Integral™ Guide

Applies to:
Integral 23.10.1
– Web Application
– Integral Plugin for Phoenix
– Client Application

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Contents

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Integral Introduction

The ability to analyze and manage pharmacokinetic/pharmacodynamic (PK/PD) data from a variety of sources in a centralized, systematic, and organized manner is increasingly important as pharmaceutical scientists attempt to process and analyze data from early stage drug development and apply that information in the later stages of clinical testing. Added to this need are growing demands for regulatory compliance to Food and Drug Agency guidelines with respect to the way drug development data are collected and submitted for review.

Integral is a secure central repository for PK/PD and related data such as demographics and covariate information, as well as modeling and analysis files from other tools, with the resulting output data, images, and reports. Integral supports the use of Certara tools as part of an improved decision-making process within the pharmaceutical development organization. The system can manage and provide effective access to data across a diverse set of compounds and development phases to support an improved, information-driven decision process during drug development.

Integral enables users to capture essential data from internal studies as well as publicly available information. With this information, users can build models of drug, disease, and subject interactions useful for clinical trial design. Integral enables members of the clinical development team, including biostatisticians, clinical pharmacologists, physicians, and trial designers, to communicate using the language of drug models and clinical trial simulation.

Select one of the following links to learn more:

- User Interface Description
- Working with Folders
- Working with Files
- Copy and Link
- Controlling Notifications
- Folder Types
- Property Types
- File Types
- Auditing Changes to Integral Data
- Database Security
- Glossary
- Integral Plugin, synchronize Phoenix projects with data stored in Integral
- Integral Client Application, synchronize local data with data stored in Integral.

See the “Compatibility and Whitelisted URLs” section for browser compatibility information and a list URLs to be whitelisted.

Compatibility and Whitelisted URLs

The Integral application is compatible with Firefox version 77 or greater, Chrome version 83 or greater, Microsoft Edge version 83 or greater.

There are executables that may be flagged/quarantined by different antivirus software. This can cause Integral to function improperly or even fail. To avoid these types of problems, the following items should be included in an exception list for virus protection by your IT professional to enable all functionality, including Help and Support sites.

https://fonts.googleapis.com

https://integral.certara.com/

http://integral.certara.com/

https://integral-staging.certara.com/

http://integral-staging.certara.com/

https://auth.certara.com/

https://certara.com/

https://certara-ext-gw2ywp.okta.com/

https://api.segment.io

https://cdn.segment.com

https://ok11static.oktacdn.com

https://api.certara.io

https://onlinehelp.certara.com/

https://support.certara.com/

https://www.certara.com/

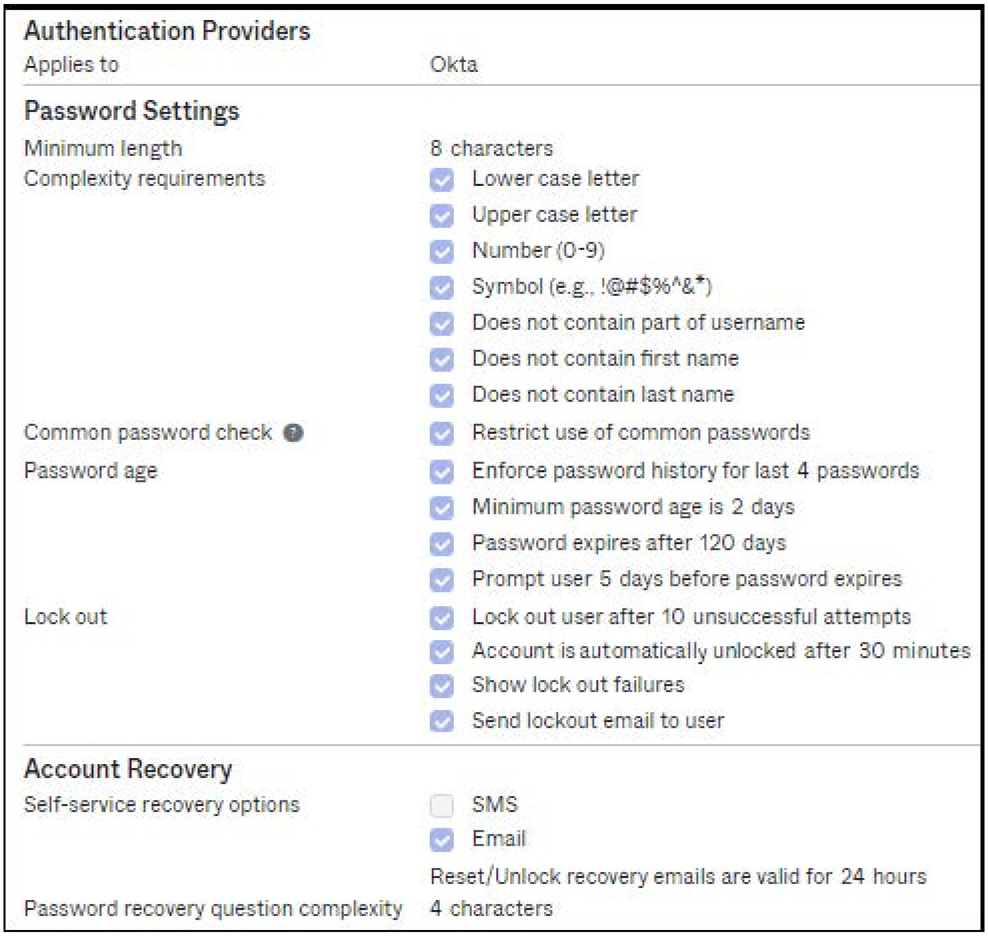
Note: *On the login page, if you are unable to see the “Need help signing in” option, you may need to adjust your font size or display resolution.*

After entering your log in credentials, if you are returned to the same login page, verify that your browser settings allow cookies to be saved and read.

User Interface Description

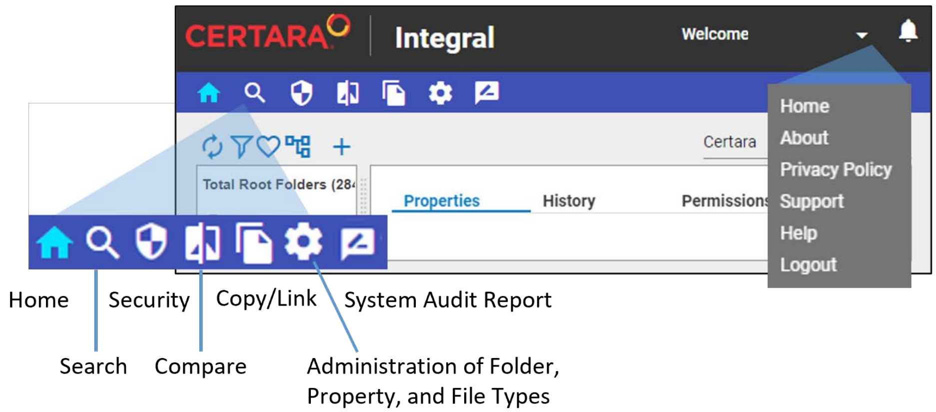
Log in

Certara provides a set of rules that can be applied when an Integral user is creating their password. The default settings for these rules are shown in the following image. These settings may be updated, if requested by your organization, by contacting Certara.



Authentication Providers	
Applies to	Okta
Password Settings	
Minimum length	8 characters
Complexity requirements	☑ Lower case letter
	☑ Upper case letter
	☑ Number (0-9)
	☑ Symbol (e.g., !@#$%^&*)
	☑ Does not contain part of username
	☑ Does not contain first name
	☑ Does not contain last name
Common password check	☑ Restrict use of common passwords
Password age	☑ Enforce password history for last 4 passwords
	☑ Minimum password age is 2 days
	☑ Password expires after 120 days
	☑ Prompt user 5 days before password expires
Lock out	☑ Lock out user after 10 unsuccessful attempts
	☑ Account is automatically unlocked after 30 minutes
	☑ Show lock out failures
	☑ Send lockout email to user
Account Recovery	
Self-service recovery options	☐ SMS
	☑ Email
	Reset/Unlock recovery emails are valid for 24 hours
Password recovery question complexity	4 characters

Toolbar



For more information, see:

- Search
- Database Security
- Compare files
- Copy and Link
- Folder Types
- Property Types
- File Types
- System Audit Report

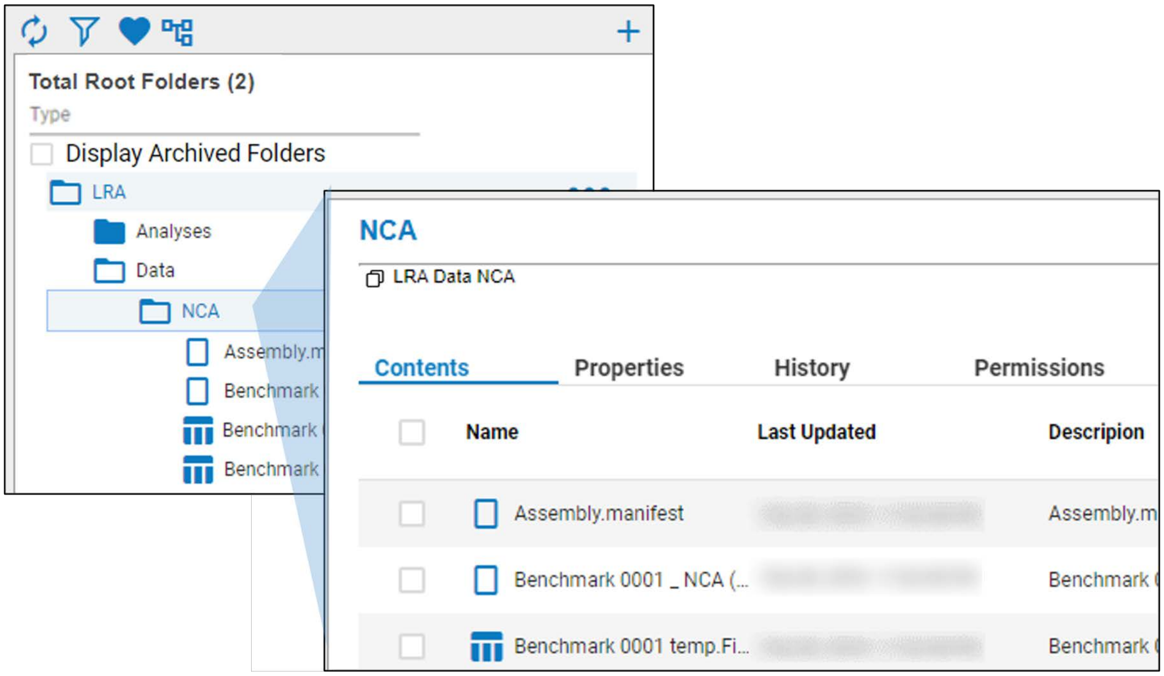
Repository

The name of the repository is shown on the right, under the toolbar.

Click to select a different repository to which you have access. Once a repository is selected that is not the default, **Set to default** is displayed.

Clicking **Set to default** changes the default repository to be the one currently selected.

Browser



Select a folder in the Integral browser to expand the listing and see subfolders and files. The contents of the selected folder are also shown in the panel on the right, with some additional details, such as the date each item was last updated and the description.

Near the top of the right panel, below the item's title, is the path to the selected item. Click the icon to copy the path to the clipboard. The copied path Is the full path with slashes, etc.

Below is a list of some of the folder and file icons that can appear in the browser:

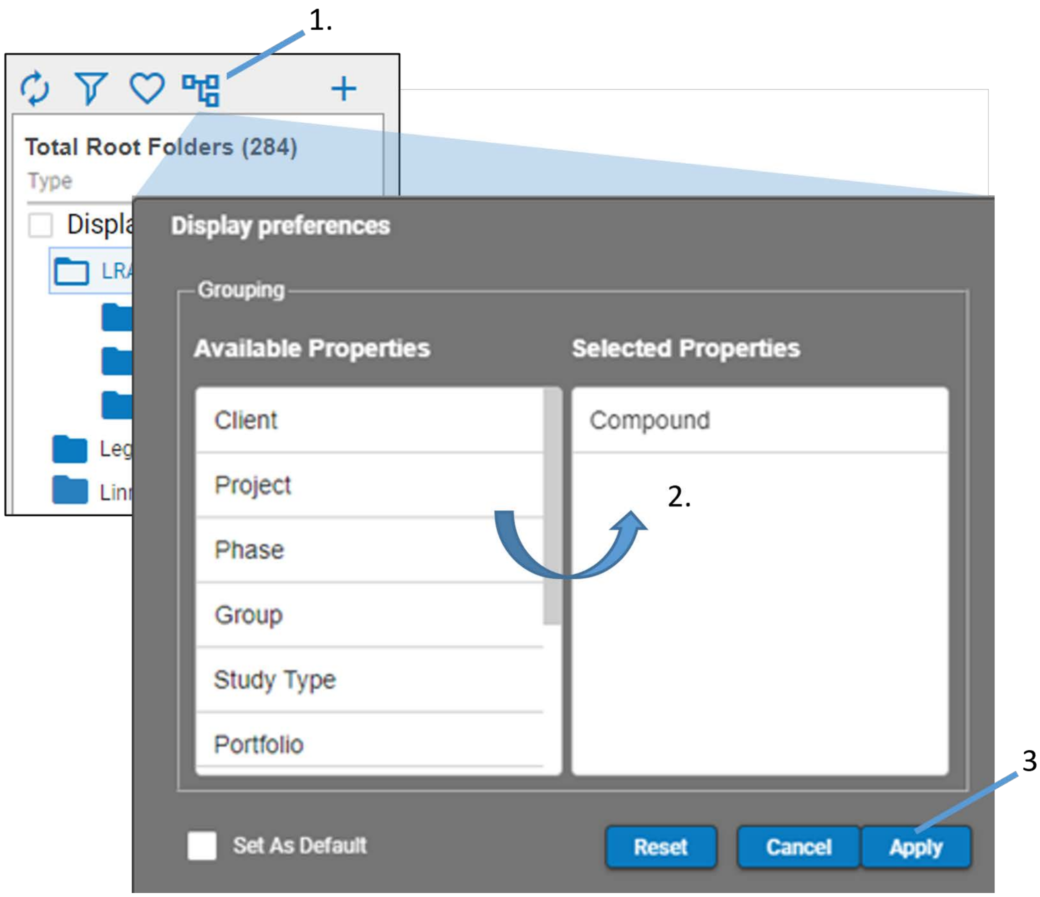
Up-to-date folder	Locked
Folder containing an out-of-date item	Blinded
Selected folder	eSignature enabled
Link	Grouped by metadata
Data file	
Image file	
Text file	
Unknown file type	

The Display Archived Folders checkbox controls whether locked (archived) folders are visible in the tree. See "Lock and Unlock Files" for more information on archiving files and folders.

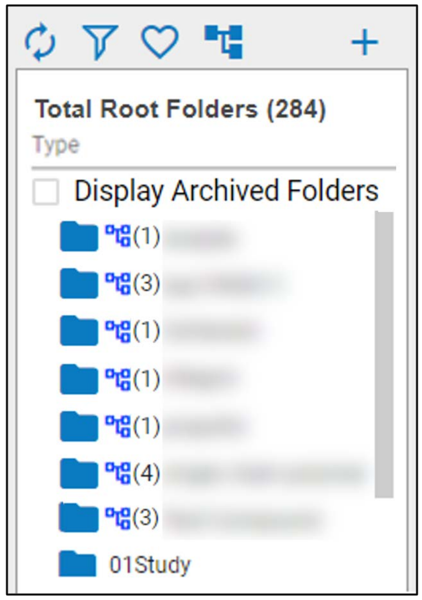
Grouping

Grouping allows folders to be organized in the browser based on properties associated with those folders.

1. Click  in the Integral browser toolbar.
2. From the list of Available Properties for root folders, drag any properties to use for grouping folders to the Selected Properties list.
3. Press **Apply**.



When grouping is applied, the Grouping icon above the browser changes to  and the same icon appears to the right of the grouped folders. Grouped folders will be listed first in the browser, followed by all folders where grouping is disabled. Notice the number in parentheses, indicating the number of root folders that fall into that particular category of the grouping.

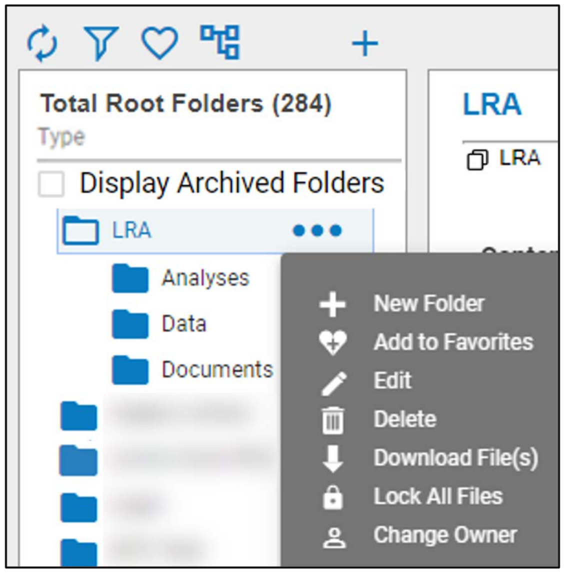


Control of whether a folder type can be included in grouping is located in the Admin module using the **Grouping enabled** setting. See “To add a folder type” for more information.

The grouping settings are remembered until the properties selected are changed in this window. To save the Selected Properties list as the default grouping, check the **Set As Default** box. Then, when the **Reset** button is pressed, the list will reflect the saved default.

To return to the original default setting of grouping by root folder, drag all properties out of the Selected Properties list and check the **Set As Default** box.

Browser options menu

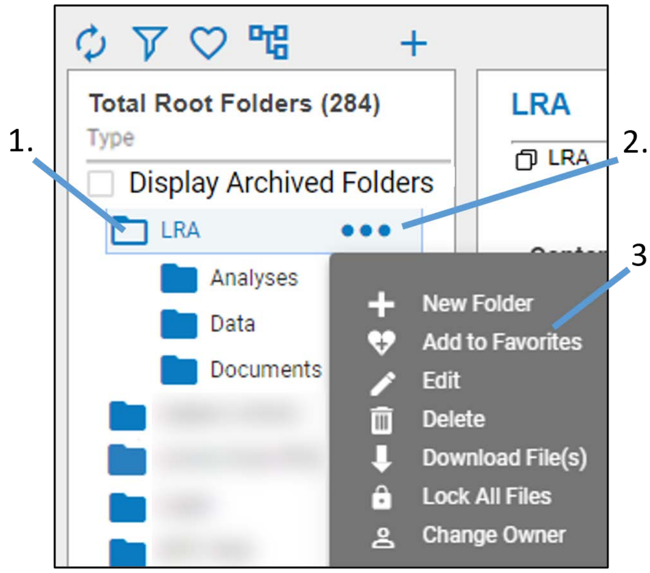


Selecting or hovering over an item in the Integral browser shows an ellipsis to the right. Click the ellipsis to display a pop-up menu of options. The options available in the menu depends on the type of the item and user's permissions. Click the link for more information.

- Add a top-level folder
- Add a sub-folder
- Edit properties of a folder
- Edit properties of a file
- Favorites
- Upload file(s) to a folder
- Download a file
- Lock and Unlock Files
- Blind and Unblind Folders and Files
- Delete one or more folders
- Delete a file

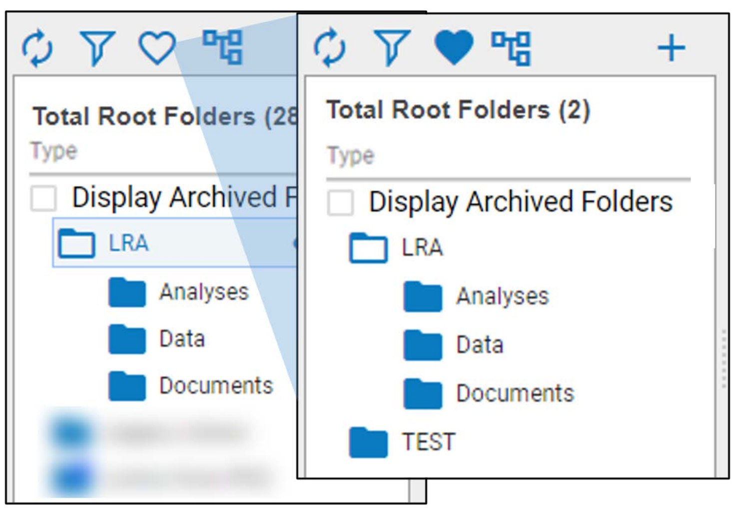
Favorites

Add Favorites



1. Select an existing folder.
2. Click the ellipsis button.
3. Select **Add to Favorites** from the pop-up menu.

View Favorites



Toggle the Favorites icon above the Integral browser to switch between the full list of items and favorites list.

Contents Tab

The contents of the item selected in the Integral browser are shown in the Contents tab along with the date each item was last updated and the description.

If the selected item is one of the following types, the contents of the file is displayed:

- Plain text files (TXT, LOG, etc.)
- CSV
- DAT
- HTML
- PDF
- Microsoft Word documents (DOC, DOCX, RTF)
- XPT
- Supported image file (BMP, GIF, JPEG, etc.)

Properties Tab

The properties for a particular item are controlled by the system administrator (see "Property Types"). Some of the more common ones are listed here:

Created On: Date folder/file originated.

Blinded: Indicates whether the folder/file is blinded (**True**) or unblinded (**False**).

Compound: Name of the drug(s) that used in the study.

Created By: Name of the person who created the file/folder.

Description: Optional narrative text that can be entered to describe the folder/file.

eSignature Required: Indicates whether the folder eSignatures are enabled (**True**) or disabled (**False**)

Folder Type: Shows the value set for the Folder Type property.

Indication: The condition or illness that is being treated in the study (e.g., depression).

Locked: Indicates whether the folder/file is locked (**True**) or unlocked (**False**).

Name: Name of the folder/file.

Owner: The name of the user who owns the folder/file.

Portfolio: Different groupings of projects or compounds. For example, it could be used to group studies in a therapeutic area such as CNS.

Revision: Numeric identifier indicating the number of times the folder/file has been changed and saved up to that point.

Security Context: Shows if the folder is a Root Folder.

Size: File size.

Study Design: Design of the study you selected.

Study End Date: The ending date for the study.

Study Start Date: The beginning date for the study.

The Inherited Properties section lists any properties inherited from the parent folder.

View properties of a folder or file

1. Select the folder or file in the browser on the left.

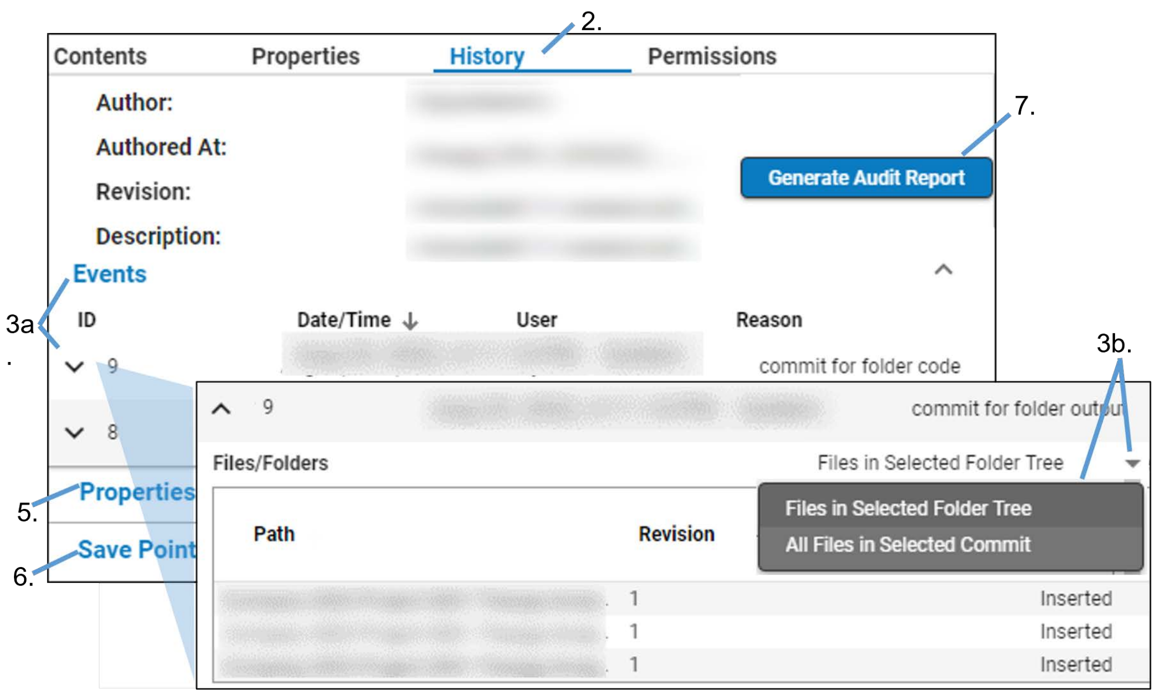
Note: *If needed, the list of studies can be filtered. (see* "Filter the Browser List"*).*

2. Click on the **Properties** tab on the right:

History tab

Every change that is made to a Integral file or folder is logged in an audit trail. A brief overview the history can be viewed or a full audit report can be generated. Users with a minimum of READ access to the study can view the history and generate audit reports.

