.
 - b. Review the imported content carefully in the imported/replaced target document after it is opened, for any discrepancies and to reconcile findings listed in the report. Note that imported content and any changes made are not committed/saved in *InteliNotion* until saved or checked in. This affords the user one more opportunity to discard imported content should any issues be found, that cannot be reconciled/repaired.
- 12. Use the cloud **Save** button to either save or save and check in the document to create a new version in the system.
 - Note that an **Update Object** audit event associated with the save (and check in) operation will capture the document name used for the import

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3. SAVING DOCUMENT TO AN EXTERNAL REPOSITORY

Documents authored in *InteliNotion* can be configured to save to external document management repositories used to electronically approve the documents and as systems of record. Typically, the systems are used for Regulatory Info Management (RIM) and Electronic Trial Master File (eTMF) purposes.

Depending on the organization specific configuration, the documents can be either transferred automatically at appropriate times and/or can be transferred manually as needed. This section describes these activities, as well as viewing the history of transfers and navigating to the documents located in the repositories.

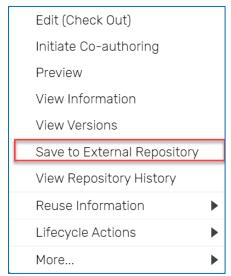
Note: System configuration is client specific and may vary from the examples shown here.

3.1 SAVING DOCUMENTS TO A REPOSITORY (USER-INITIATED)

If enabled, any user with edit privilege can request a document be saved to a configured repository on demand. This option will be available only when the specified criteria is met, eg, the criteria can require the document to be in one or more lifecycle states or a major version for it to be saved to repository.

Note: When a checked-out document is sent to repository, it may not reflect the latest changes (eg, because the document was in co-authoring without an interim save or finish co-authoring prior to the transfer).

1. Right click on the document and click **Save to External Repository**.



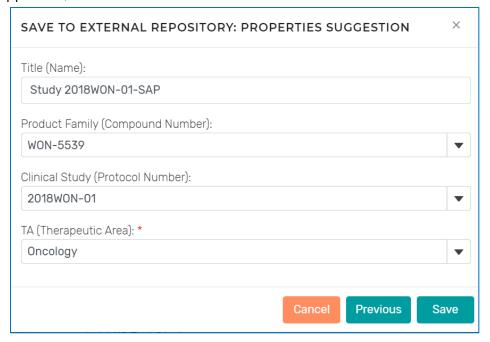
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2. In the **Save to External Repository: Select Repository Connector** form, select the appropriate repository name from the drop-down list and click **Next**.



3. The Save to External Repository: Properties Suggestion form will display. The contents of this form will vary depending on the selected business object class and metadata mapped to and required by the repository. Most of the entries will be auto populated as shown in the example below. Verify the existing values, enter values for the empty entries as applicable, and click Save.



4. If the document was saved successfully, a successful publication pop-window will display.



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- 5. An error message will display if the document cannot be saved to the repository; contact the system administrator for support. Examples for why the error message occurred are listed below.
 - Specified metadata value or combination of values do not exist in the repository. Eg, a nonexistent study number was specified, or compound number and study number combination is not valid.
 - The required value is not specified. This is an unlikely scenario that can be caused by incomplete configuration or configuration changes in the repository.
 - Certain business rules or validation in the repository prevent the document or its new version from being created at this time.

Note: The save to repository icon next to the document will be displayed upon successful publication to the repository.

3.2 SAVING DOCUMENTS TO A REPOSITORY (AUTOMATED EVENTS)

If enabled, documents can be transferred to one or more repositories automatically when the specified event (ie check-in or a lifecycle state change) takes place as described below.

- Check-in Event: With this configuration, the following events will result in the document check-in operation followed by its transfer to one or more repositories if the check-in was successful:
 - User initiated check-in of a document (see Module 5, Section 2.1)
 - Finish Coauthoring (see Module 5, Section 3.9)
- **Lifecycle State Change Event**: With this configuration, document transfer to 1 or more repositories will take place every time the document enters into 1 or more specified lifecycle states. A state change could occur due to the events listed below:
 - User changes the lifecycle state manually via the document's Edit Information page
 - All assigned tasks are completed which triggers a state lifecycle change (ie, promotion to the next or 'higher' state)
 - User performs an action such as edit/checkout, task cancellation or rejection (ie, demotion to the prior or 'lower' state)

After successful processing of the triggering event in *InteliNotion*, the document will be saved to the configured repository or repositories, along with its metadata. If a prior version of the document was saved to the repository, a new version will be created following the rules configured in the target repository. The **save to repository icon** will appear next to the document once the document is saved. If configured, the document owner and optionally, other specified

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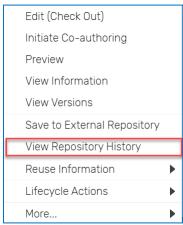
users/teams will be notified via email. The email will include links to the document in *InteliNotion* as well as the repository.