View history of a folder or file



1. Select the folder or file in the browser on the left.

Note: *If needed, the list of studies can be filtered. (see "Filter the Browser List").*

2. Click on the **History** tab on the right:
3. For a folder, expand the **Events** section, and click the arrow next to an ID to expand the row and view the files related to the event.

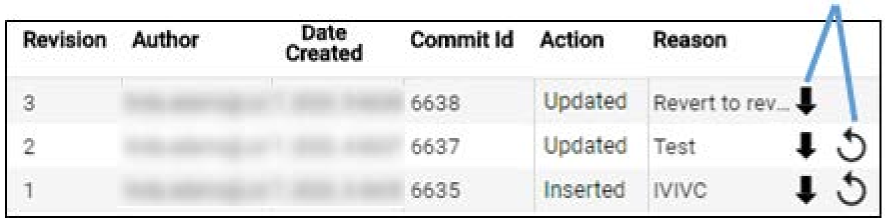
   If the event involved the deletion of a file, the file can be recovered by clicking to download it. Then upload the file back to Integral as a new file.

   Use the **Files in Selected Folder Tree** dropdown to switch between only listing the files in the folder or listing all of the files that were part of the selected event.

4. For a file, a list of revisions is given. Click to download a copy of the revised file.

   When there are multiple revisions for a file, click to go back to that version of the file. The content of the file is reverted and it is logged as another revision. (If the file is within a savepoint and further work is needed on a particular version of the file, either revert the entire savepoint or download the needed file version.)

4.



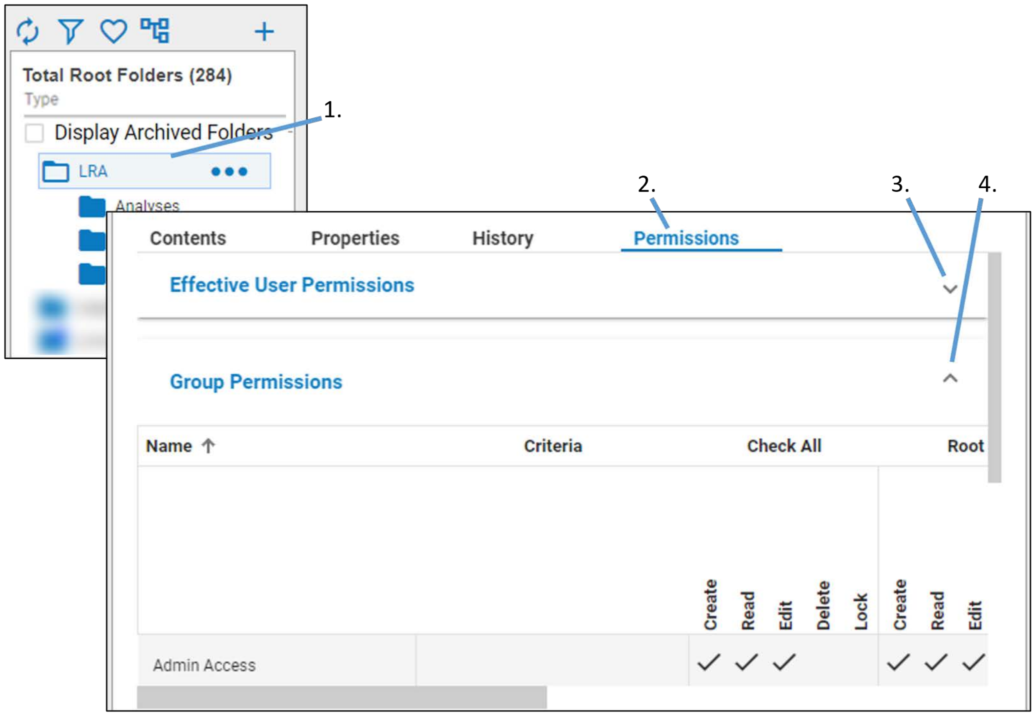
Revision	Author	Date Created	Commit Id	Action	Reason
3	[illegible]	[illegible]	6638	Updated	Revert to rev...
2	[illegible]	[illegible]	6637	Updated	Test
1	[illegible]	[illegible]	6635	Inserted	IVIVC

5. Expand the **Properties** section to view a list of associated properties, their values, the date of creation and the author.
6. Expand the **Save Points** section (available only for savepoint-enabled folders) to see a list of previously saved savepoints, the date/time of creation of each savepoint (in UTC), and the author.

   See “Load a prior state of a folder” for more information.
7. To generate an audit report, click **Generate Audit Report**. See “Auditing Changes to Integral Data” for more information.

Note: *The History tab for a study only displays the current data; it does not show the data prior to any changes.*

Permissions tab



1. Select the folder or file in the browser on the left.
2. Click on the **Permissions** tab on the right:
3. Click **Effective User Permissions** to expand the list of users and their permissions for the selected folder or file.

   Type in the **Search Users** field to filter the list.
4. Click **Effect Group Permissions** to expand the list of groups and their permissions for the selected folder or file.

These permissions are determined by the permissions assigned to the author of the folder or file. See "Edit a user in the system database" for more on user permissions.

Note: *If a folder's author is editing the Effective User Permissions of a folder and an administrator is making changes to the same folder in the Security module at the same time, whatever changes that are made last will be applied.*

Folders

Predefined Folder Types

View information about a folder

Add a top-level folder

Add a sub-folder

Edit properties of a folder

Transfer ownership of root folder

Delete one or more folders

Load a prior state of a folder

See also

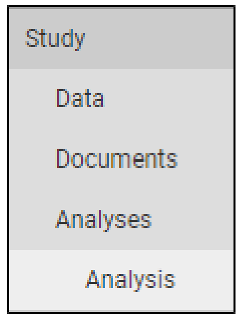
- Folder Types
- Copy and Link.
- Blind and Unblind Folders and Files.
- Lock and Unlock Files
- Grouping

Predefined Folder Types

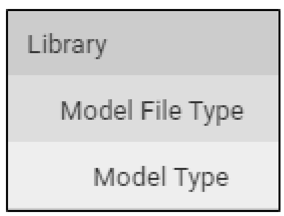
The predefined folder structure in Integral is described in this section. It is important to remember that Integral is very flexible and that a very large percentage of the folder structure is customizable.

There are two predefined, top-level folder structures:

Study - Set up for storing all information for a particular study, e.g., a clinical study. The study may be centered around a client, an indication, a study type, a study design, a compound, a therapeutic area, a group (team) of Integral users, a program, a phase, or a portfolio.



Library - As a top-level folder, this folder type could be used to store templates, reports, code files, graphics, or documents that might be used by multiple projects or studies.

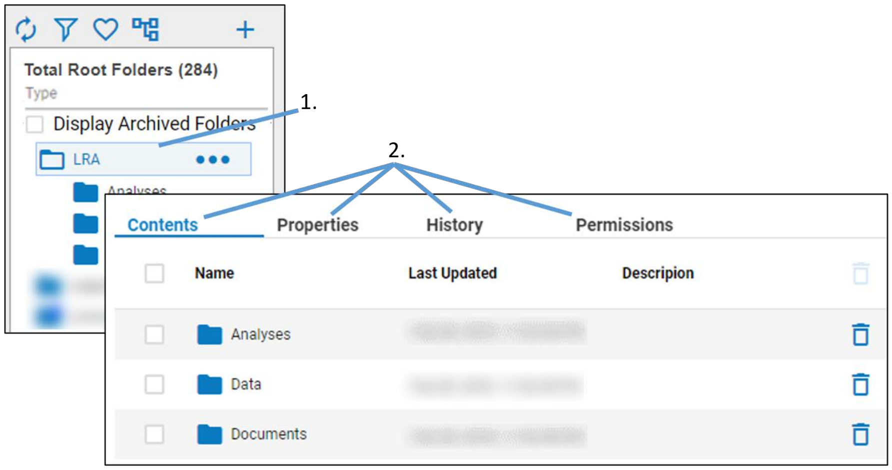


Folder properties are set when adding or editing a folder. (See “Add a top-level folder” and “Edit properties of a folder”.) They are used when setting up permission rules to identify the people who can access the folder and what they can do with the information in the folder. (See “Manage group rules”.)

Note: *Two additional folder types have been designed to help PKS users move between PKS and Integral by keeping the same folder structure as PKS: Legacy Study and Legacy Library. If you have the legacy PKS plugin, you can continue to use it to update data and scenarios. Any changes made through the PKS plugin will be synced with the information in Integral. However, the reverse situation is not true. Change made through Integral will not be synced to PKS.*

PKS scenarios can be opened in Phoenix through the Integral plugin by going to the corresponding project and loading the desired scenario. Phoenix will open the scenario as a project. Note that a new version of the scenario cannot be saved, but it can be saved as a new project in Integral. (Right-click the scenario in the Object Browser and select **Save to New Project in Integral***.)*

View information about a folder



1. Select the folder in the list on the left.
2. Click one of the tabs on the right:

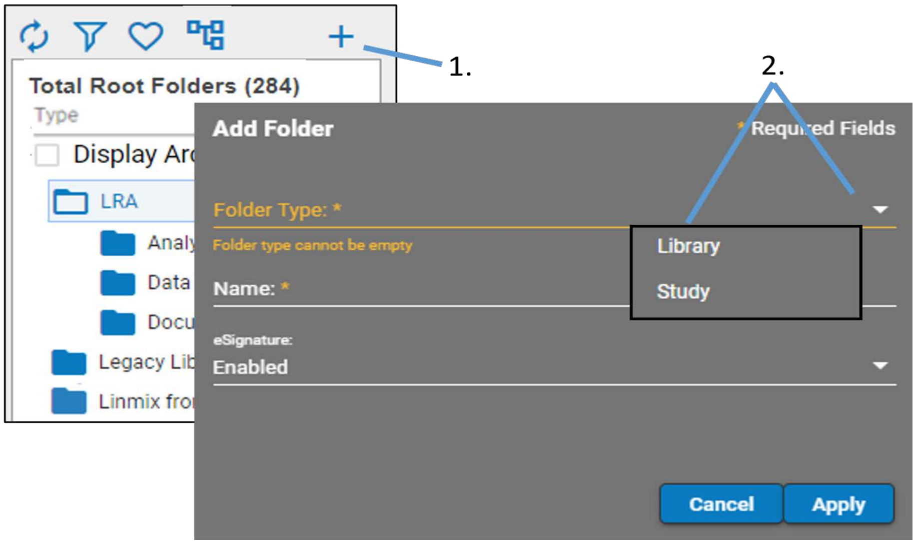
   Content: Lists the sub-folders and files within the selected folder, the date the folder was last updated and any description that is associated with the folder.

   Properties: Shows the file property values for the selected file. See "Properties Tab" for more details.

   History: Shows details about changes made to the selected file. See "History tab" for more details.

   Permissions: Lists permissions of the selected file. See "Edit a user in the system data-base" for more information on permissions.

Add a top-level folder

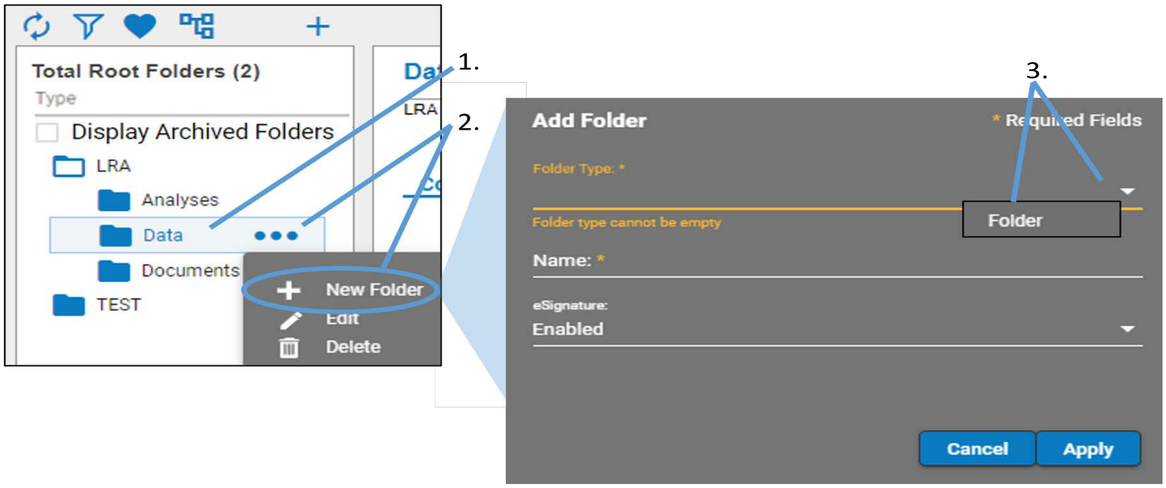


1. Select .
2. In the *Add Folder* pop-up, select a type from the **Folder Type** drop-down list.

   The types listed are defined by the Administrator (see “Folder Types” for more information).
3. Enter a name for the new folder.
4. Select whether the new root folder will require eSignatures to make updates (**Enabled**) or not require eSignatures (**Disabled**).
5. Depending on the selected type, other options for entering information may appear in the pop-up.

   Refer to “Predefined Property Types” for a list of predefined properties by folder type.
6. When finished, click **Apply**.

Add a sub-folder

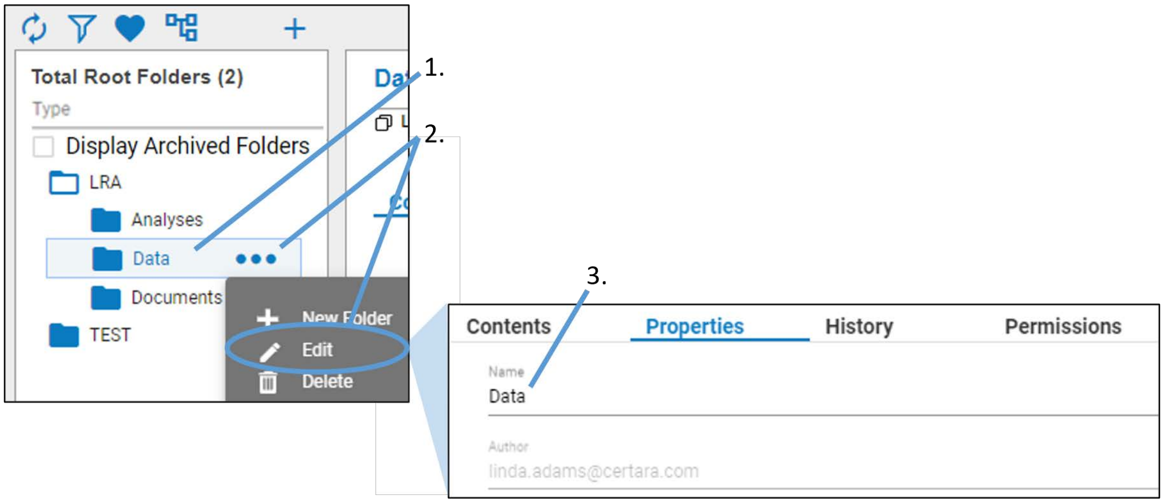


1. Select an existing folder in the browser.
2. Click ••• and select **New Folder** from the pop-up menu.
3. In the *Add Folder* pop-up, select a type from the **Folder Type** drop-down list.

   Folder types are defined by the System Administrator (see “Folder Types”).
4. Enter the name for the folder.
5. Select whether the new folder will require eSignatures to make updates (**Enabled**) or not require eSignatures (**Disabled**).
6. Depending on the selected type, other options for entering information may appear in the pop-up.

   Refer to “Predefined Property Types” for a list of predefined properties by folder type.
7. For some Folder Types, a **Description** field is available for entering information about the new folder.
8. When finished, click **Apply**.

Edit properties of a folder



1. Select an existing folder in the browser.
2. Click ••• and select **Edit** from the pop-up menu.
3. In Properties tab, edit the name and/or other folder properties.

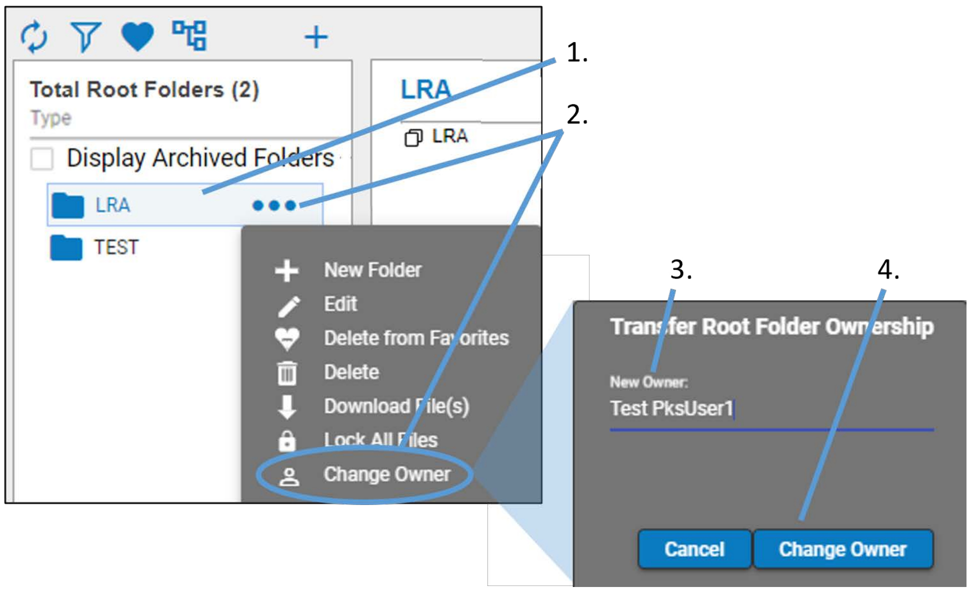
   Information that cannot be modified is grayed out.
4. When finished, click **Apply**.
5. Because you are making a change to the contents, an electronic signature is required.

Note: *Some properties of system folders are not editable.*

Only the owner can change the name of a root folder.

Transfer ownership of root folder

Only a user with an Administrator license or the current owner can change the owner of a root folder. Once the change is completed, the previous owner will lose Security Admin permission for that folder.

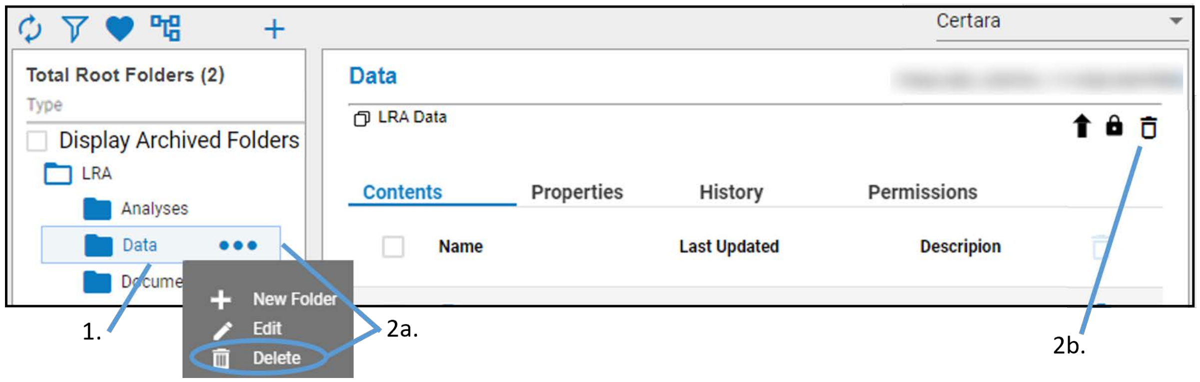


1. Select an existing root folder in the browser.
2. Click ••• and select **Change Owner** from the pop-up menu.
3. In dialog, select the name of the new owner from the list of available users.

   Only users with Security Admin permission are listed.
4. Click **Change Owner**.
5. Once the owner is changed, refresh the effective permissions by changing and resetting a permission (e.g., turn a permission on and then off again).

Delete one or more folders

The action described here is a soft deletion of the folder. It does not permanently delete the folder from the database.



1. Select the folder to be deleted in the browser.
2. Click ●●● and select **Delete** from the pop-up menu.

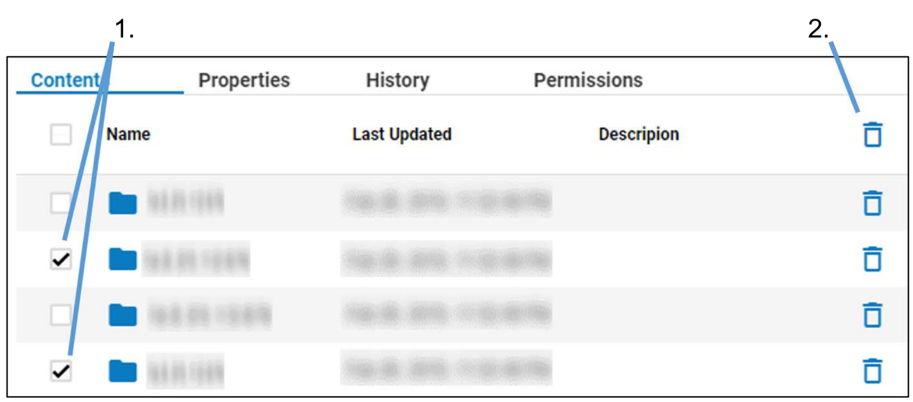
   Or

   In the panel, select in the toolbar.

   Or

   In the Contents tab for the ***parent*** folder, click to the right of the folder to be deleted.
3. In the *Delete* pop-up, click **OK** to confirm the folder deletion.

To delete multiple folders:



1. In the Contents tab for the ***parent*** folder, check the boxes in front of the folders to be deleted.

   Check the box in the column header to check all of the boxes.
2. Click in the column header.
3. In the *Delete* pop-up, click **OK** to confirm the folder deletion.
4. Because you are making a change to the contents, an electronic signature is required.

Load a prior state of a folder

A “normal” folder is one where each item it contains is treated independently. That is, each item is versioned independently. A savepoint represents the state of a folder at a point in time, where the state is the collection of file revisions that are currently active in that folder and all children, recursively. Basically, a savepoint is a “snapshot of the analysis at a point in time.

The entire contents of a savepoint enabled folder is treated as a single entity. Any versioning occurs at the folder level.

Saving a project from Phoenix to Integral automatically creates a savepoint to record the state of the project.

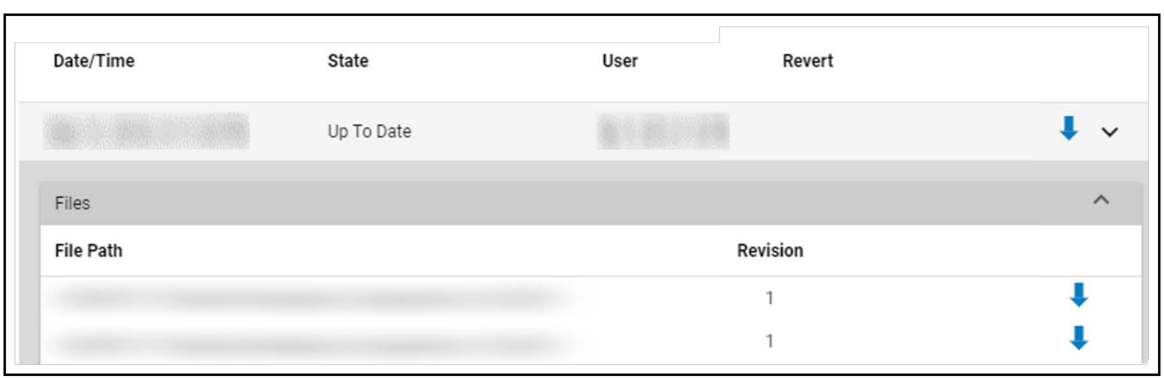
If two users are simultaneously working on the same version of a savepoint, the version that is saved later is branched off and saved as a new file. The history of the branched version will show the origin of the savepoint.

1. With the savepoint folder selected, go to the **History** tab.
2. Expand the **Save Points** section of the page.
3. Expand one of the savepoints.

There are two categories of information stored with a savepoint: file and dependency information.

Files

Expanding **Files** shows the full path to each file saved in that savepoint and its revision number.

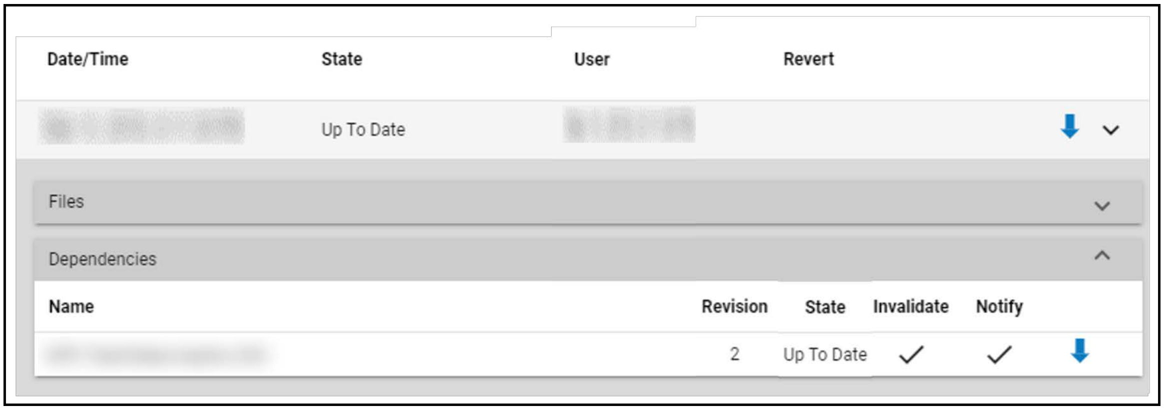


Click next to a file to download the state of the file as it was when the savepoint was created.

Use the popup at the bottom of the browser window to specify what is to be done with the file.

Dependencies

Expanding **Dependencies** shows the full path to each identified by Phoenix as a dependency when the savepoint was created, its revision number, status (indicates if the file has been updated since the savepoint was created, and notification settings.



Savepoint dependencies are saved to track dependencies on objects that exist in Integral. A very common dependency is when analysis output is dependent on the data collected as part of a study.

Integral is configured by default to store study data files in the “Data” folder. In Phoenix, when a new project is created from the Integral plug-in, the user can select multiple source files to be included in the project. Phoenix retains the source of these objects in Object Browser.

When saving projects back to Integral from Phoenix, Phoenix will determine what dependencies to save with the project by locating all objects in the project that have an External source that is an Integral object.

Levels of dependency that can be set when saving to Integral include:

Invalidate and **Notify**: New version of referenced object is created or object is deleted, dependent projects are marked as out-of-date (invalidated), and notifications are created.

Invalidate: New version of referenced object is created or object is deleted, dependent projects are marked as out-of-date (invalidated).

Notify: Do not invalidate projects but create notification for any user with access to projects.

Neither: Dependency references particular revision of file and user is not concerned if new versions are created. Notifications are not created and the project is not marked as out-of-date.

Click  next to a file to download the state of the file as it was when the savepoint was created.

When a dependency is broken (e.g., the dependency file is updated or deleted), a notification is sent to the user who created that dependency. Additionally, the savepoint folder and all parent folders up the tree will change to red (out-of-date). Once the broken dependency is resolved, the savepoint is updated and saved back to Integral, then the savepoint folder and parent folders change to blue.

Files

View information about a file

View and edit contents of a file

Edit properties of a file

Change status of a file

Delete a file

Upload file(s) to a folder

Upload a file revision

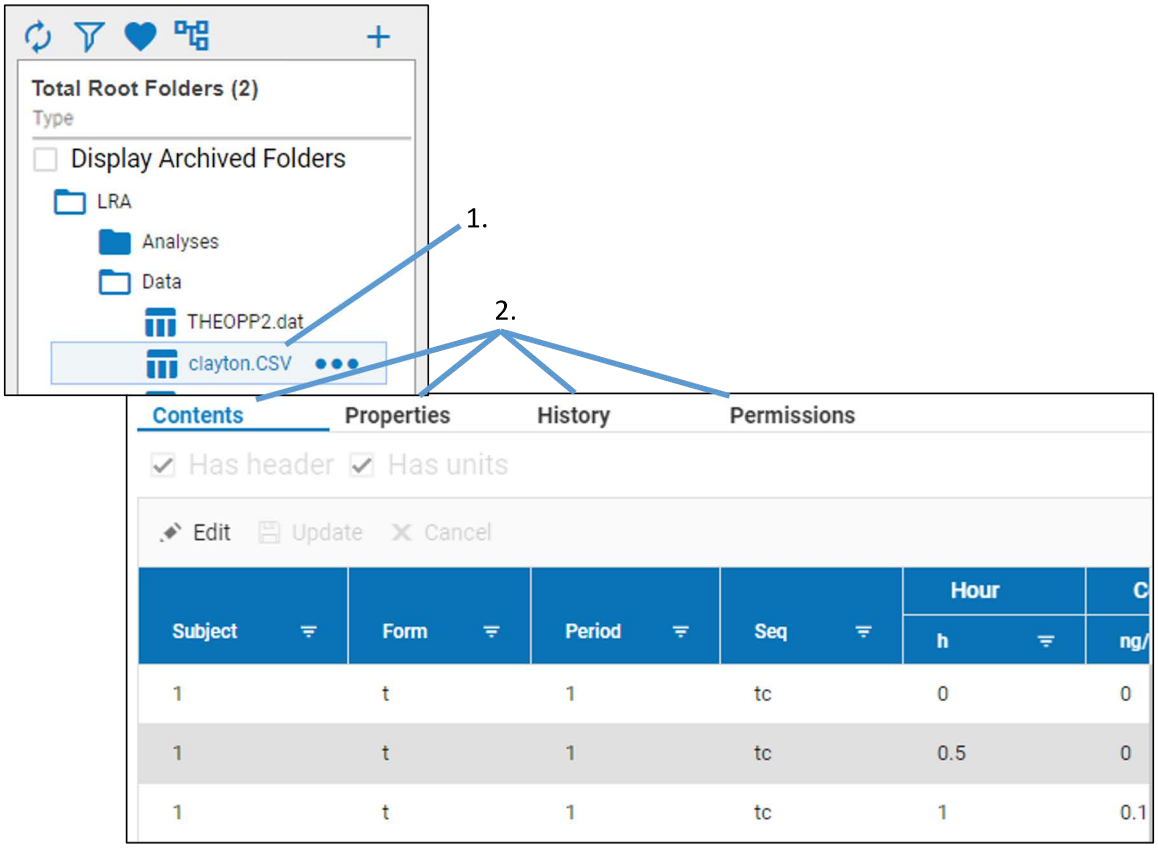
Download a file

Compare files

See also:

- File Types
- Copy and Link
- Blind and Unblind Folders and Files
- Lock and Unlock Files

View information about a file



1. Select the file in the list on the left.
2. Click one of the tabs on the right:

   Content: If the selected file is a csv, dat, or other format recognized by Integral, the content of the file is displayed and, depending on the file format, may be edited. See “View and edit contents of a file” for more details.

   Properties: Shows the file property values for the selected file. See “Properties Tab” for more details.

   History: Shows details about changes made to the selected file. See “History tab” for more details.

   Permissions: Lists permissions of the selected file. See “Edit a user in the system database” for more permission details.

View and edit contents of a file

When a file is editable, a tooltip becomes available in the Contents tab explaining that the data can be modified by double clicking the cell.

Text files

1. Select the text file.
2. Go to the **Contents** tab.
3. Edit the displayed text.
4. Click **Apply**.

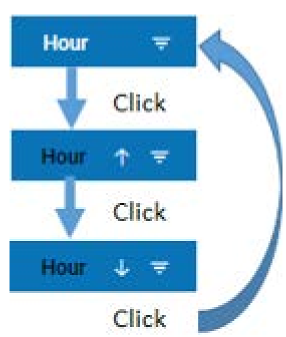
Because you are making a change to the contents, an electronic signature is required.

The modified file is saved as a new revision, as can be seen in the History tab after refreshing the display.

.csv or .dat files

1. Select the file.
2. Go to the **Contents** tab.
3. Use the navigation tools below the table to page through the data, go to a particular page, or to set the number of items to display per page.

Sorting the columns can be accomplished by simply clicking on the column header. Clicking the header multiple times will toggle between ascending, descending, and unsorted. A sort direction indicator is shown in the header. When a column is sorted, the column header label is black.

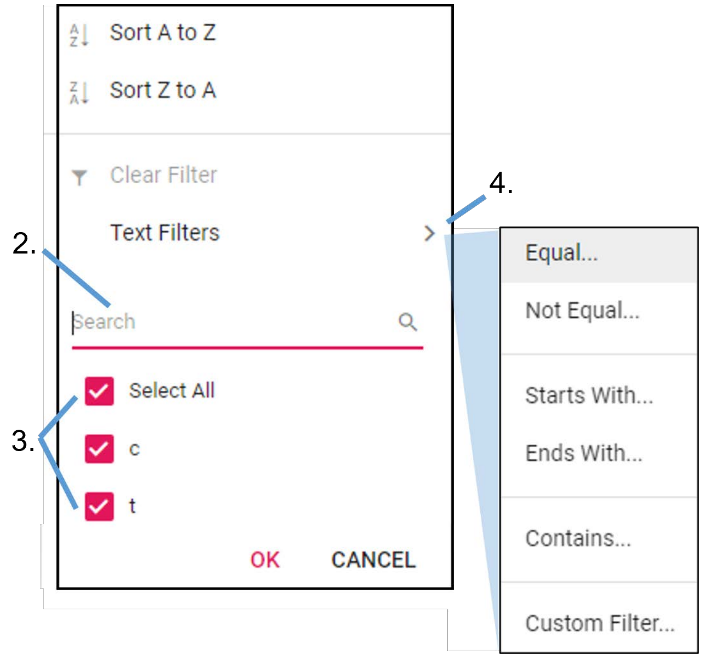


Alternatively, click in the column header and select **Sort A to Z** or **Sort Z to A** in the popup.

Filtering a worksheet is done through the icon in the column header.

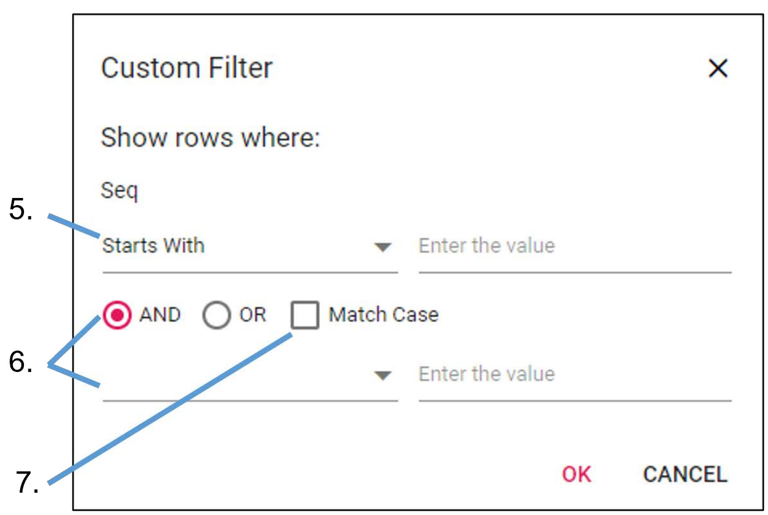
1. In the header of the column to be filtered, click .

   The popup lists all values found in that column.



2. To search for values, begin typing the text in the **Search** field and the list in the popup will automatically be filtered as you type.
3. Use the check boxes in the list to control which rows are shown (checked boxes) or hidden (unchecked boxes) in the result worksheet. Use the **(Select All)** check box to check or uncheck all items in the list at the same time.
4. To define a filter criteria, click "**>**" next to **Text Filters** and select the operator.

   When using text filters, all data in the grid are handled as text, even numeric values.
5. In the dialog, use the dropdown menu to change the operator and enter the value(s) to set the criteria.



6. To include a second criteria, select the **AND** or **OR** radio button and use the second dropdown menu and field to define the second criteria.
7. Check the **Match Case** box to make the criteria case sensitive.

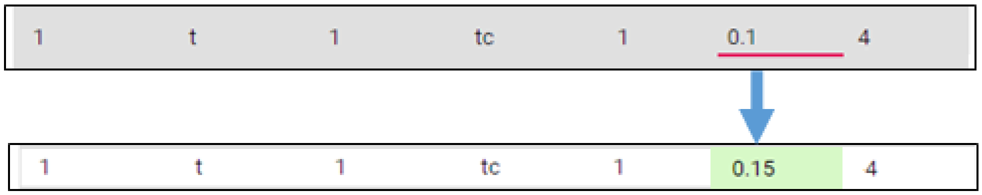
Editing cell content is done directly in the displayed table.

8. To edit cell contents, double-click a cell.

   A red underline displays to indicate the cell being edited.

9. After editing, press the **Enter** key or click outside of the edited cell.

   The edited cell's background changes to light green to indicate an unsaved change.



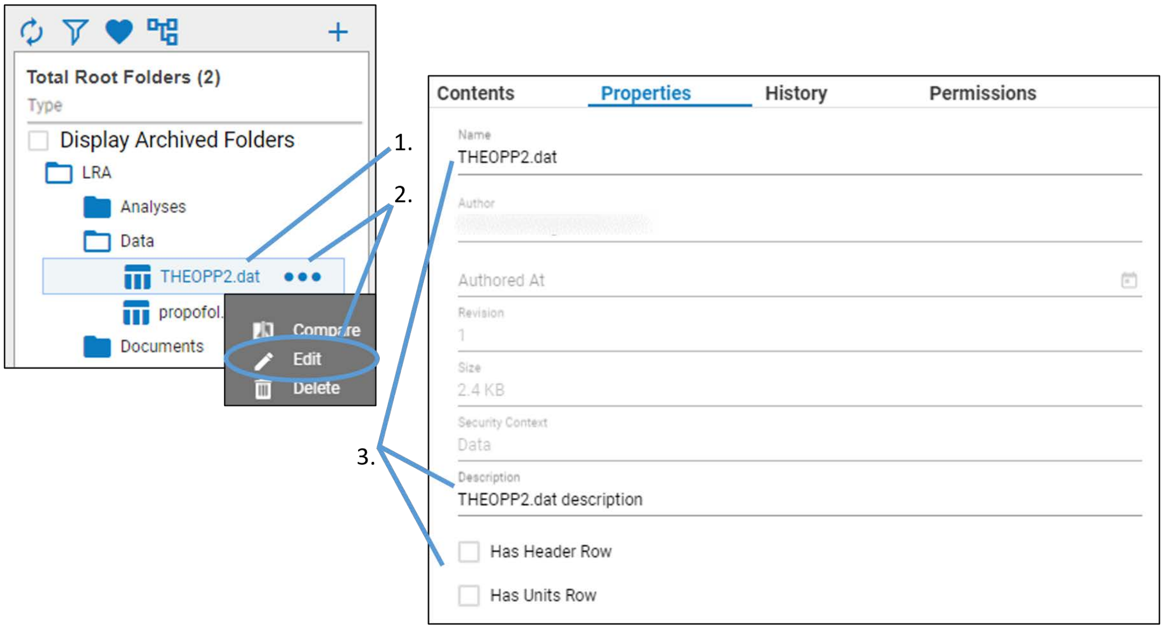
10. Press the **Update** button above the table and press **OK** to confirm.

Because you are making a change to the contents, an electronic signature is required.

The modified file is saved as a new revision, as can be seen in the History tab after refreshing the display.

Note: *For locked files, even though it is possible to edit values displayed in the Contents tab, click* **Update** *and submit an electronic signature, the contents of the file stored in Integral will not be updated.*

Edit properties of a file



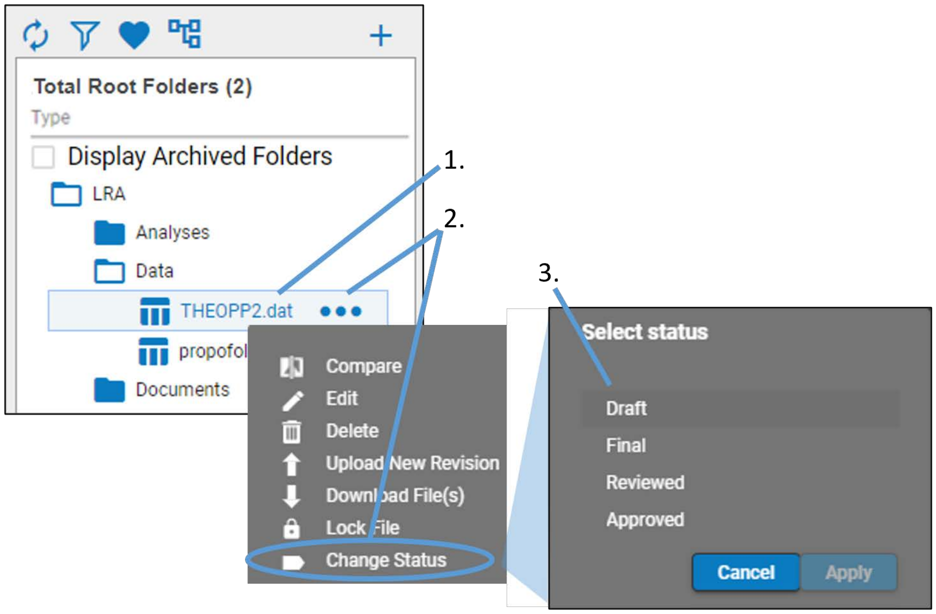
1. Select a file.
2. Click ••• and select **Edit** from the pop-up menu.

   Or

   In the panel, select in the toolbar.
3. In Properties tab, edit the **Name**, **Description**, and/or **Status** of the file. Depending on the type of file, **Has Header Row** and **Has Units Row** settings may be available. For CDISC files, you can change the **CDISC Model**.
4. When finished, click **Apply**.

Change status of a file

The status of a savepoint-enabled folder or any file located outside of a savepoint-enabled folder can be changed.

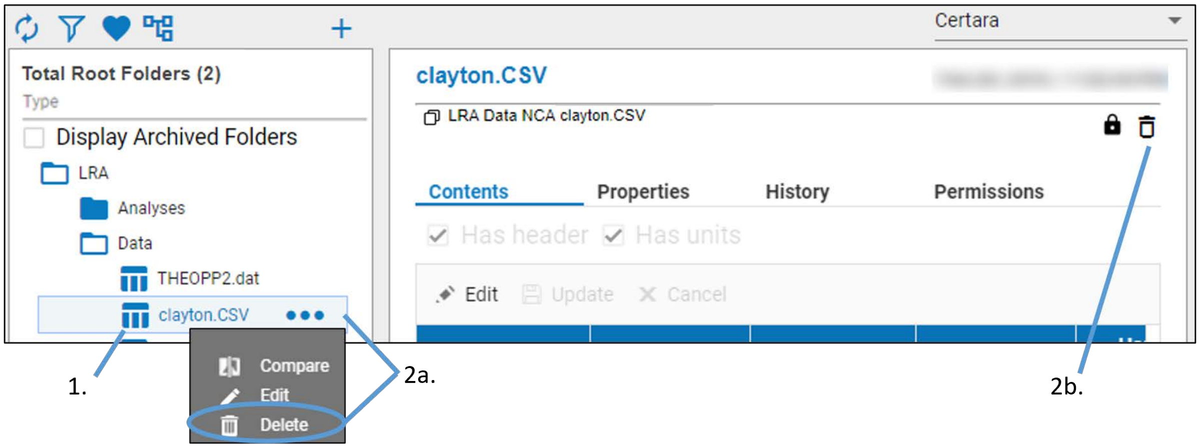


1. Select an existing savepoint-enabled folder or a file that is outside of a savepoint-enabled folder in the browser.
2. Click ••• and select **Change Status** from the pop-up menu.
3. In dialog, select the desired status.
4. Click **Apply**.

The list of available status values can be edited by an Administrator, see “To modify a property” for details.

Delete a file

The action described here is a soft deletion of the file. It does not permanently delete the file from the database.



1. Select the file to be deleted.

   Click and select **Delete** from the pop-up menu.

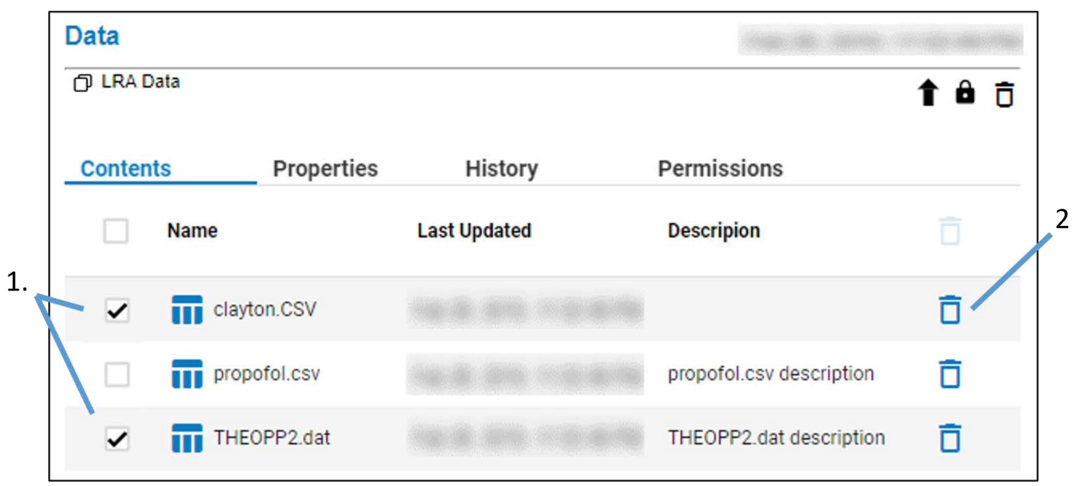
   Or

   In the panel, select in the toolbar.

   Or

   In the Contents tab for the ***folder***, click to the right of the file to be deleted.
2. In the *Delete* pop-up, click **OK** to confirm the file deletion.

To delete multiple files:



1. In the Contents tab for the ***folder***, check the boxes in front of the files to be deleted.

   Check the box in the column header to check all of the boxes.
2. Click in the column header.

3. In the *Delete* pop-up, click **OK** to confirm the deletion.

Because you are making a change to the contents, an electronic signature is required.

The deleted file can be recovered through the “History tab”.

Upload file(s) to a folder

Up to 5 GB can be uploaded to Integral at one time. Note that the filename cannot exceed 255 characters and the full path (including the filename) cannot exceed 4096 characters).

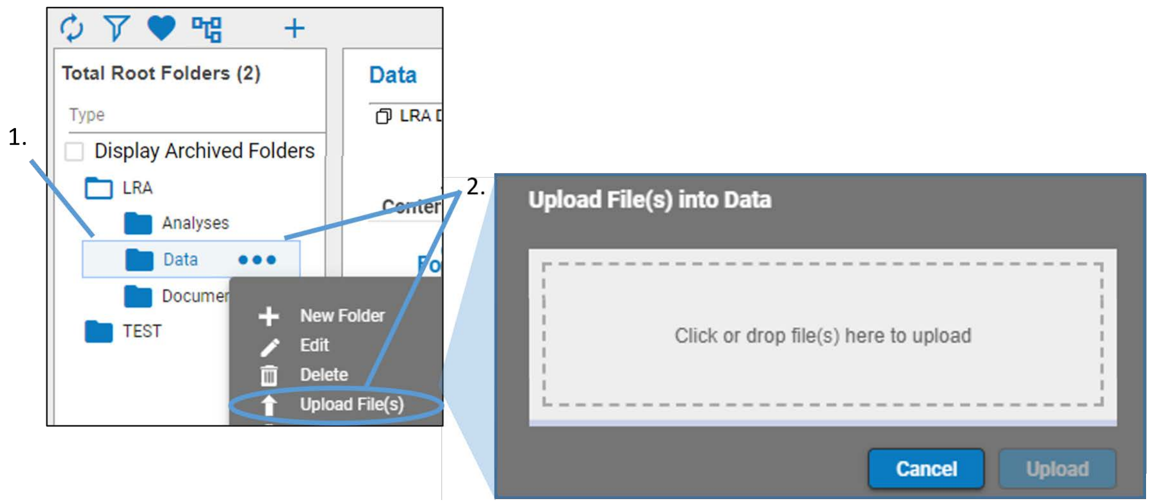
Drag file(s) from the Explorer window to the Contents tab of the folder.