If the document cannot be saved for reasons similar to those described in Section 3.1, the document owner and optionally, other specified users/teams will be notified via email. The email will include details of the error to aid in troubleshooting and resolution.

3.3 VIEWING REPOSITORY HISTORY AND RELATED INFORMATION

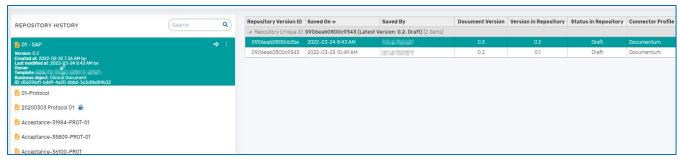
The history of document transfers and related information can be viewed for an individual document, or a group of documents (eg, study level) as described below.

1. Navigate to a document or the Study/Product level in the *InteliNotion* Navigator. Right click and select **View Repository History**.



Note: The **View Repository History** option will not be displayed if the selection does not have any prior history of external repository transfers.

2. The repository history page will display. On the left side, it lists all documents in alphabetical order for the selected node in the Navigator. Double-click the document name or click the icon to view its history. Additionally, the list can be filtered by entering a partial document name.



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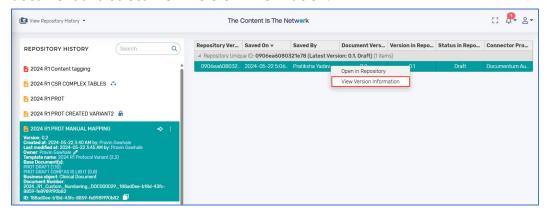


- 3. The right side of the page will list the current status and the prior history for each transfer as described below:
 - Latest/Current information for the document:
 - Repository Unique ID: Globally unique ID for the document in the repository. All
 historical entries for the selected document are grouped under this ID.
 - Latest Version in Repository: Version number for the latest/current version of the document. The document may have up-versioned in the repository since the last transfer.
 - Latest Status in Repository: Document status for the latest/current version of the document. The document state may have changed in the repository since the last transfer.
 - Historical information: The following information is captured for each transfer and is listed in reverse chronological order.
 - Repository Version ID: Version specific ID for the document. This may be the same as the unique ID depending on the repository type (eg, Veeva).
 - Saved On: Date and time of document transfer in user's local time zone.
 - Saved By: InteliNotion username who directly or indirectly (via task completion) initiated the transfer.
 - Document Version: Document version number in InteliNotion that was transferred.
 - Version in Repository: The version number created in the repository as the result of the transfer. For Documentum-based repositories, this will be the latest version in the repository.
 - Status in Repository: The document status in the repository at the time of document transfer. For Documentum-based repositories, this will be the latest state in the repository.
 - o **Connector Profile**: The connector profile used to perform the transfer.

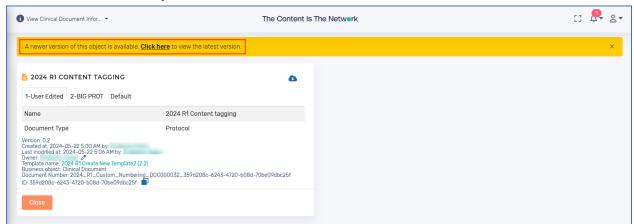
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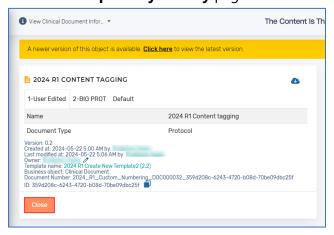
4. To view the information of the document version used for the transfer, right click on the document and select **View Version Information**.