Or

1. With the desired folder selected, click in the right panel toolbar.

   This icon is displayed only if you have permission to upload files to the folder.
2. In the Explorer window, select the file(s) to be uploaded.

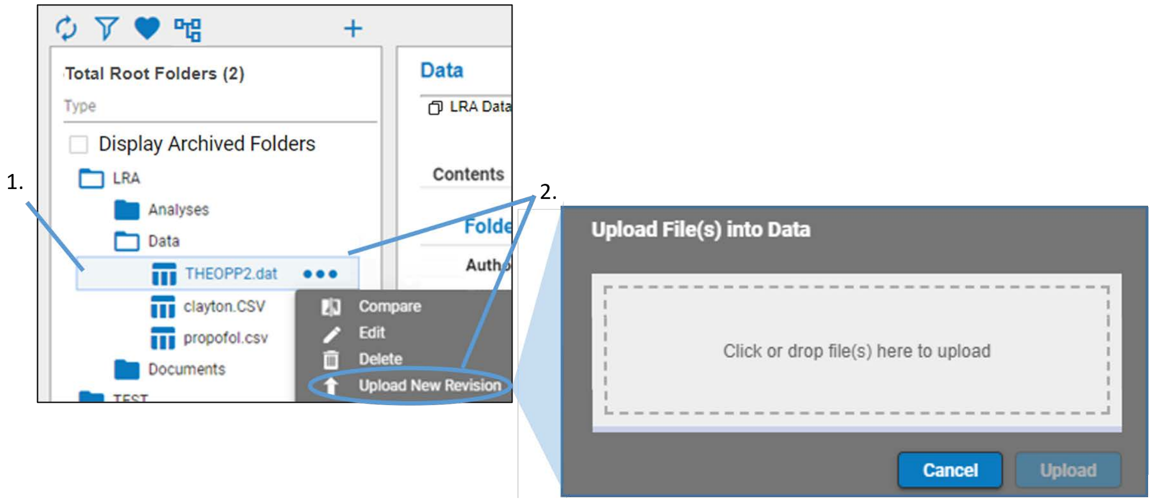
Or



1. Select the folder in which to add the file(s).
2. Click ••• and select **Upload file(s** from the pop-up menu.
3. In the *Upload File(s)* dialog drag and drop the files into the central area or click the central area to display the *Open* dialog to browse and select the files.

Because you are making a change to the contents, an electronic signature is required.

Upload a file revision



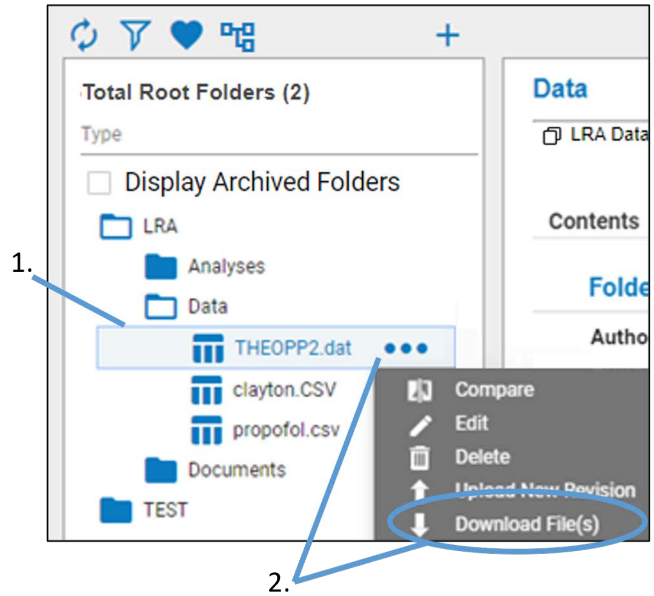
1. Select a file.
2. Click ••• and select **Upload a New Revision** from the pop-up menu.
3. In the dialog, drag the files from an Explorer window to the central area or click in the central area to display the *Open* dialog to browse and select the files.

The file being uploaded does not have to have the same filename as the file you are uploading to. When the names are different, a confirmation is required and then the contents of the old file are replaced with the contents in the new file, but the file name remains unchanged.

Because you are making a change to the contents, an electronic signature is required.

Download a file

Up to 5 GB can be downloaded from Integral at one time.



1. Select the file to download.
2. Click ••• and select **Download file(s)** from the pop-up menu.

To download multiple files in a folder:

1. With the folder containing the files selected, check the boxes of the files to download in the panel on the right.
2. Click ⬇ in the panel toolbar.

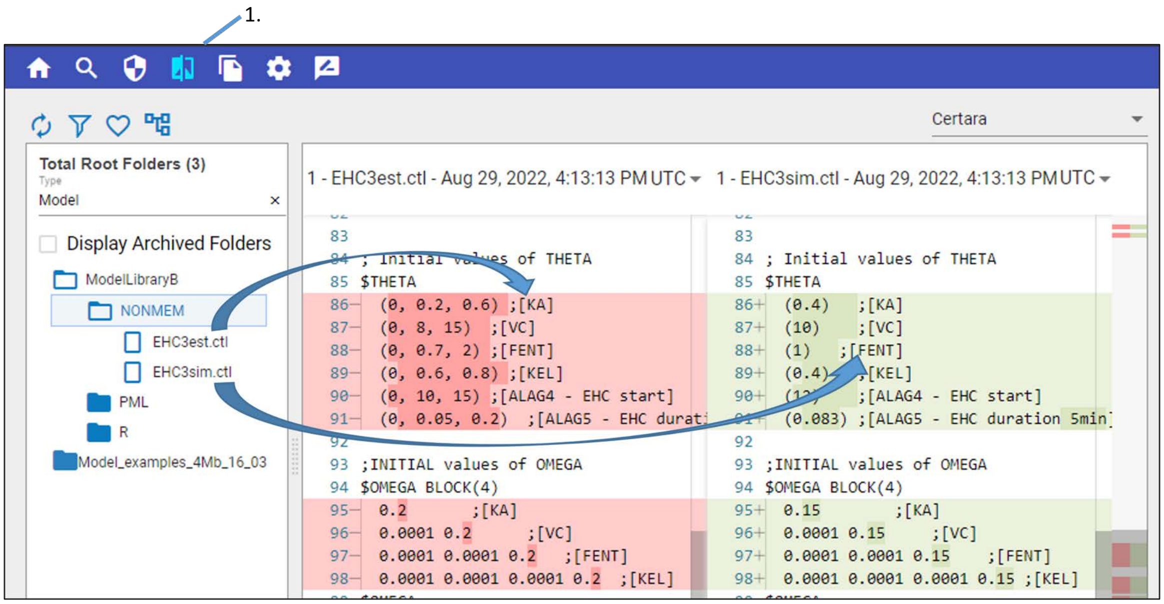
   This icon is displayed only if you have permission to download items in the folder.

Note: *It can take time to create the zip file, when the file is ready, you will see a pop-up at the bottom of the web browser window.*

3. In the browser pop-up, specify what to do with the zip file of data.

Compare files

Note: *Comparison of files is restricted to text files only.*



1. Click  in the main toolbar.
2. In the browser on the left, click to select one of the files to compare.

   The contents of the file appear in both fields on the right.
3. Drag and drop the second file to compare from the browser to the comparison area.

   The second file's contents are loaded into the right comparison field.
4. To change the file being compared, drag and drop another file.

   The contents of the right comparison field are updated. Anytime another file is dropped in the comparison area, it is only the right field that is updated.
5. To change the contents appear in the left field, repeat step 2.

   Once again, the content of the selected file is loaded into both comparison fields. Continue by dragging the file to compare as in step 3.

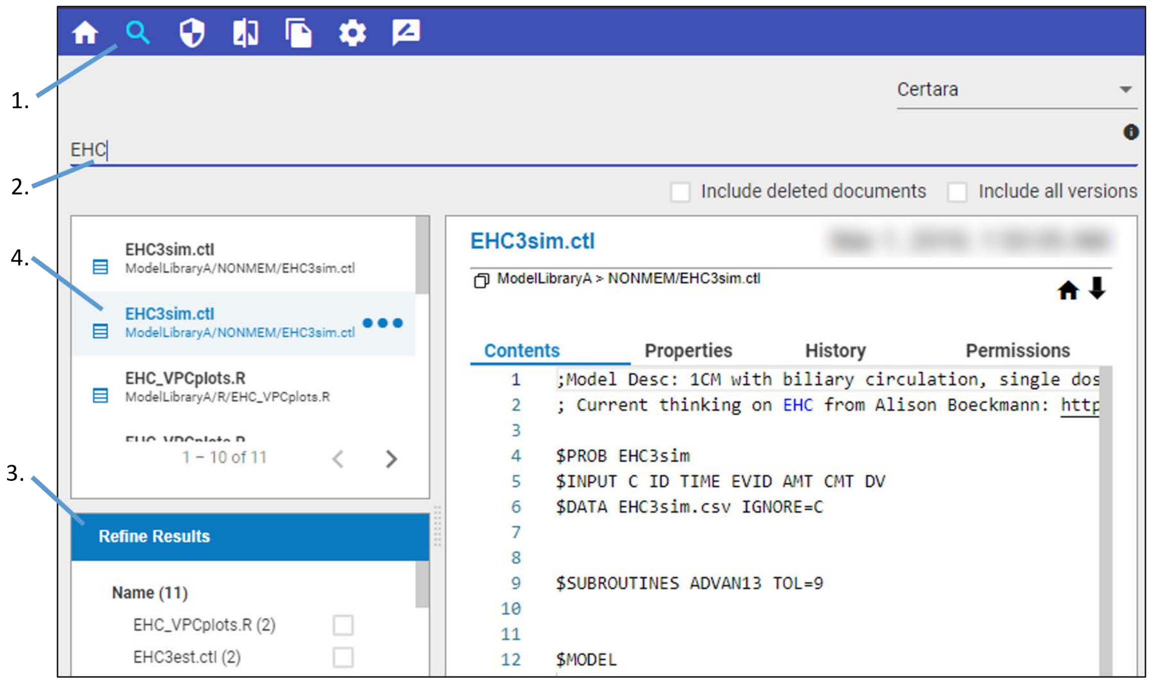
Depending on the size of the files, it may take some time to display the comparison. Scrolling is synchronized vertically between the files. Differences between the files are highlighted in red and green. A small area on the far right, next to the second file's scrollbar provides a visual indicator of where the differences are located within the files so you can scroll directly to those lines.

Search

When using the Search functionality, the results are always files, not folders. A search will return files that:

– Have a property matching the search criteria
– Have content that contains the search criteria (text files or text datasets)
– Have inherited properties matching the criteria (all files inherit properties from the parent (and their parents, back to the root)).

(In contrast, when using the Filter functionality, you are filtering root folders.)



1. On the Integral main window, click in the main toolbar.
2. In the Search page, type all or part of the name (using wildcards) to search for and press the `Enter` key. (When entering a text string, such as a URL, use double quotes.)

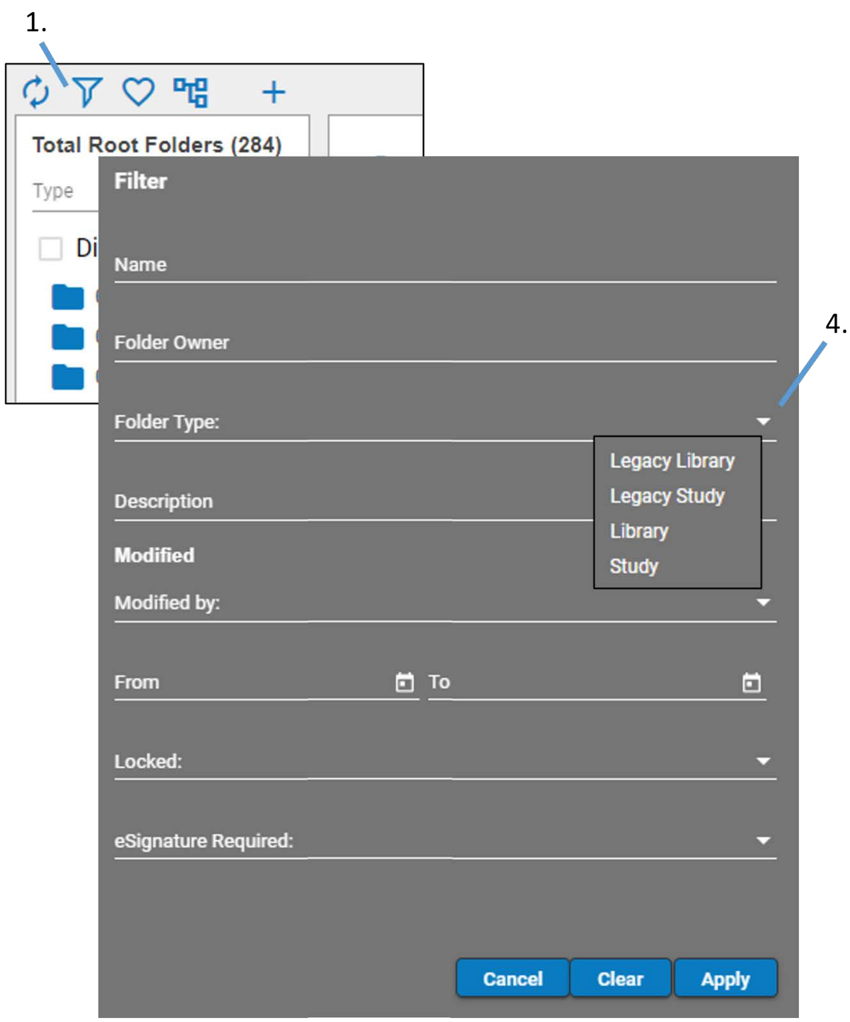
   For additional assistance with syntax, click the information button at the end of the query field.

   Additional filter options to **Include deleted documents** and to **Include all versions** can be specified by checking the corresponding box(es).
3. When the results are returned, you can optionally use the Refine Results list at the bottom left to select categories that were found to contain one or more matching items.
4. Select the item in the results list to display the contents in the panel on the right.

Notice that, on the far right side, there is a thumbnail of the overall file contents to help you track where the lines you are currently viewing are located in the file.

Filter the Browser List

Many functions in the Integral Web client require selection from a list in the Integral browser. To locate specific items, the user may filter the list using the filter icon at the top of these windows.



1. Above the Integral browser, select the filter icon .
2. In the *Filter* pop-up, specify a name for the filter.
3. Enter the name or partial name of a user to view root folders owned by that person.

   As you type, a list of matches is provided from which to select the desired name.
4. Select a type of root folder using the **Folder Type** drop-down list.
5. Filter folders by property values that are specific to the selected folder type.

Note: *Pop-up menus only allow selection of a single item from the menu. If there are check boxes in the pop-up, you may check multiple items. Typed fields are not case-sensitive and accept the wildcard "*".*

6. Filter folders based on their descriptions by entering keywords/phrases in the **Description** field.

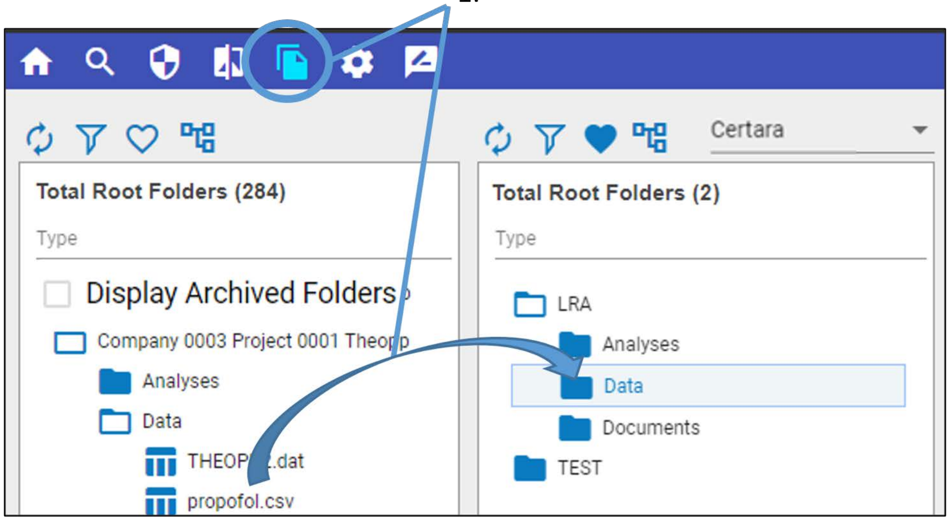
   An exact match is applied to the text entered in this field. Only folders that have the exact text, and only that text, as a description are returned. Therefore, it is important to add an asterisk as a wildcard before and/or after the text to return items that contain the entered text as part of their description.
7. List folders that have been modified by a particular person using the **Modified by** menu.
8. List folders that have been changed during a time period by entering dates in the **From** and **To** fields (click on the calendar icon to use a calendar pop-up).
9. Use the **Locked** menu to list only folders that are locked (**True**) or unlocked (**False**).
10. Use the **eSignature Required** menu to list only folders that require an eSignature (**True**) or do not require an eSignature (**False**).
11. When finished, click **Apply**.

Whenever a filter is in effect in the browser, the icon appears as .

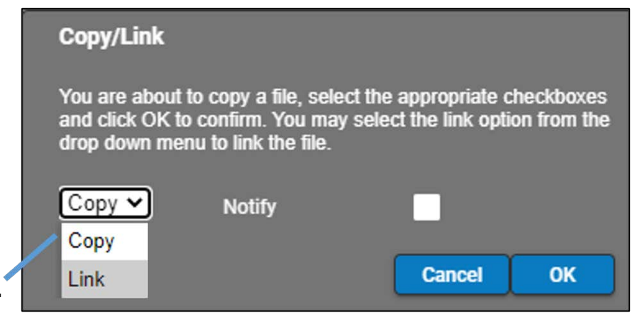
Use the **Clear** button to remove all selection or entries from the **Filter** pop-up.

Copy and Link

1.



1. Click in the main toolbar, select the folder/file to copy in the list on the left and dragging it to the folder where the copy is to be saved in the right panel.



2.

2. In the *Copy/Link* pop-up, select **Link** from the menu to create a link between the original and the copied file or select **Copy** to create a separate copy of the item.
3. For folders, check the **Include all subfolders** box to link/copy all subfolders and their content as well.
4. When linking items, check the **Auto Update** box to automatically update the destination file(s) if the ***linked*** source file(s) are updated.
5. When copying items, check the **Notify** box to be notified when the source file changes.

   (Notifications are automatically sent for linked items when the source file changes.)
6. Because you are making a change to the contents, an electronic signature is required for copying and linking.

When linked, the icon for the linked file changes to and the menu options available when clicking include **Get Latest**, to update the linked item with any changes that have been made to the source, and **Unlink**, to remove the connection.

Note: *When a file is copied or linked to a folder, the copy or linked version will inherit the permissions of the folder to which it has been copied or linked. It does not retain the permissions of its source folder.*

To unlink a file

1. In the Copy/Link panel, click  for the file to unlink.
2. Select **Unlink** in the pop-up menu.
3. In the **Unlink** pop-up, click **OK** to remove the file from the location.

   Or

   Check the **Keep as a copy** box and click **OK** to remove the link, but keep the copied file in the location.

Unlinking requires an electronic signature.

Blind and Unblind Folders and Files

Note: *If you do not see the icon or menu options for blinding, you may not have the necessary permissions. Check with your Administrator.*

To blind a single file

1. Select the file to blind in the browser.
2. Click and select **Blind File** from the pop-up menu.

   Or

   Click in the panel toolbar.
3. An electronic signature is required for this action.

Once the file is blinded, the Content tab is no longer available for viewing and the **Blinded** property in the Properties tab is set to **True**. In the browser, a blinded folder or file will have .

To blind all files in a folder

1. Select the folder in the browser.
2. Click and select **Blind All Files** from the pop-up menu.
3. An electronic signature is required for this action.

To unblind files

1. Use the same instructions for blinding, but select **Unblind File** or **Unblind All Files** from the pop-up menu.

   Or

   Click in the panel toolbar.
2. An electronic signature is required for this action.

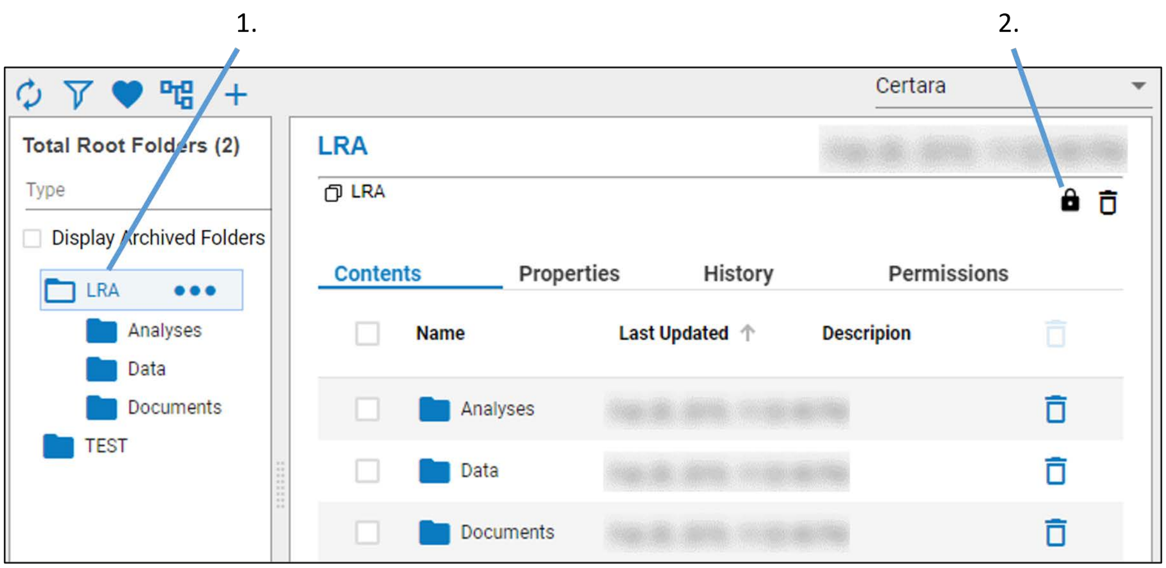
Once the folder/file is unblinded, the Content tab becomes available for viewing and the **Blinded** property in the Properties tab is set to **False**.

Multiple folders/files can be unblinded using the same process as described above for blinding multiple folders/files.

Lock and Unlock Files

Note: *Only a user assigned the license of Archivist will have access to the unlock functionality. Files or folders within a savepoint folder cannot be locked.*

To lock files



1. Select the file or the folder containing the files to lock in the browser.
2. Click in the panel toolbar.

   Or

   Click and select **Lock File** (**Lock All Files**, if a folder is selected) from the pop-up menu.
3. An electronic signature is required for this action.

Once the file is locked, no changes can be made to the contents of the file and the **Locked** property in the Properties tab is set to **True**. In the browser, a locked folder or file will have next to the name. Use the **Display Archived Folders** checkbox to control whether locked folders are visible in the tree.

To unlock a file

Note: *Only a user assigned the license of Archivist will have access to the unlock functionality.*

1. Select the file to unlock in the browser
2. Click in the panel toolbar.

   Or

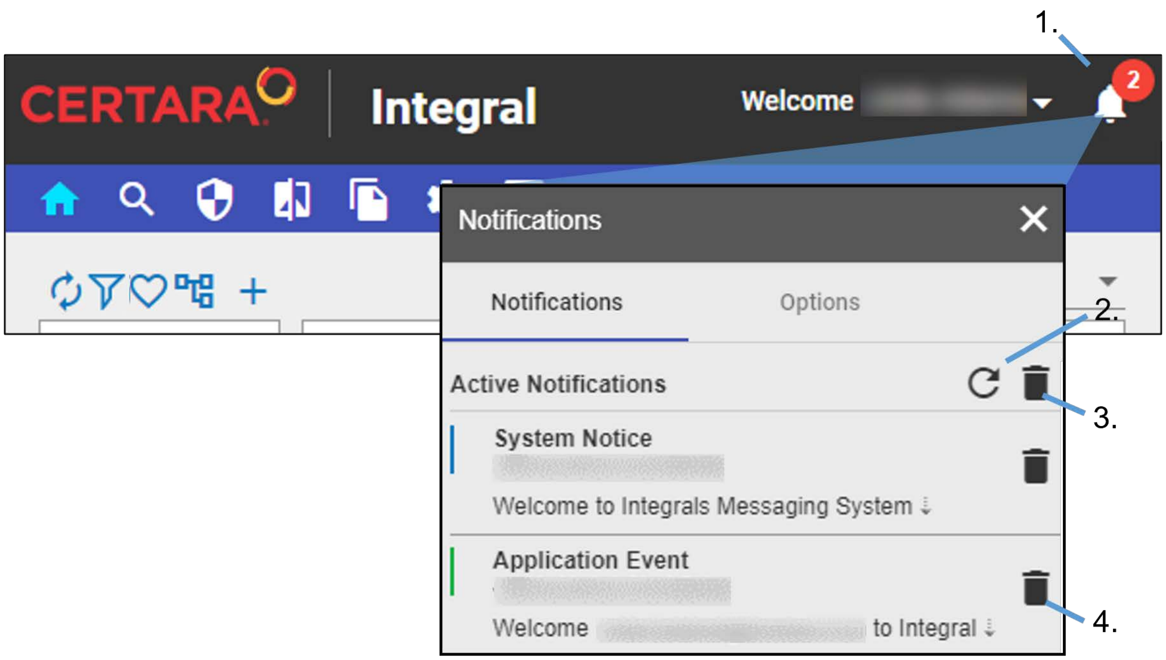
   Click and select **Unlock File** (**Unlock All Files**, if a folder is selected) from the pop-up menu.

3. An electronic signature is required for this action.

Once the file is unlocked, the contents of the file can be modified and the **Locked** property in the Properties tab is set to **False**.

Notifications

Integral has several types of notifications that can be sent to users: System Notices, Application Events, Application Errors, File Change Notice, and Application Warnings.



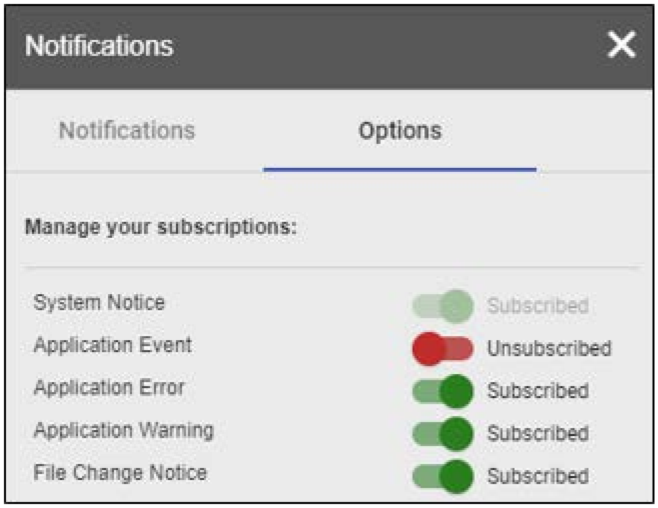
The Notifications icon in the banner will show the number of notifications received.

1. Click the icon to display the Notifications panel.

   The Notifications tab lists the notifications received. Each notification has a colored bar indicating the severity. red is critical, orange is important, yellow is normal, and green is low. The Options tab allows you to control subscription to different types of notifications.

   To view the details of the notice, click the title of the notification
2. Click the Refresh icon in the Notifications tab to reload the list of received notifications and include any new ones.
3. Click the Delete icon at the top of the list of notifications to delete all received notifications.
4. Click the Delete icon next to an individual notification to delete that specific one.

Subscribe/unsubscribe

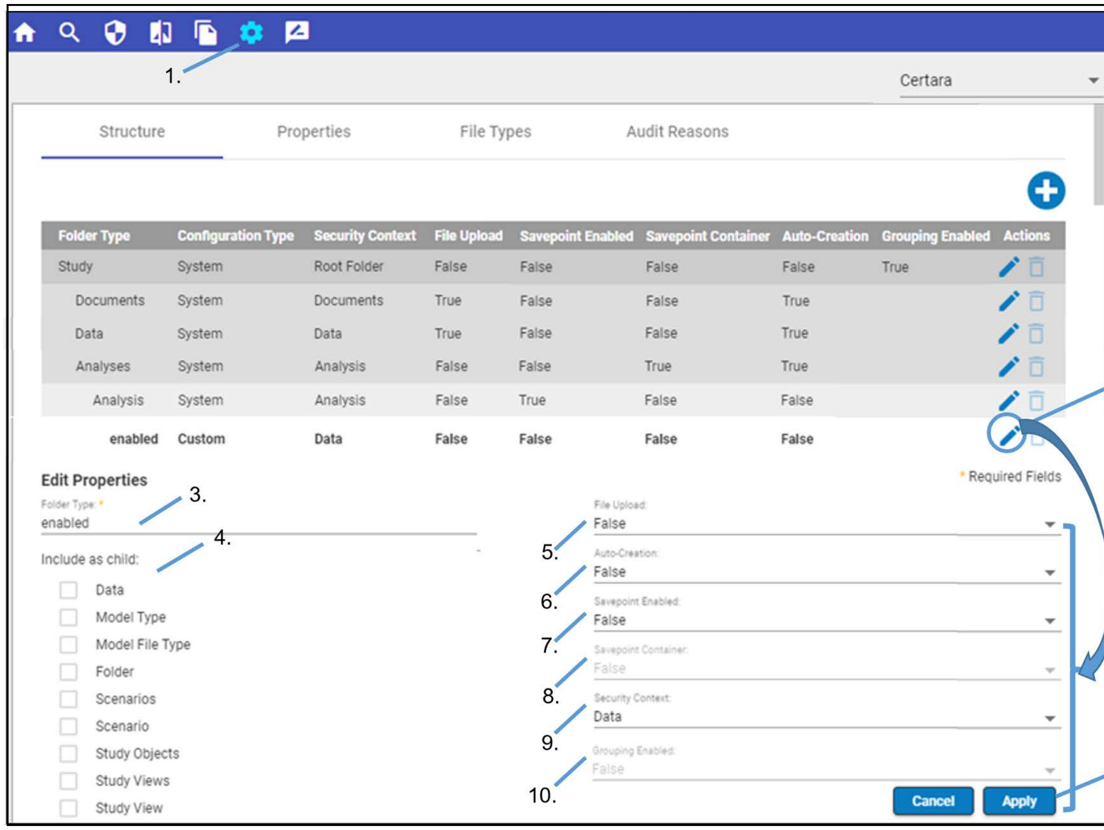


Click the slider of the subscription to change between Subscribed and Unsubscribed.

Folder Types

Integral has a number of predefined folder types. See “Predefined Folder Types”for information about these types.

To add a folder type



1. Click  in the main toolbar.
2. In the Structure tab, click .
3. In the *Add Folder Type* popup, enter a name for the new folder type.
4. Indicate if this folder type is a root folder (select **Yes**) or not (select **No**).

   Selecting **Yes** sets the **Security Context** to **Root Folder** and disables the selection of any **Parent** folder type. Selecting **No** removes **Root Folder** from the **Security Context** menu.
5. Check the boxes for all parent folder types (list on the left) in which the new type can be added.

   Check the boxes for all child folder types (list on the right) that can be added to a folder of this new type as child folders.
6. Toggle the **File Upload** menu to control if files can be uploaded into this folder type (**True**) or not (**False**).
7. Toggle the **Auto-Creation** menu to control if a folder of this new type is automatically created when a folder of the new type is added (**True**) or not (**False**).

8. Toggle the **Savepoint Enabled** menu to control if this folder and all its contents are to be saved as a savepoint when changes are made and uploaded (**True**) or not (**False**).
9. Toggle the **Savepoint Container** menu to control if savepoints can be created within this folder.

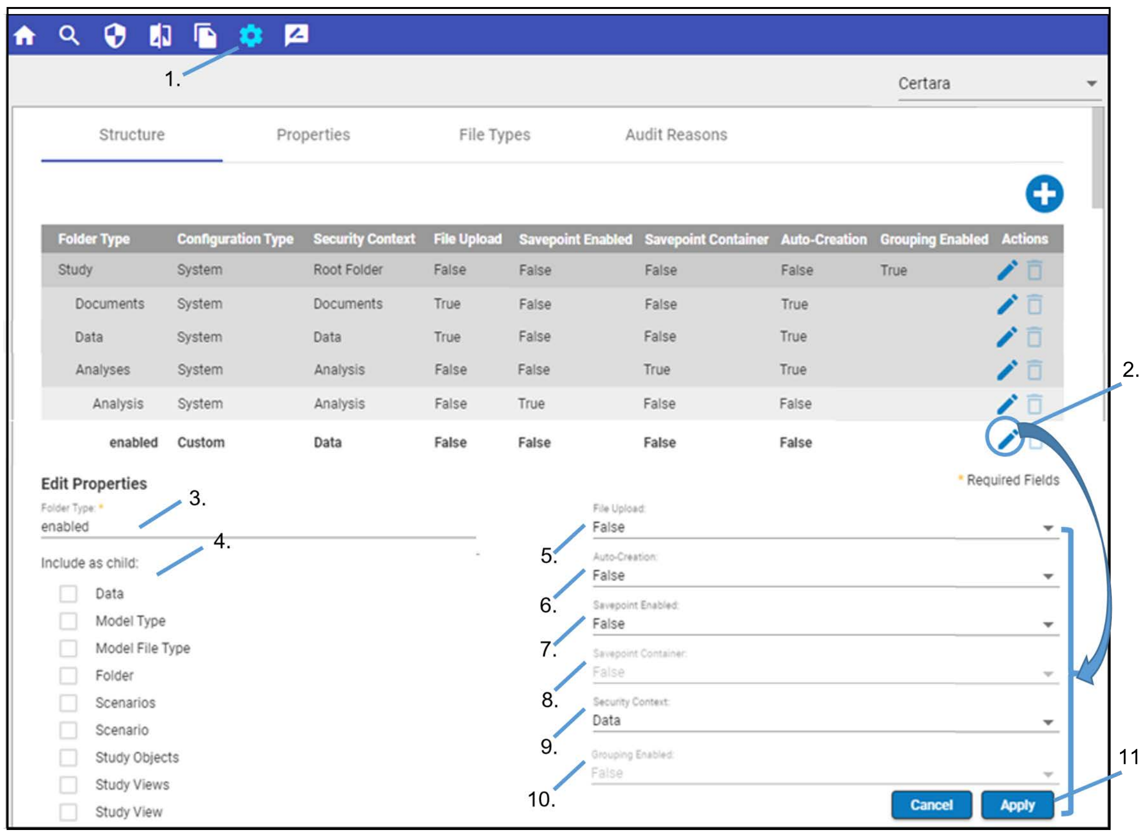
   When this option is set to **True**, the **File Upload** and **Savepoint Enabled** options will automatically be set to **False**.
10. Select a **Security Context** for the new folder type from the menu. Choose from **Root Folder**, **Data**, **Analysis**, or **Documents**.

    These categories are used when setting up permissions. (Refer to “Edit a user in the system database” and “Manage group rules” for more details on setting permissions.)

    Unlike the other contexts, if **Root Folder** is selected when the folder type is created, it cannot be changed to a different context later.
11. Toggle the **Grouping Enabled** menu to control if this folder type can be grouped by properties (**True**) or not (**False**).
12. Click **Apply**.

The new folder type is added to the table and has an entry in the Configuration column of Custom.

To modify a folder type



1. Click  in the main toolbar.

2. In the Structure tab, click next to the folder type to edit.
3. In the *Edit Properties* expanded section, modify the name by typing in the **Folder Type** field.
4. Check the boxes for all parent folder types in which the new type can be added.
5. Toggle the **File Upload** menu to control if the files can be uploaded into this folder type (**True**) or not (**False**).
6. Toggle the **Auto-Creation** menu to control if this folder type is automatically created when a parent-type folder (which was set when this folder type was created) is added (**True**) or not (**False**).
7. Toggle the **Savepoint Enabled** menu to control if this folder type is included in a save-point (**True**) or not (**False**).
8. Toggle the **Savepoint Container** menu to control if savepoints can be created within this folder type (**True**) or not (**False**).
9. Select a different **Security Context** for the folder type from the menu.

   The folder permissions will update to match the ones associated with the selected context.

   If **Root Folder** was selected when the folder type was created, this option cannot be changed.
10. Toggle the **Grouping Enabled** menu to control if this folder type can be grouped by properties (**True**) or not (**False**).
11. Click **Apply**.

To delete a folder type

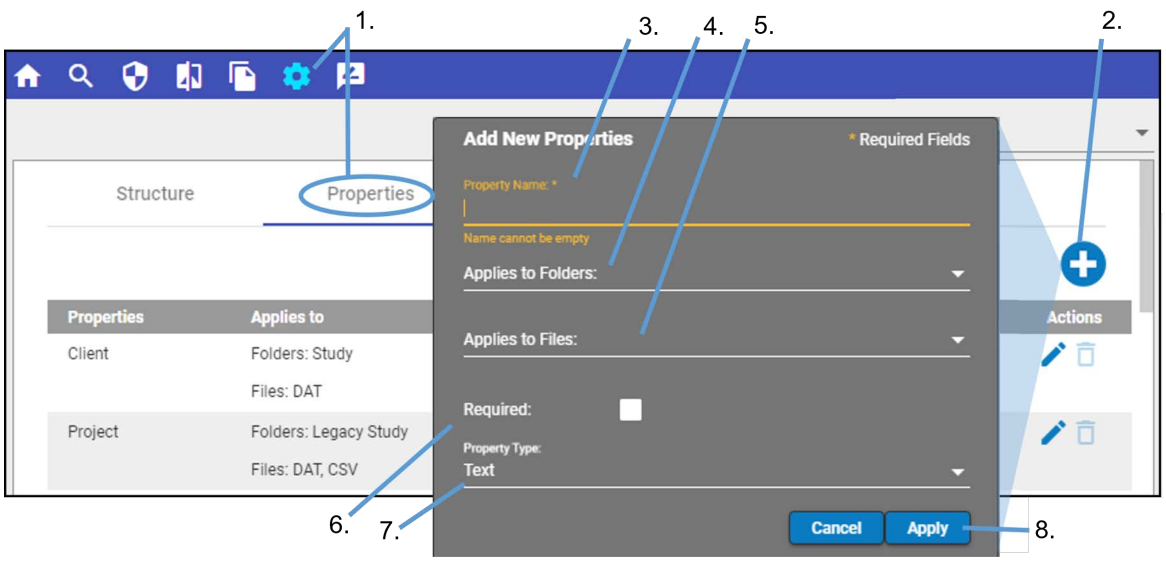
To delete a folder type, click next to the folder type and then confirm the deletion in the popup.

Note: *If a folder type is in use, you will not be able to delete it and selecting will generate a warning message. If the icon is inactive ( ), the corresponding folder type a built-in System configuration type and cannot be deleted.*

Property Types

Refer to “Predefined Property Types” for a list of predefined properties by folder type.

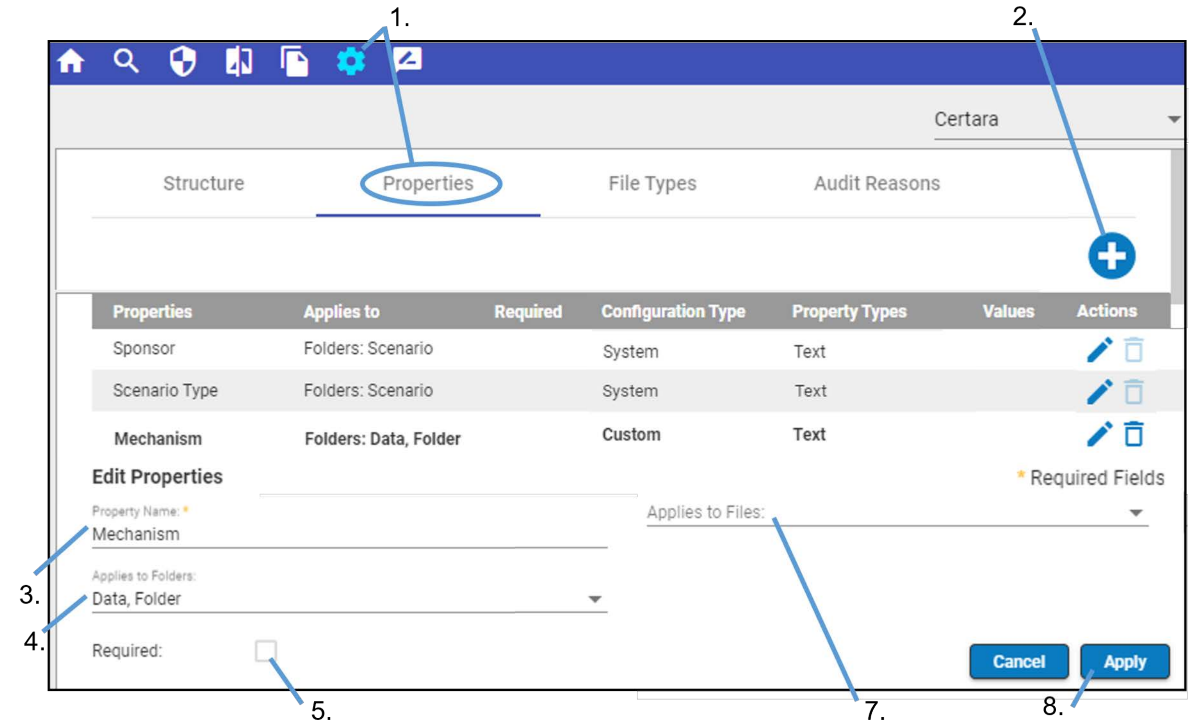
To add a property



1. Click in the main toolbar and select the Properties tab.
2. Click below the list of properties.
3. In the *Add New Properties* popup, enter the name by typing in the **Property Name** field.
4. In the **Applies to Folders** popup menu, check all of the folder types where this property is to be applied.
5. In the **Applies to Files** popup, check all of the file types where this property is to be applied.
6. Check the **Required** box to mark this property as required when adding folders of the type(s) specified in the **Applies Folders** popup.

   If unchecked, the specified folders are able to be created without this property being defined.
7. In the **Property Type** popup, select interface mechanism to use for specifying the property value(s). Depending on the type selected, the **Values** field is displayed for entering all of the values from which users can choose for this property.
8. Click **Apply**.

To modify a property



Note: *If a property has* *at the end of the row, it is locked and requires a password to edit or delete. See* "Lock and Unlock Files"*.*

Any modifications made to properties only affects new folders or files generated after the change. Existing folders or files are unaffected.

1. Click in the main toolbar and select the Properties tab.
2. Click next to the property to edit.
3. In the *Edit Properties* expanded section, modify the name by typing in the **Property Name** field.
4. In the **Applies to Folders** popup menu, check all of the folder types where this property is to be applied.
5. Toggle the **Required** check box to switch whether this property is required when adding folders of the type(s) specified in the **Applied Folders** popup or not required.
6. For Radio, Dropdown, Combobox, and Multiselect property types, modify the list of **Values** from which users can choose for this property. The list is editable, just click and type.
7. In the **Applies to Files** popup, check all of the file types where this property is to be applied.
8. Click **Apply**.

Predefined Property Types

The predefined property types in Integral are listed below. It is important to remember that Integral is very flexible and that property types (with the exception of System Properties) are highly customizable.

Analysis Type   CDISC Model   Compound

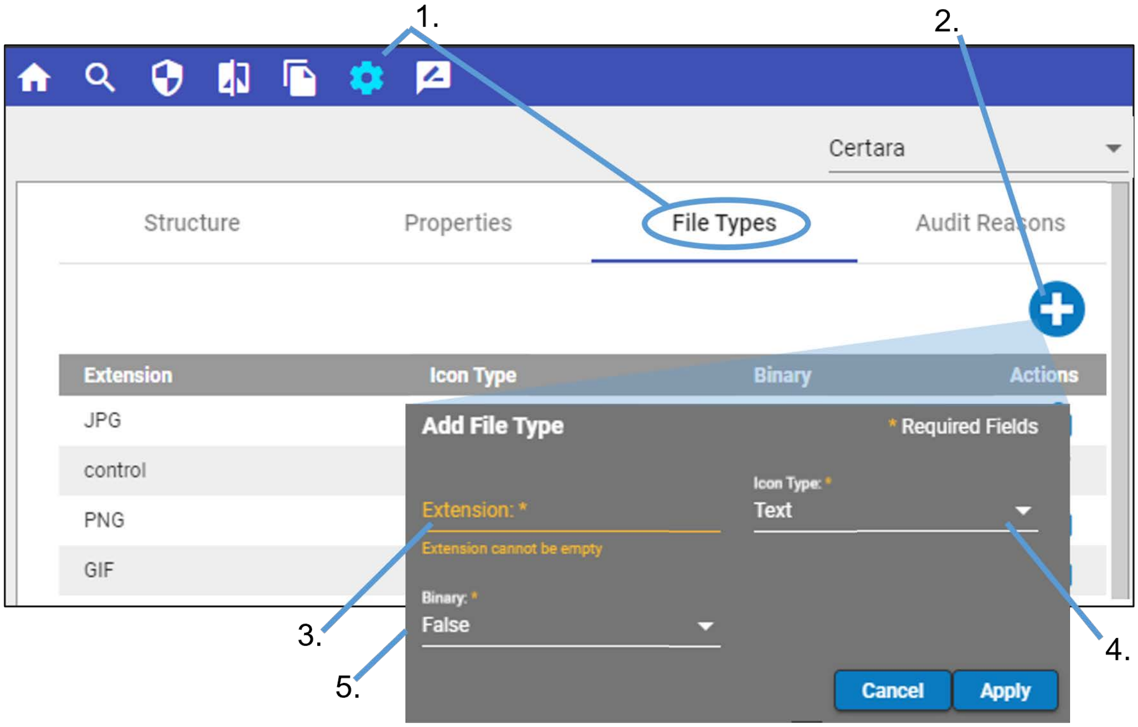
Has Header Row   Has Units Row   Legacy Properties

Phase   Status   Study Design   Study Type

Therapeutic Area   Tool Version

File Types

To add a file type

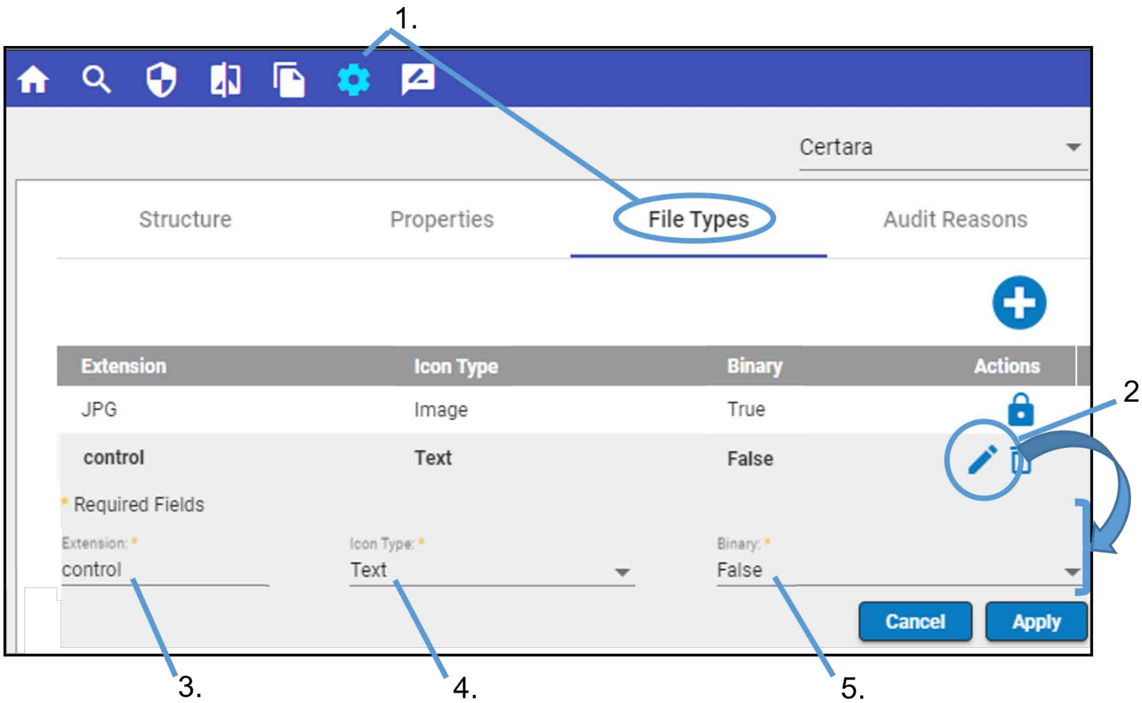


1. Click in the main toolbar and select the File Type tab.
2. Click .
3. In the *Add File Type* popup, enter the extension of the new file type.
4. In the **Icon Type** popup menu, select the icon to associate with the file type.