5. The **View Version Information** screen will display, with the option to view the latest version of the object.



6. Click **Close** to return to the **Repository History** page.



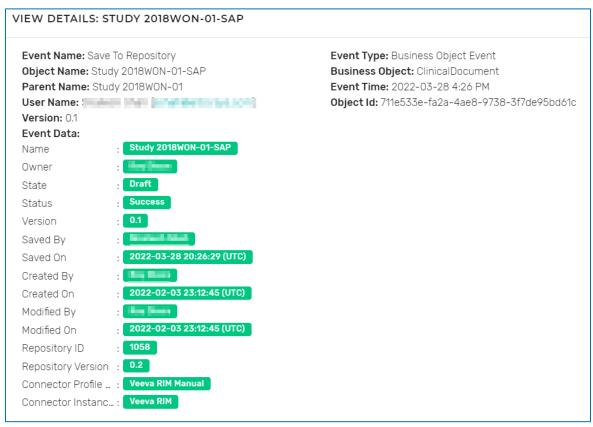
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Note: If desired, users can view the document in repository by right clicking and selecting **Open** in Repository. [] 🔑 გ View Repository History ▼ The Content Is The Network Repository Ver... Saved On ▼ Saved By Document Vers... Version in Repo... Status in Repo... Connector Pro... REPOSITORY HISTORY Repository Unique ID: 0906ea6080321e78 (Latest Version: 0.1, Draft) (1 items) 2024 R1 Content tagging Open in Repository View Version Information 2024 R1 CSR COMPLEX TABLES ♣ 2024 R1 PROT ₱ 2024 R1 PROT CREATED VARIANT2 ♣ 2024 R1 PROT MANUAL MAPPING n: 0.2 d at: 2024-05-22 3:40 AM by: Pravin Gawhale odified at: 2024-05-22 3:45 AM by: Pravin Gar avin Gawhale // name: 2024 R1 Protocol Variant (2.3) iment(s):

Additionally, if enabled, the document transfer events are audited and can be viewed in the system audit logs along with relevant details. There are two events that are related to repositories: **Export from System** and **Save to Repository**. The following is an example of **Save to Repository** event.



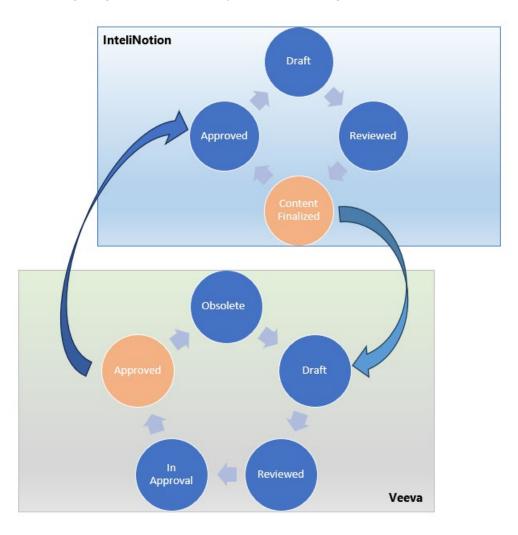
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3.4 SYNCHRONIZING INTELINOTION DOCUMENT STATUS FROM VEEVA REPOSITORY

In addition to transferring documents to external document management systems, InteliNotion provides the ability to detect lifecycle state changes for these documents as they go through the review and approval workflows in the repository and promote/demote the lifecycle state in InteliNotion according to business process needs. Currently, this feature is supported only for Veeva Vault systems. This is an optional feature that must be turned on and configured to align with InteliNotion and Veeva document lifecycles.

If this feature is enabled, then depending on the configuration, the document lifecycle state in InteliNotion will be changed automatically whenever the designated state change occurs in Veeva Vault. The following diagram illustrates a hypothetical configuration.



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In the example above, the document is tranferred to the repository when it reaches **Content Finalized** state in InteliNotion. This document then goes through review and/or approval workflows and is promoted to **Approved** state in the repository. This triggers the lifecycle state update in InteliNotion to then promote the document to **Approved** state as well.

If the automatic component lifecyle state update is configured then all components will also be promoted or demoted along with the document document. If one or more components could not be transitioned to the new lifecycle state, the document owner is notified by email.

Note: If a document has open tasks, they may be auto completed, and the document will be promoted to the new lifecycle state.

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