   Data file = , **Image** = , **Text** = , unknown file type = .
5. In the **Binary** popup, select **True** to indicate the file is to be considered as binary or **False** if it is not binary.
6. Click **Apply**.

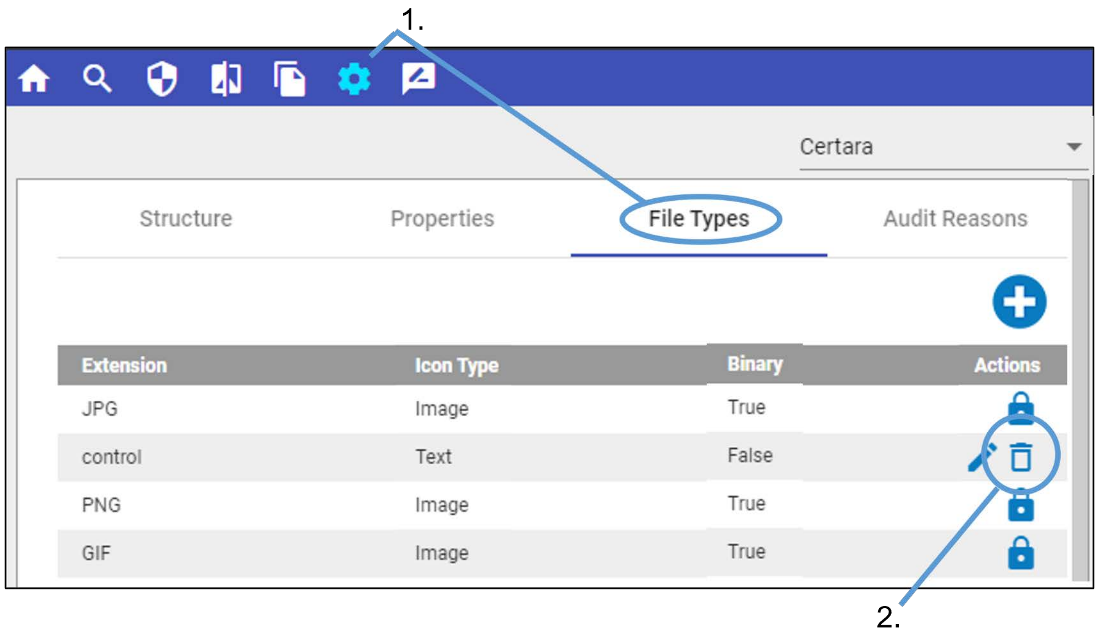
To modify a file type

Note: *If a file type has at the end of the row, it is prepopulated and cannot be edited.*



1. Click in the main toolbar and select the File Type tab.
2. Click next to the file type to edit.
3. In the expanded section, modify the extension by typing in the **Extension** field.
4. In the **Icon Type** popup menu, select the icon to associate with the file type.
5. In the **Binary** popup, select **True** to indicate the file is to be considered as binary or **False** if it is not binary.
6. Click **Apply**.

To delete a file type



1. Click in the main toolbar and select the File Types tab.
2. Click next to the file type and then confirm the deletion in the popup.

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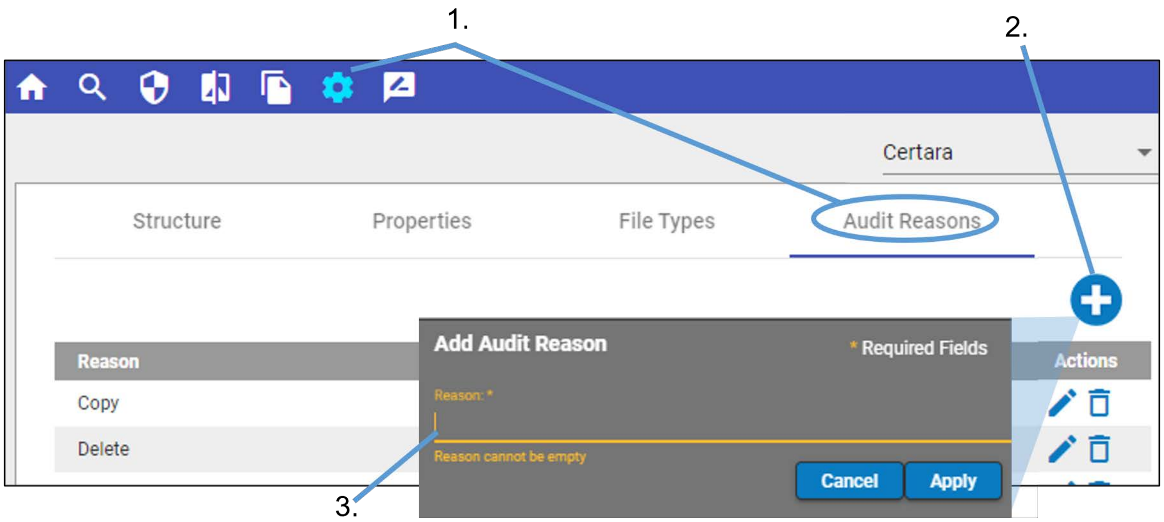
Audit Reasons

Administrators can add or remove audit reason.

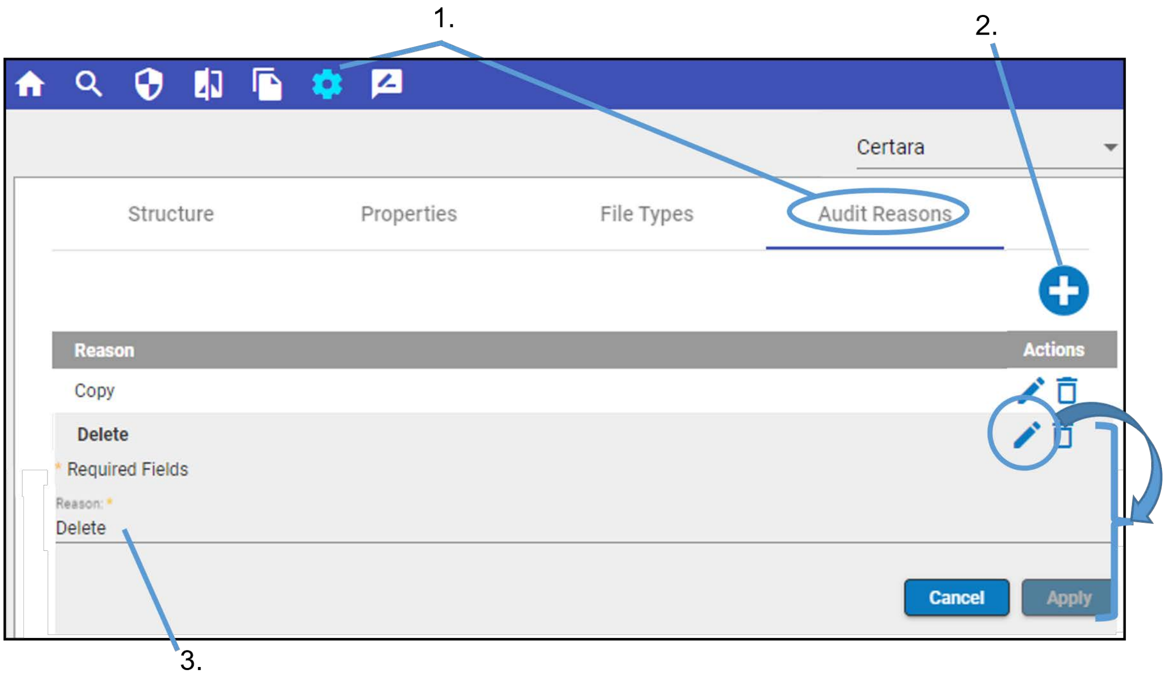
To add a reason



1. Click in the main toolbar and select the Audit Reasons tab.
2. Click .
3. In the *Add Audit Reason* popup, enter the text for the new reason.
4. Click **Apply**.

The new reason is added to the table and will appear in the **Reason** menu when an eSignature is required. For eSignature disabled folders, a system-generated reason will be recorded in the audit trail.

To modify a reason



1. Click in the main toolbar and select the Audit Reasons tab.
2. Click next to the reason to edit.
3. In the expanded section, modify the text by typing in the **Reason** field.
4. Click **Apply**.

To delete a reason

1. Click in the main toolbar and select the Audit Reasons tab.

Click next to the reason and then confirm the deletion in the popup.

Database Security

1. On the Integral main window, click in the main toolbar.

Note: *The Security icon is only visible if you have the "Administrator" role.*

2. Choose one of the tabs:
   – Users (individual user)
   – Groups (group of users labeled as a group name)

The security tools can be used to accomplish the following tasks:

Add a user to the system

Search for a user within the system

Edit a user in the system database

Add a group to the system database

Search for a group within the system database

Edit a group in the system database

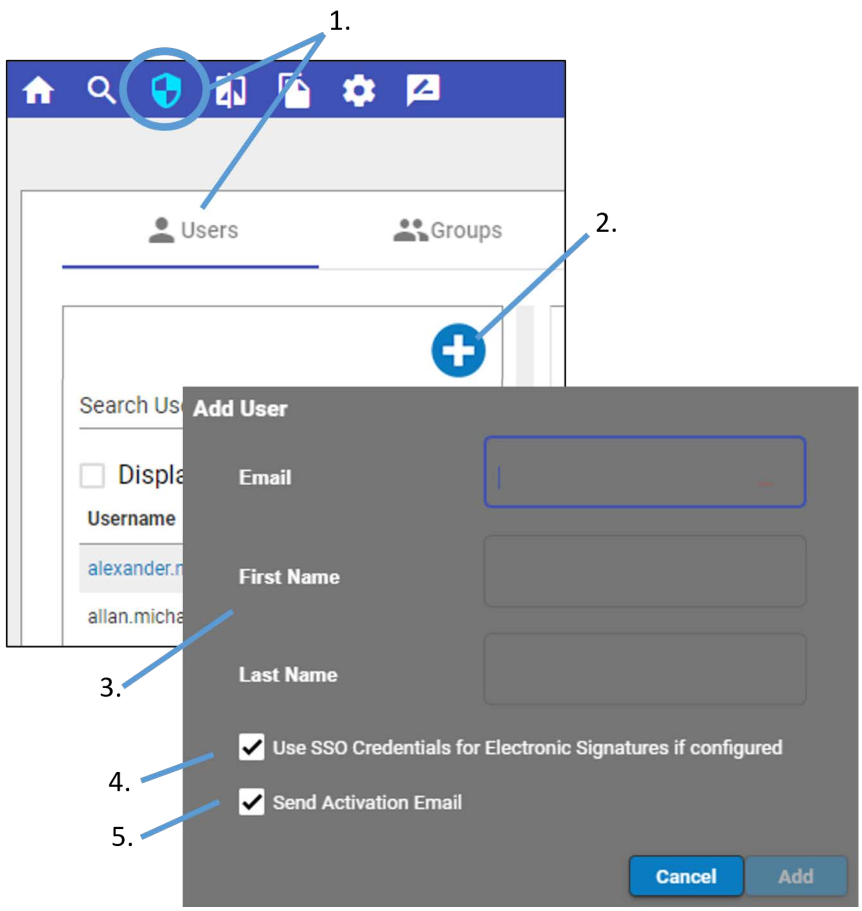
Manage group rules

Manage members within a group

Delete a group in the system database

Example of permission setup for an external partner

Add a user to the system

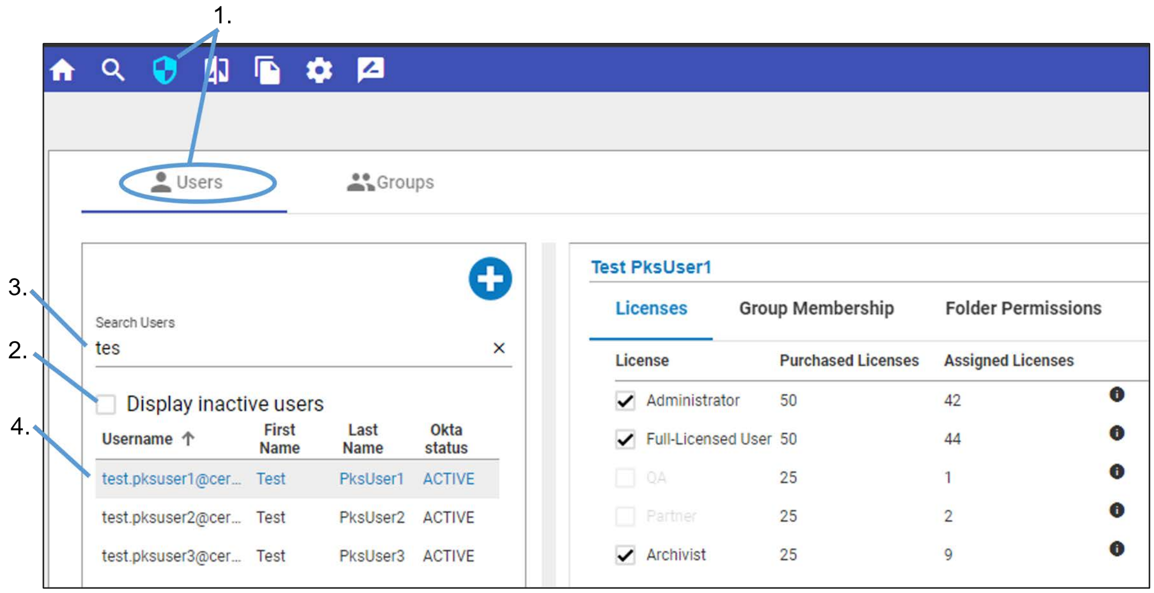


1. Click in the toolbar to display the Users tab.
2. Click above the list of existing users.
3. In the *Add User* popup, type the email, first name, and last name of the user to add.
4. Check the **Use SSO Credentials...** box to automatically use the SSO credentials when eSignatures are required.

   If unchecked, the user will need to enter their Integral username and password when an eSignature is required.
5. Check the **Send Activation Email** box to forward an email notification to the user being added.
6. Either click **Add** to add user to the Integral system or **Cancel** to close the popup without adding the user.

See “Edit a user in the system database” to assign license types to users.

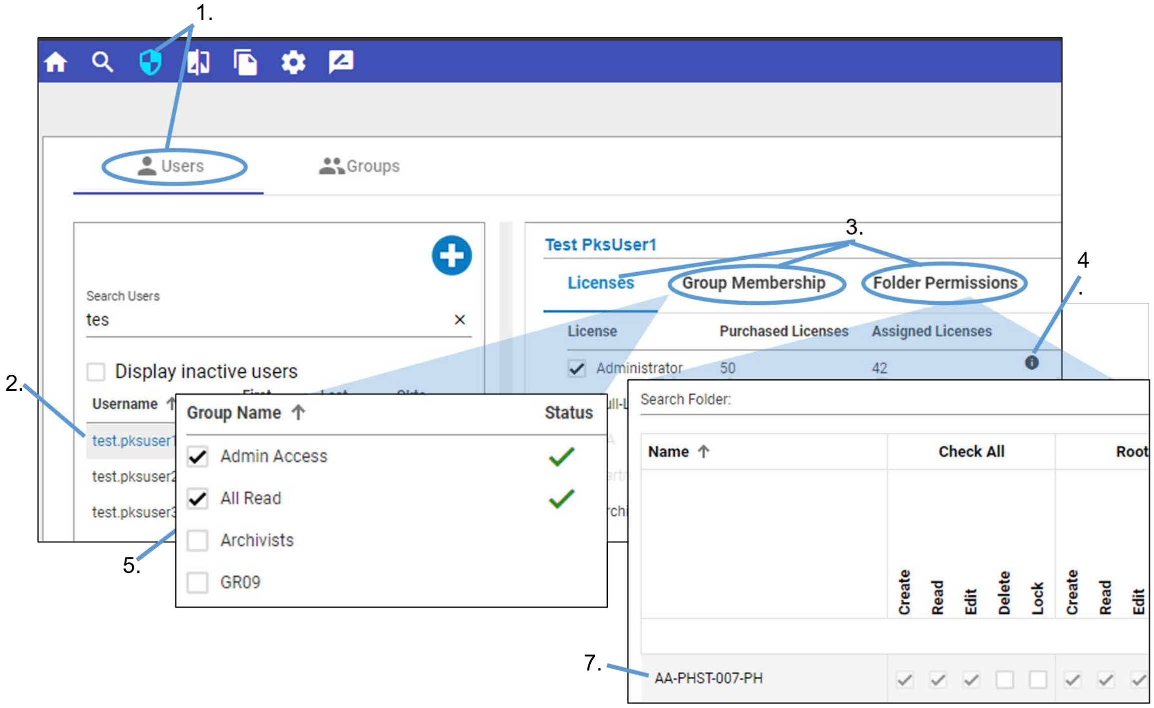
Search for a user within the system



1. Click  in the toolbar and select the Users tab.
2. Check the **Display inactive users** box to view users whose OKTA status is inactive as well as active.
3. Click near the **Search Users** heading and begin typing the name.
4. Click on a name in the filtered list to view the user's properties on the right panel.

Notice the up arrow next to the **Username** column header in the previous image. This indicates that the list is currently sorted in ascending order. Click the **Username** column header multiple times to switch between ascending, descending, and no sorting.

Edit a user in the system database



1. Click in the toolbar to display the Users tab.
2. Select a user to edit from the list.
3. Toggle between three tabs in the right panel.

   Licenses, Group Membership, and Folder Permission govern user access to content.

   – Licenses: The “maximum” permissions a user can have for any root folder. It is largely tied to license type.

   – Group Membership: Provides access to “folder types” according to defined properties.

   – Folder Permissions: Provides additional permissions to folders beyond those set by group membership, assuming that the assigned Role allows for that permission.

Note: *A user that is assigned a license must also be assigned as a group member or granted permissions in the Folder Permissions tab, or both to access any data in Integral:*

Permissions are additive. Thus, if a user belongs to two groups, his/her permissions are a sum of the permissions for the two groups. Similarly, if a user belongs to a group, he/she can be granted permissions, via the Folder Permissions tab, to additional folders that are outside of the group’s access.

If a folder’s author is editing the Effective User Permissions of a folder and an administrator is making changes to the same folder in the Security module at the same time, whatever changes that are made last will be applied.

If all Licenses and Permissions are removed from a user, that user will no longer be able to log into Integral.

4. In the Licenses tab, check on/off the box(es) to assign a license to the selected user:

   Click the information icon ( ) to see additional details about each license.

   Predefined License Types Table

	Create	Read	Edit	Delete	Lock	Security Admin (Administer security)	Set/Unset Blind	View Blind	Others	Allowed Role Combinations
	Feature									
Administrator										
	No, except root folder	Yes	No	No	No	Yes	No	No	- Add users to Integral; - Create root folders and set eSignatures requirement; - Disable eSignatures for existing root folder; - Transfer ownership of root folder; - Assign users to system licenses/roles; - Grant folder permissions individually or through security groups; - Access to Security, Admin, and System Audit Report (SAR) modules	Full-Licensed User; Archivist
Full-licensed User										
	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	- Create root folders and set eSignatures requirement; - Disable eSignatures for existing root folder, if user is the owner; - No access to Security, Admin, or SAR modules	Administrator; Archivist
Limited-Licensed User										
	Yes	Yes	Yes	Yes	Yes	Yes**	Yes	Yes	- Create only eSignature disabled root folders; - Write access to only eSignature disabled root folders; - Read access to eSignature enabled root folders; - No access to Security, Admin, or SAR modules	None
QA										
	No	Yes	No	No	Yes	Yes*	No	Yes	- Access to System Audit Report Module; - No access to Security or Admin modules	Archivist
Archive										
	No	Yes	No	No	Yes	Yes*	No	Yes	- Unlock folders or files; - No access to Security, Admin, or SAR modules	QA or Administrator (not at the same time) or Full-Licensed User
Partner										
	Yes, except root folder	Yes	Yes	Yes	No	Yes*	No	Yes	- No access to Security, Admin, or SAR modules	None
Limited-Partner User										
	Yes, except root folder	Yes	Yes	Yes	No	Yes**	No	Yes	- Write access to only eSignature disabled root folders; - Read access to eSignature enabled root folders; - No access to Security, Admin, or SAR modules	None
Note	A user must be granted permissions to folders explicitly or through group membership. Features will be limited to those allowed by folder permissions and those enabled by the user's assigned license. *Granted when user creates the root folder, are made the owner of that root folder, or are granted Security Admin for that root folder either manually or through groups. **Only applies to root folders where eSignature is disabled.									

Note: *The Archivist license is free of charge when other licenses are purchased and multiple Archivist licenses may be requested.*

5. In the Group Membership tab, check on/off the box(es) to specify the groups of which the selected user is to be a member.

   An administrator can grant other users (Full-Licensed User, QA, Archivist, Partner etc.) permissions in the Group Membership tab as long as there are no permission conflicts. A permission conflict is indicated by a ⚠ in the Status column. It means despite group membership, this user will not have all the permissions that the Group is trying to give him/her. Therefore, when an administrator is assigning licenses, make sure to also check the permissions in Group Membership tab.
6. In the Folder Permissions tab, check on/off the box(es) to define the folder permissions to grant the selected user. The permissions are grouped into 5 categories. Checking a box in the **Check All** category checks all boxes with the corresponding label in all of the other categories (e.g., if **Read** is checked under **Check All**, then **Read** will be checked for **Root Folder**, **Data**, **Document**, and **Analysis**). The remaining 4 categories represent the security contexts that were assigned when the folder type was created: Root Folder, Data, Document, and Analysis.

   Name and **Has Permissions** columns can be sorted by clicking the column header.

For each security context, the following permissions can be set:

Read

- Access to folder and its files and subfolders
- Download file from the folder
- Generate search results that include files from the folder
- Load a Phoenix project into Phoenix
- Load a selected item into Phoenix
- Sync a folder from Integral to the local directory

Create (when combined with Read permission)

- Upload files to folder
- Add subfolders to folder
- Copy/Link files to folder
- Add a savepoint
- Add selected items to folder
- Sync folder or new files to folder from the local directory to Integral

Edit (when combined with Read permission)

- Edit name and properties of folder or of file within folder
- Edit content (data) of files in folder
- Upload new versions of files within folder
- Perform a Save or Save As for a savepoint
- Save options when saving a savepoint

- Sync updated files to folder from local directory to Integral

Delete (when combined with Read permission)

- Delete folder, which also deletes all content in folder
- Delete individual files and subfolders within folder (unless it is a savepoint)

Lock (when combined with Read permission)

- Lock the folder, which also locks all content in the folder
- Lock individual files and subfolders within folder (unless it is a savepoint)

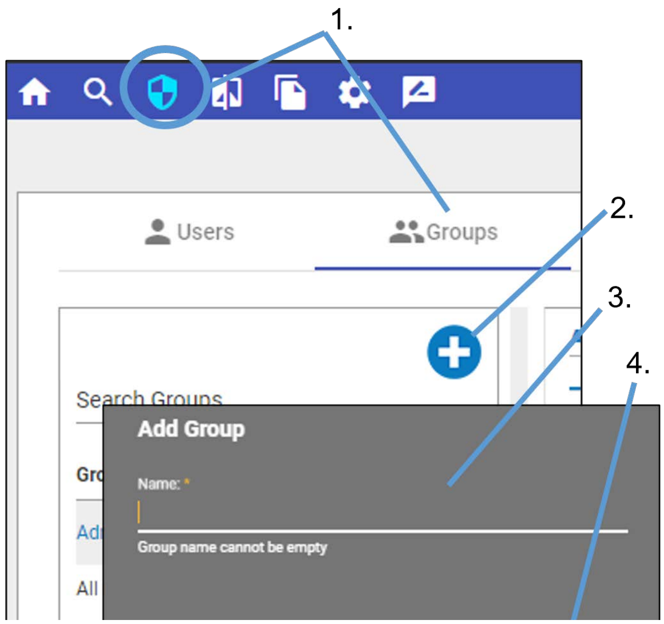
View (when combined with Read permission)

- View contents of blinded folder or of files and subfolders within blinded folder
- Use a blinded file as a dependency for a savepoint
- Sync a blinded folder or blinded file or blinded subfolder from Integral to local directory
- Sync a new file or subfolder or updated file to a blinded folder from local directory to Integral

Set/Unset blind (when combined with Read permission)

- Blind/Unblind folder, which also blinds/unblinds all content in folder, respectively.
- Blind/Unblind files or subfolders within folder

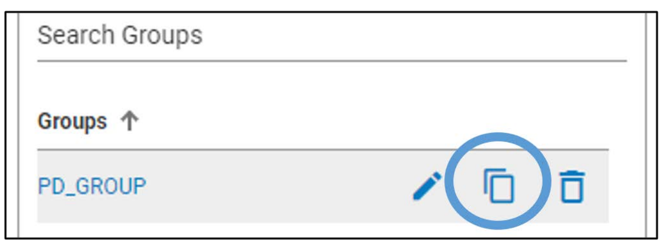
Add a group to the system database



1. Click  in the toolbar and select the Groups tab.
2. Click  above the group list.
3. In the *Add Group* popup, type the new group's name.
4. Either click **Add** to add the group to the list or **Cancel** to close the popup.

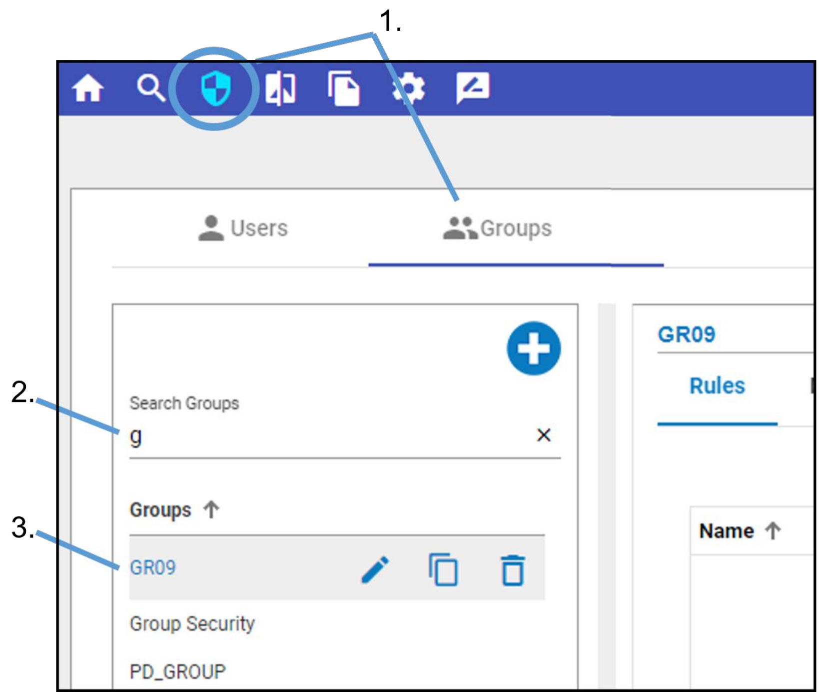
The group is add to the list on the left and selected so that rules and members can be immediately defined. See "Edit a group in the system database" for more information.

New groups can also be created by copying an existing group and then editing it as needed.



1. Select the group to copy in the list on the left.
2. Click .
3. In the *Copy Group* popup, type the new group's name.
4. Either click **Copy** to create a copy of the group or **Cancel** to close the popup.

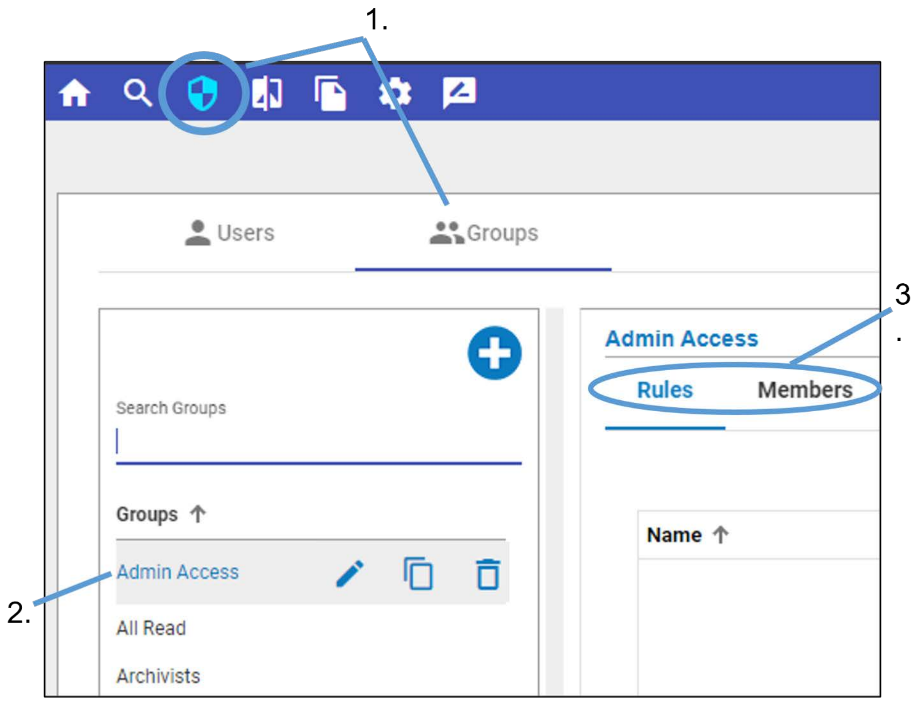
Search for a group within the system database



1. Click  in the toolbar and select the Groups tab.
2. Click the **Search Groups** heading and begin typing the name.
3. Click on a group name in the filtered list to view the group's properties on the right panel.

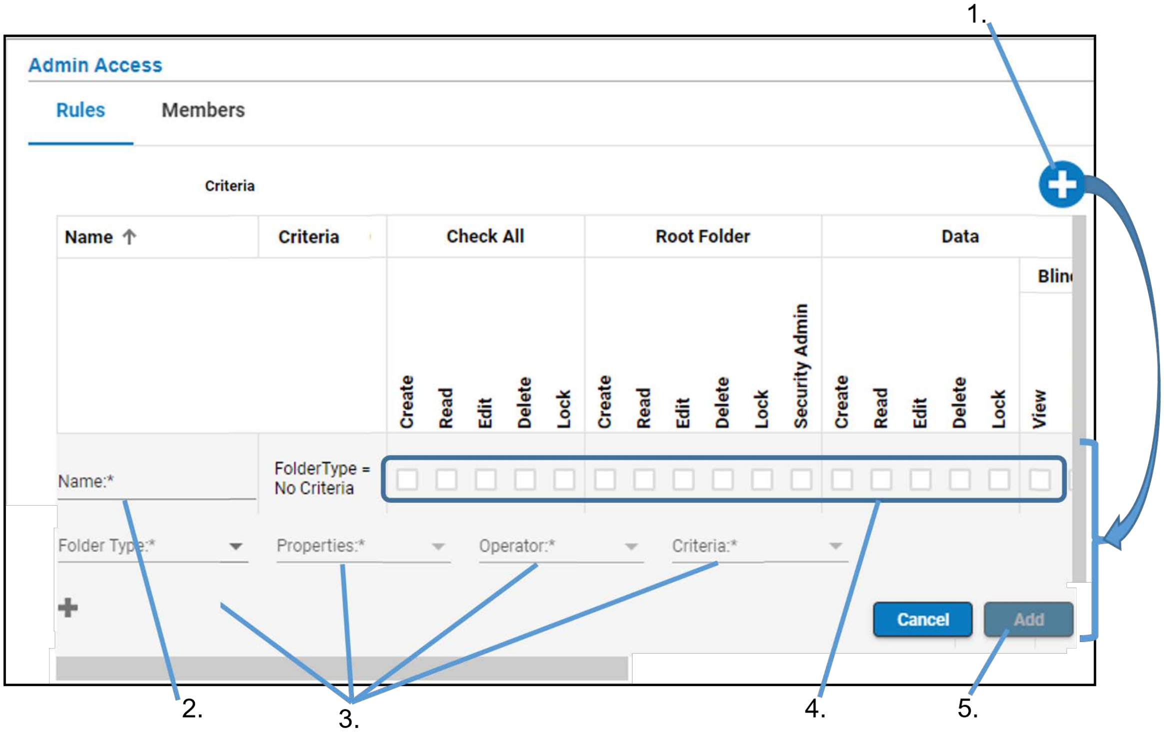
Notice the up arrow next to the **Group** column header in the previous image. This indicates that the list is currently sorted in ascending order. Click the **Group** column header multiple times to switch between ascending, descending, and no sorting.

Edit a group in the system database



1. Click [icon] in the toolbar and select the Groups tab.
2. Select a group to edit from the list.
3. To edit the group name, click [icon]. type the name, and click the checkmark to apply the modified name or click X to ignore any changes.
4. Toggle between the Rules (see Manage group rules) and Members tabs (see Manage members within a group) in the right panel.

Manage group rules



1. In the Rules tab, click  to add a rule.

   To edit a rule, click the rule name.
2. In the expanded area, enter or edit the **Name** for the rule.
3. Define the rule criteria by selecting the **Folder Type**, **Properties**, an **Operator**, and **Criteria** from the respective menus.

   To add more criteria to the new rule, click  and repeat the selections of **Folder Type/ Properties/Operator/Criteria**. Multiple criteria within a rule for a group are applied using ***AND***. For example, if a rule is specified that has 2 criteria, one stating that group permissions should be applied to folders of type “GRT Study” that have Indication = “GRT,” the other stating that group permissions should be applied to folders of type “GRT Study” that have Portfolio = “ABC,” the rule will apply permissions to folders of type “GRT Study” that have Indication = “”GRT” AND Portfolio = “ABC”.

Note: **Description** *should not be used when defining rule criteria.*

4. Check on/off the box(es) to define the permissions to grant the group when the rule criteria are met. The permissions are grouped into 5 categories. Checking a box in the **Check All** category checks all boxes with the corresponding label in all of the other categories (e.g., if **Read** is checked under **Check All**, then **Read** will be checked for **Root Folder**, **Data**, **Document**, and **Analysis**). The remaining 4 categories represent the security contexts that were assigned when the folder type was created: Root Folder, Data, Document, and Analysis. For each of these 4 categories, permissions can be set to allow a group to:

Create content (add subfolders and upload files)

Read the contents of the folder

Edit the contents of the folder

Delete the folder and its content

Lock the folder or files in the folder

View the folder contents even when blinded in a study

Set the folder or files to be blinded in the study

As an example, a rule is defined that, for all folders of the “Project” type, that have the “Therapeutic area” property “equal” to “Cardiovascular,” Read and Edit permissions of Documents will be granted to members of the group. This means that a user who is a member of the group for which this rule is defined, will be able to read and edit documents that are located in Cardiovascular-related projects. Refer to “Example of permission setup for an external partner” for another example.

5. Click **Add** to save the new rule or **Apply** to accept the modifications to the existing rule.

To delete a rule, click  to the far right of the rule.

Manage members within a group

1. With the desired group selected in the list on the left, select the **Members** tab on the right.

   The list on the right shows all the users in the directory, but only the checked ones have access to the selected group.
2. To search for a member, type the name in the **Search** area above the list on the right.

3. To sort the list of members, click a column header. Click the column header multiple times to switch between ascending, descending, and no sorting.
4. To add a user to the group, check the corresponding box. To remove a user from the group, uncheck the corresponding box.

Delete a group in the system database

1. Click  in the toolbar and select the Groups tab.
2. Select the group name in the list on the left.
3. Click  next to the name and press **OK** in the confirmation popup.

Example of permission setup for an external partner

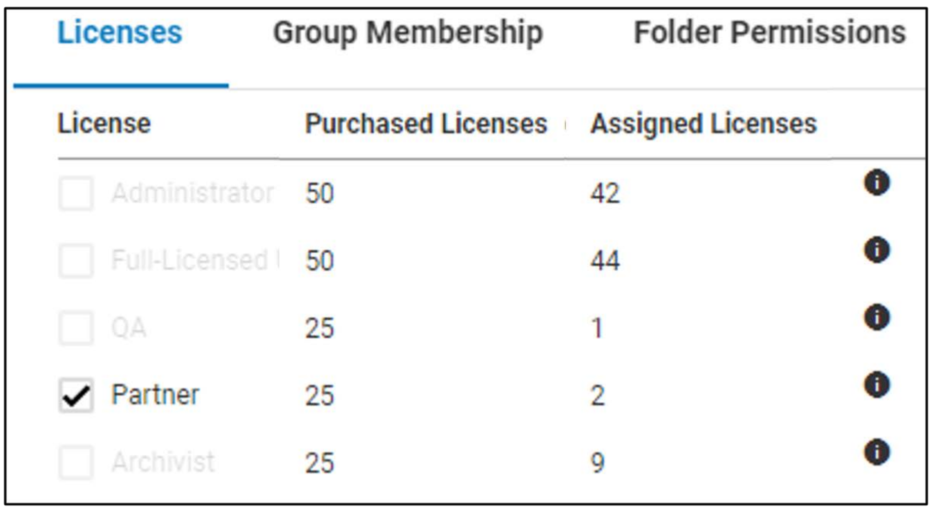
For this example we will be setting up permissions for an external partner, named Tester Smith. Tester Smith will need the ability to create/read/edit data, create/read/edit documents, and read analyses for all projects to which the Clinical_BA group is given access.

Assign the role of Partner to the user

Assume that Tester Smith has been granted an account by Certara Support.

1. Click to display the Users tab.
2. Locate and select **Tester Smith** in the left list.
3. With the Licenses tab selected on the right, check the box for the **Partner** license to assign it to Tester Smith.

Partner licensed users can create, read, edit, delete, view, and blind any folder, except the Root folder, which they cannot delete, view, or blind. However, Tester Smith must first be granted access to some folders before any of these permissions can take effect. Access can be granted by Group membership or specifically at the folder level, or by a combination of both.



Create a new group

Set up a Clinical_BA group. Later, we will assign Tester Smith as a member of this group.

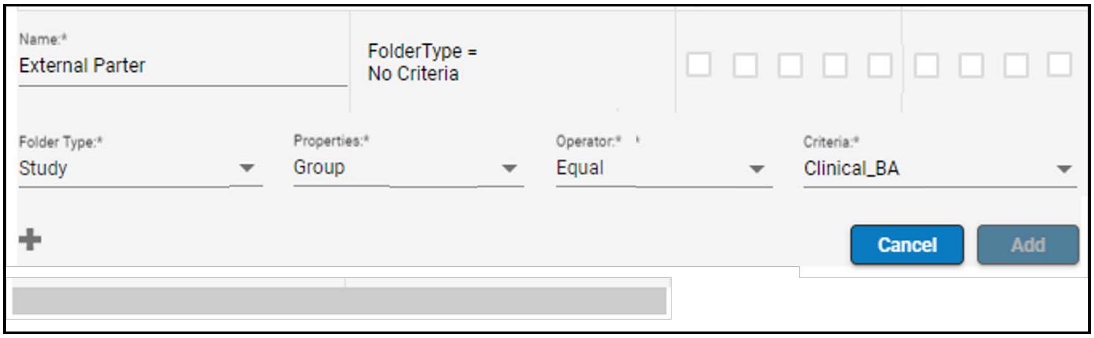
1. Click and select the **Groups** tab.
2. Click at the top of the left list.
3. In the pop-up, enter `Clinical_BA` as the name of the new group and click **Add**.

We will add a rule for the Clinical_BA group that will define the criteria that must be met for certain permissions to be granted to its members.

All information that the Clinical_BA group needs access to are in folders that are of the Project type and have the Group property set to Clinical_BA. Therefore, a rule can be set up as follows:

4. Select **Clinical_BA** in the left list.

5. With the Rules tab selected on the right, click .
6. Type `External partner` as the name of the rule.
7. Set the **Folder type** to **Project**, **Properties** to **Group**, **Operator** to **Equals**, and **Criteria** to **Clinical_BA**.



8. Check the **Read** box under **Check All**.
9. In the **Data** and **Documents** sections, check the **Create** and **Edit** boxes.

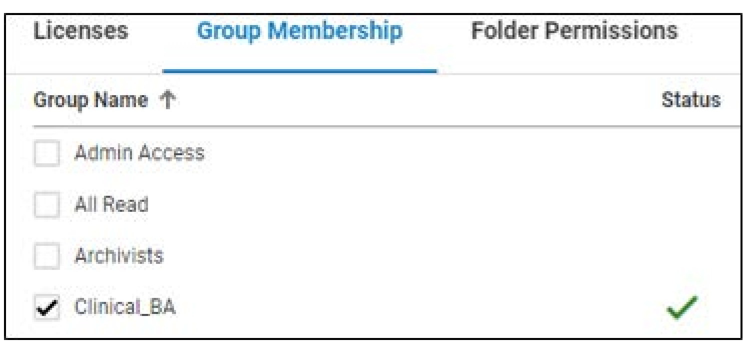
10. Click **Add**.

With this rule defined, members of the Clinical_BA group will be able to read all items and to create and edit data and document items within project folders that have the Group property set to Clinical_BA.

(Members could now be added to the new group, using the Members tab. However, this step will be skipped for this example.)

Add the user to the group

1. Select the Group Membership tab.
2. Check the **Clinical_BA** checkbox to add Tester Smith as a member.



Tester Smith now has access to some folders as a member of the Clinical_BA group. Remember, as a Partner, a user can potentially create, read, edit, delete, view, and blind any folder, except the Root folder. However, the Clinical_BA group does not allow members to delete or blind a folder.

Adjust folder permissions for the user

At this point, Tester Smith has access to any Project folder where the Group property is set to Clinical_BA. Let’s say that he is only involved with the PMX02 project. To allow access to only the information relevant to this project and no other project data, Tester Smith must first be removed from the Clinical_BA Group and then permissions need to be set for the PMX02 project folder.

For this example, assume that a project folder called PMX02 exists in Integral.

1. Select the **Group Membership** tab and uncheck the **Clinical_BA** box.
2. Select the **Folder Permissions** tab.
3. Locate the **PMX02** folder in the table.

   Use the **Search Folder** field to filter the table by typing `PMX`.
4. Check the **Select All** box for the PMX02 row.

Notice that appears under some of the column headers to indicate that the permission required for the action is not currently granted to the user’s role.

Note: *The presence of the warning icon simply notifies you that the associated action will not be allowed for the user, even though the box is checked. There is no need to adjust the checkboxes in an attempt to get rid of the warning icon, as the action will be prevented regardless of the status of the checkbox.*

Auditing Changes to Integral Data

Audit Reports are performed on files existing in the Data, Documents, or Analysis(es) folders only; folder changes are not included. However, a report can be initiated from the folder level, which will walk the folder/file tree and recursively create a report that includes all applicable files.

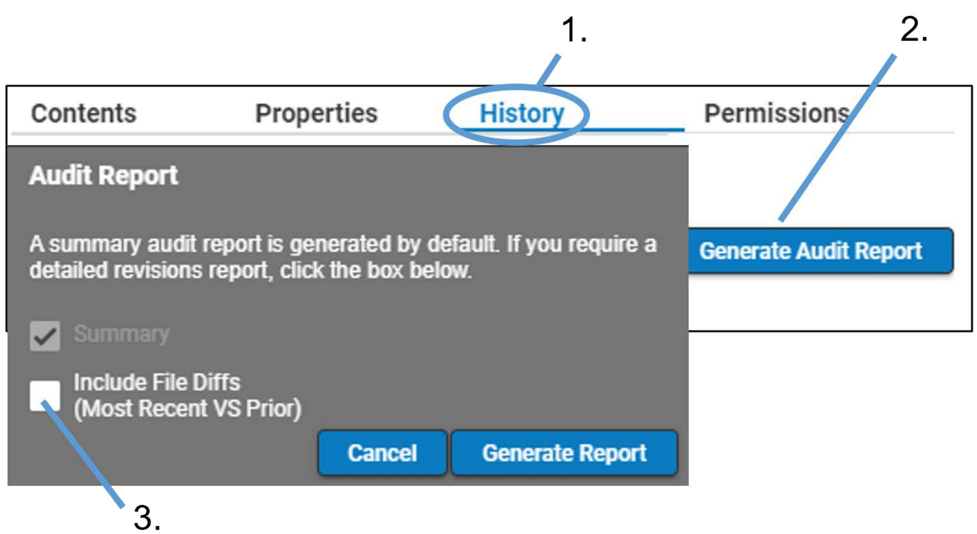
To generate an audit report for a folder

To generate an audit report for a savepoint

To generate an audit report for a file

Audit report contents

To generate an audit report for a folder



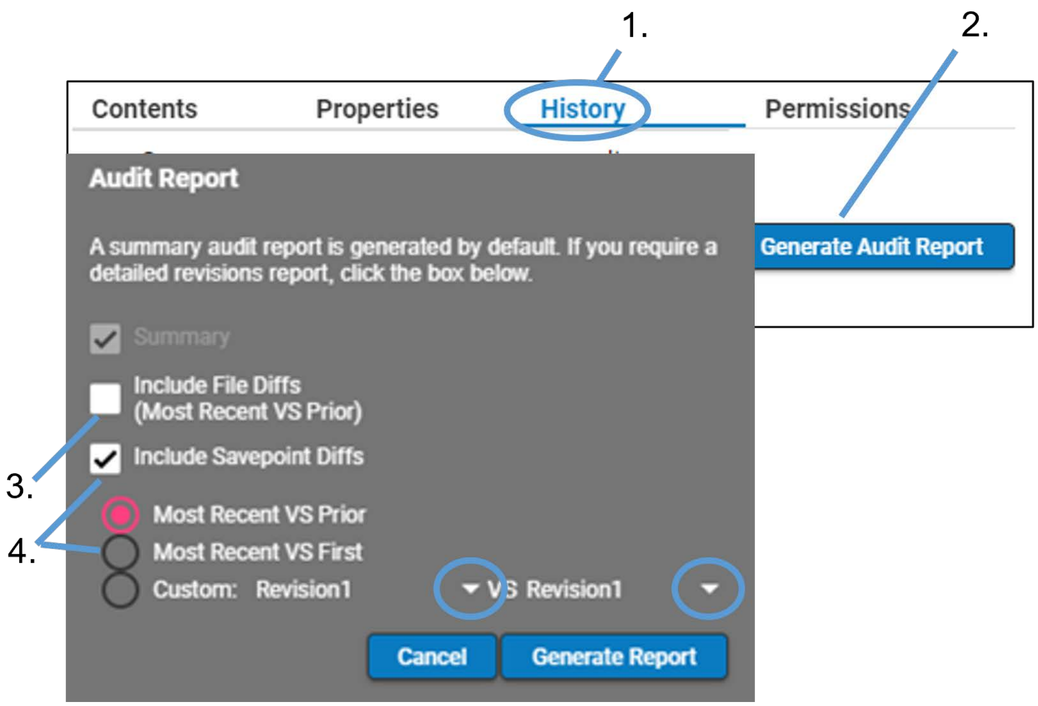
1. Go to the History tab of a folder.
2. Click the **Generate Audit Report** button.
3. In the popup, check the box for **Include File Diffs** if you want to include a comparison of the two most recent revisions of each file.

Click **Generate Report** to generate the report as a .zip file.

Note: *If you are using the Integral Plugin for Phoenix, the Save As dialog is displayed to allow you to change the filename and identify the directory in which to save the .zip file. Should you decide to change the name in the* **File Name** *field, it is important to include the .zip extension.*

See "Audit report contents" for more information.

To generate an audit report for a savepoint



1. Go to the History tab of a savepoint-enabled folder.
2. Click the **Generate Audit Report** button.
3. In the popup, check the box for **Include File Diffs** if you want to include a comparison of the two most recent revisions of each file.
4. Check the box for **Include Savepoint Diffs** and use the radio buttons to specify the save-points to compare for differences.

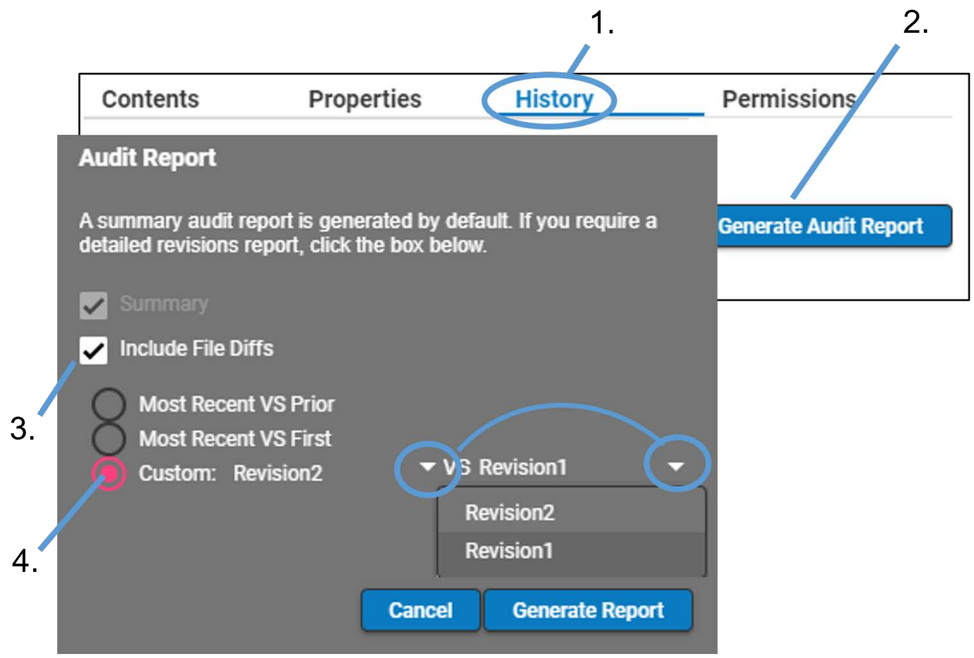
   Most Recent VS Prior: If the file had 3 savepoints, this option compares savepoint 3 with 2.

   Most Recent VS First: This option compares savepoint 3 with 1.

   Custom: Use the two pull-down menus to select the savepoints to compare.
5. Click **Generate Report** to generate the report and save it to your local directory as a .zip file.

See "Audit report contents" for more information.

To generate an audit report for a file



1. Go to the History tab of a file.
2. Click the **Generate Audit Report** button.
3. In the popup, check the box for **Include File Diffs** if you want to include comparison of revisions in the report.
4. If **Include File Diffs** is checked, use the radio buttons to specifying the revisions to compare for differences.

   Most Recent VS Prior: If the file had 3 revisions, this option would compare revision 3 with 2.

   Most Recent VS First: This option would compare revision 3 with 1.

   Custom: Use the two pull-down menus to select the revisions to compare.

Click **Generate Report** to generate the report and save it to your local directory as a .zip file.

See "Audit report contents" for more information.

Audit report contents

Compliance with 21 CFR Part 11 requires full accountability for all changes to study data, including inserting, deleting, and modifying data. Integral captures information for the following events.

- adding a file
- adding a new revision of a file
- editing content of a file
- deleting a file or a folder containing files
- creating/updating links
- creating/updating copies

- locking/unlocking
- blinding/unblinding
- changing status of files or savepoint-enabled folders
- adding/updating/removing savepoint dependencies
- disabling eSignatures for a root folder (the entered reason for disabling is reported)

For each event, the following information is collected:

- username
- date/time of modification (in UTC)
- event ID

The report itself is a .zip file that contains:

A main summary Report, in PDF format. The Integral instance and repository schema is followed by a list of the files included in the report. There is also an indication if a Diff file is available. The report continues with a separate section for each file in the list. Each file's section has three parts:

- File summary: This section shows the name, path from the repository, author, creation date, revision number, size, and description of the file.
- Revision changes: For each revision of the file, the revision number, revision creation date, author, event ID, action, and reason for the revision are presented.
- Property changes: For each change to a property in the file, the revision number, name of the property, the value, the date/time of the change, and the author of the change, and the reason for the change are presented.

A file for each Diff (if requested). For text files, the Diff file is a PDF file showing a side by side comparison. For dataset files (CSV or XPT files), the Diff file is an Excel file listing the Column Name, Action, Previous Value, Current Value, User, and Event ID.

A file for savepoint Diff (if requested), in PDF format. A list of files added to the savepoint, files removed from the savepoint, and files with a new revision number.

Note: *The audit report captures changes to files, but not folders. Therefore, not all event IDs will be found in an audit report. However, all actions are captured in the background and can be retrieved by submitting a support ticket.*

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System Audit Report

The system audit report captures activities/events that are not typically exposed in the interface. The report contains audit information pertaining to security, administration, downloading, and other activities.

Security activities

- Add/remove user
- Add/modify/remove permission group
- Add/modify/remove rule from permission group
- Add/remove user from an assigned license or from a permission group
- Add/remove a user’s folder permissions and which permissions changed
- Disable eSignature for folder

Administration activities

- Add/modify/remove folder type, property type, or file type
- Add/delete root folder
- Update the owner of a root folder

Downloading activities

- Download any file, folder, or savepoint
- Download at folder level
- Download at file level
- Download deleted file
- Syncing root folder from Integral to local
- Syncing new files or folders added to a synced root folder from Integral to local

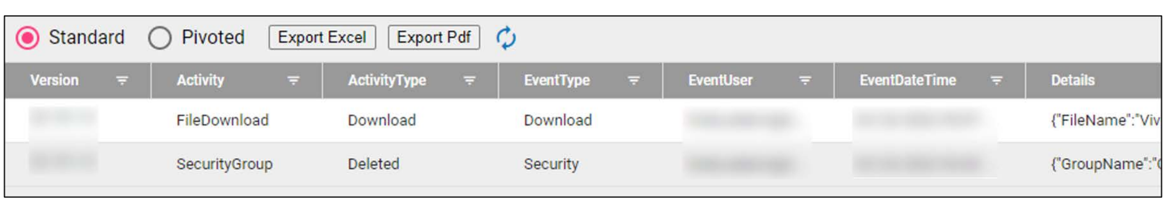
Other activities

- Locking/Unlocking files or folders
- Blinding/Unblinding files or folders
- Deleting files or folders

Using this tool, customized system audit reports can be generated without needing to contact Certara.

To access the system audit report, click in the main toolbar.

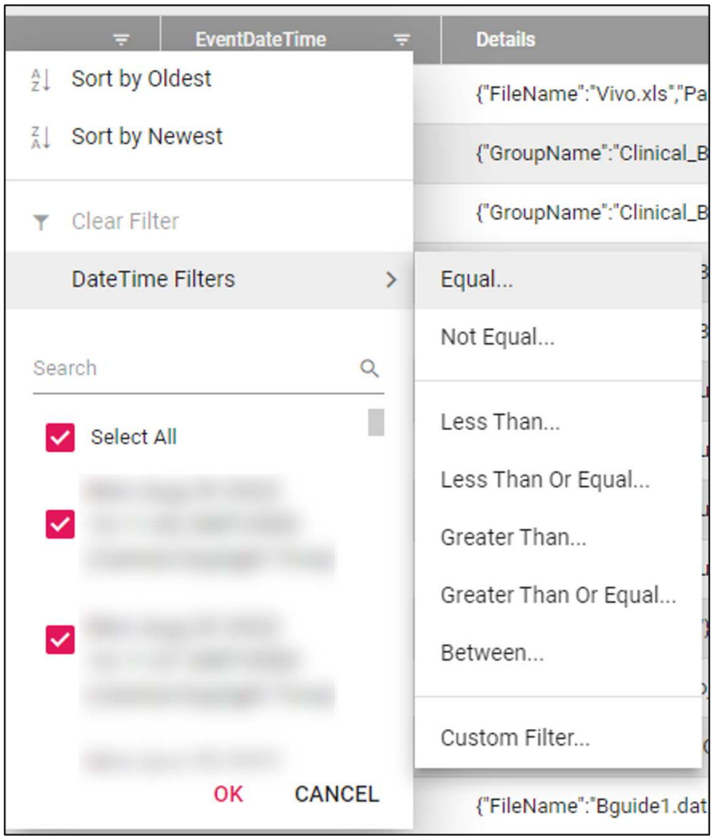
Note: *The System Audit Report icon is only visible if you have the “Administrator” or “QA” license.*



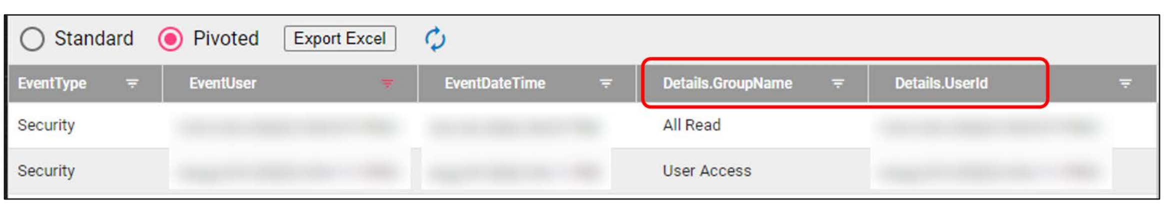
By default, the data is displayed using a **Standard** view. The **Standard** view is a stacked view, where every activity has the same structure and the details for a particular activity are contained in a column called "Details."

The **Pivoted** view separates the attributes listed in the Details column into individual columns. If no filtering of activities is applied, the width of the table can grow by a substantial amount, as there are a large number of detail attributes possible for all of the tracked activities. If filtering is applied to only show a particular type of activity, the table is compressed to only display the columns of details that are relevant to that activity. Once in Pivoted view, it is then possible to filter based on individual detail attributes.

Sorting and filtering of columns in the system audit report is very similar to what is described in the "View and edit contents of a file" section with additional operators being available for filtering date/time columns.



In the following Pivoted view image, the Activity column has been filtered to list only **SecurityGroupMember** activities (the EventUser column is also filtered to list a particular user). There are only two details relevant to this activity: GroupName and UserID.



Note: *The filter icon in the column header will appear red if filter criteria has been applied to that column.*

Use the navigation tools below the table to page through the data, go to a particular page, or to set the number of items to display per page.

To export the report, press the **Export Excel** or **Export PDF** button. Any data that has been filtered out will not be included in the report.

Click  to force a refresh of the list.

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Integral Plugin

Integral is a database system for secure storage of study data and analyses. Integral provides a secure data management system with complete auditing capabilities. The combination of Integral and Phoenix provides an effective means to share source data, models, scripts, and results among the members of a drug development team. The combination also supports compliance with the U.S. Food and Drug Administration’s 21 CFR Part 11 regulation.

Phoenix can work in conjunction with Integral for secure storage and change tracking for data and analyses. This section covers the use of Phoenix as an Integral client: loading Integral data to Phoenix and saving data from Phoenix as Integral projects and savepoints. Integral can also be accessed by way of a Web interface, which provides additional operations. See “Integral Introduction”.

This section contains the following topics:

Accessing the Integral browser

Note: *Connection to Integral from Phoenix requires the setting of some preference options. Refer to* "Setting up a connection" *for more information.*

Selecting **Integral > Browser** from the main Phoenix menu displays the login page of Integral. Once credentials are verified, the Integral interface is presented. For details on using this interface, see the "Browser" section.

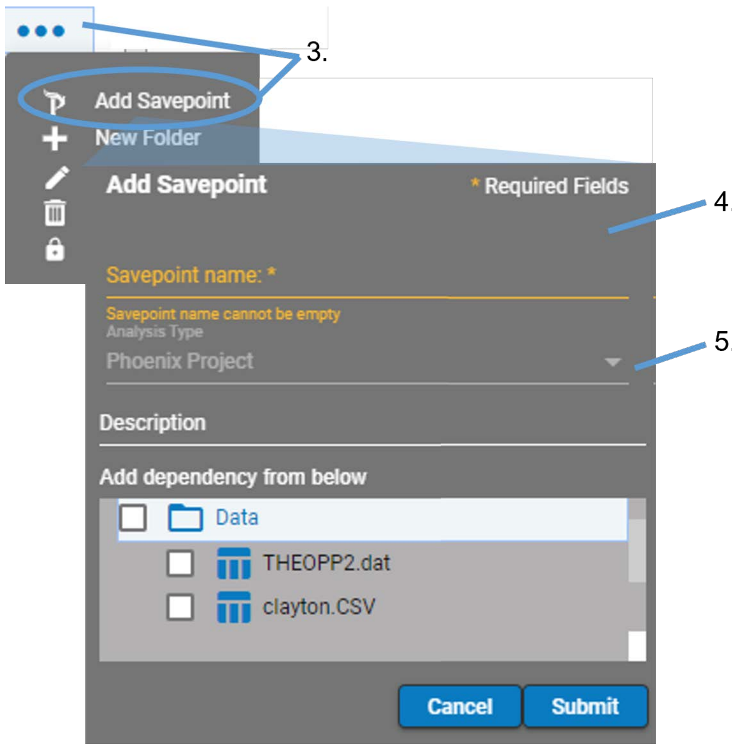
Use the red X button to close the Integral browser dialog when finished.

Adding a savepoint project

Note: *Connection to Integral from Phoenix requires the setting of some preference options. Refer to* “Setting up a connection” *for more information.*

Use Integral’s **Add Savepoint** option to create a new savepoint (Phoenix project).

1. From Phoenix, open the Integral Browser (**Integral > Browser**).
2. Select the savepoint container folder (e.g., Analyses) in which to store the savepoint project.
3. Click the ellipsis for the selected folder and select **Add Savepoint**.



4. In the *Add Savepoint* dialog, enter the title of the Phoenix project in the **Savepoint name** field.
5. Enter information in the **Description** field, if desired.
6. Check the box(es) for the folder(s) to include in the new savepoint. (Click a folder name to expand it and view the contents.)
7. Click **Submit**.

After the project is created in Phoenix, it will contain the data that was selected in the *Add Savepoint* dialog. You can proceed to work with the new project in Phoenix, for example, perform an NCA, add plots, or add some descriptive statistics. When finished with the work in Phoenix, select **Integral > Save** (or right-click the project in the Phoenix Object Browser and select **Save to Integral**). This will display the *Settings* dialog (see “Defining the settings for a savepoint project”) prior to creating a savepoint for the project in Integral.

Defining the settings for a savepoint project

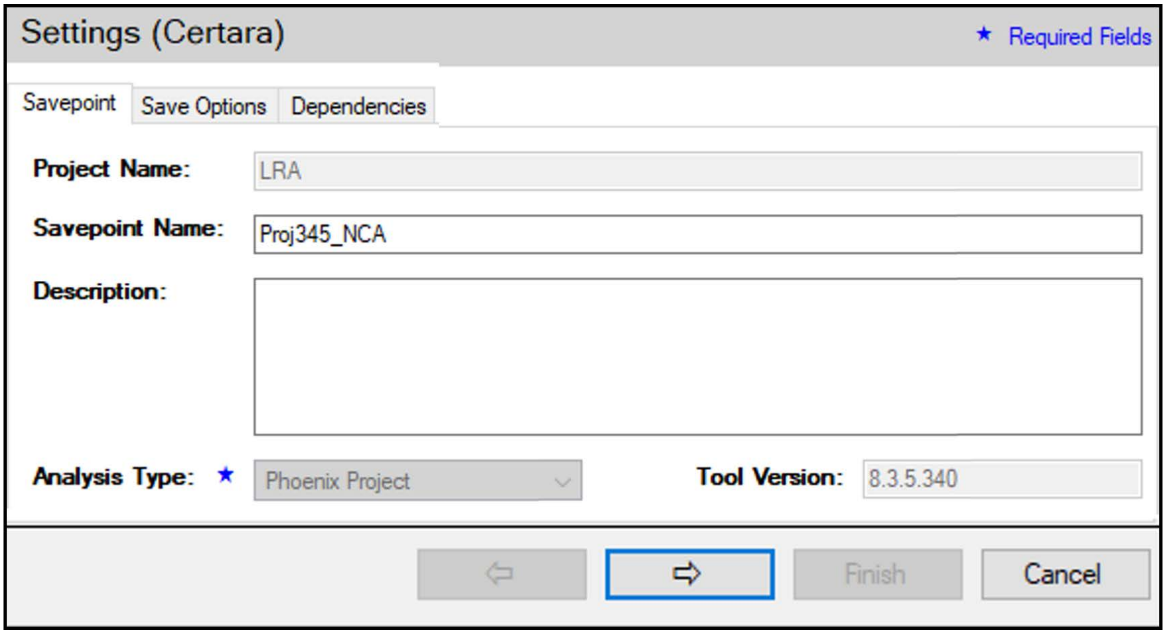
The settings for a savepoint project are divided into three separate tabs:

Savepoint tab

Save Options tab

Dependencies tab

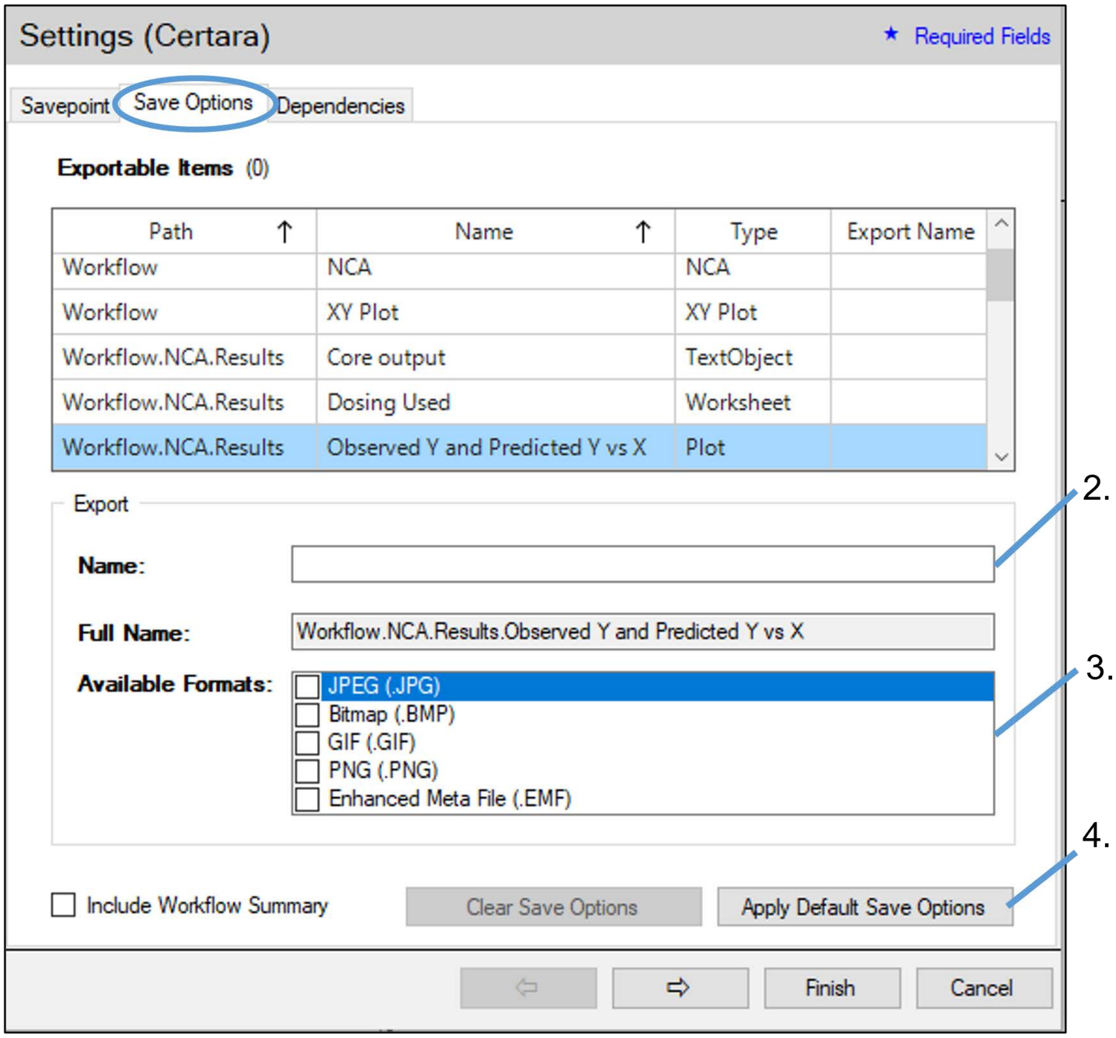
Savepoint tab



In the Savepoint tab, define the savepoint using the available fields and menus. The options available are set up by the administrator.

Save Options tab

1. Click the **Save Options** tab to choose the project items to save to Integral and the formats.



In the **Save Options Settings** tab, each item available for export is listed.

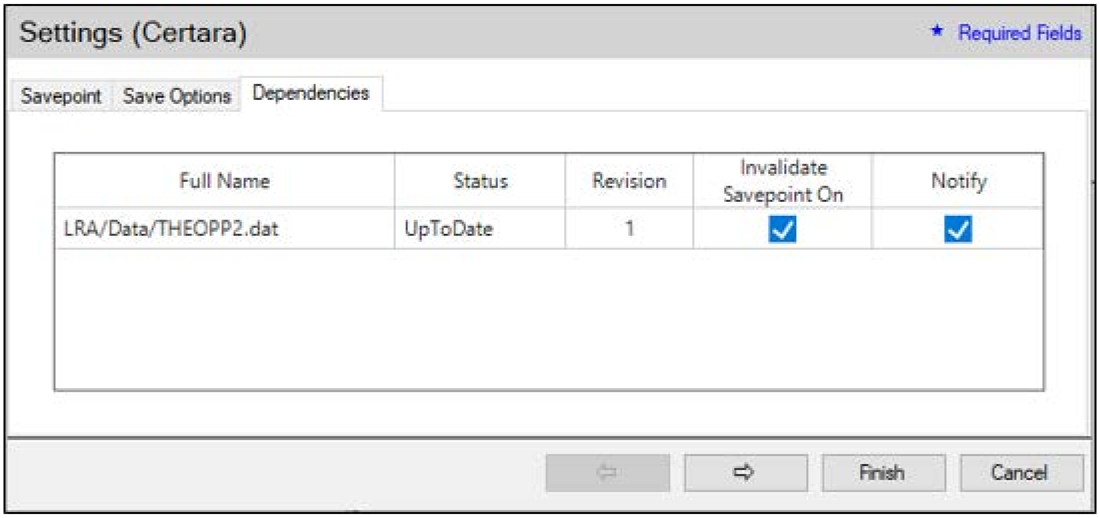
2. If a name other than the one assigned by Phoenix (shown in the **Full Name** field) is to be used when exporting an item, select the item and enter the new name, using the Latin alphabet, in the **Name** field.

Note: *When results have a similar Path, it is important to provide unique names for the export. Otherwise, the save will fail with an error message.*

3. Select the format(s) in which to export the item by checking the box(es) in the **Available Formats** list.
4. Use the **Clear Save Options** button to remove any user-entered names or format settings. Use the **Apply Default Save Options** button to use the default settings for the data type of the selected item. See "Configuring default save options" for details on setting up default save options.

Dependencies tab

1. Click the **Dependencies** tab to set dependency tracking options.



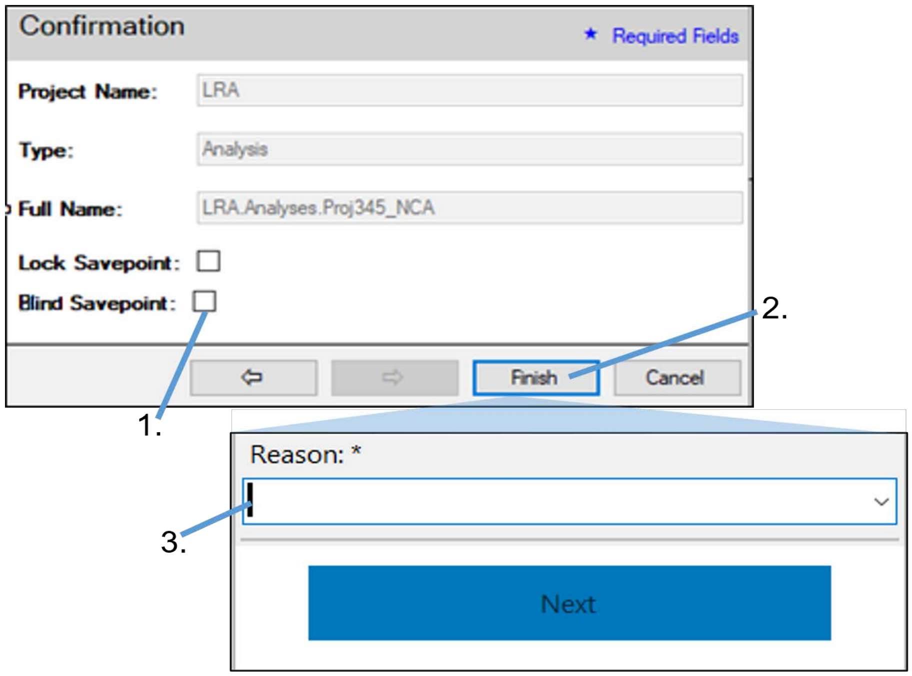
Sub-folders and files in the selected savepoint container folder to which you have read access are listed in the Dependencies tab, along with their status.

2. Select the folders/files on which the savepoint project depends. (Note that selecting a folder selects all files within that folder.)
3. Checking the **Invalidate Analysis On** box for a dependency causes savepoints that reference the object to be marked as out-of-date (i.e., invalidated) when a different version of the object is saved to Integral. Clearing the checkbox will result in a savepoint not being marked out-of-date when a new version is saved to Integral.
4. Check the **Notify** box to send a message when the savepoint is invalidated.

Objects loaded from Integral into Phoenix projects will have their dependencies maintained.

After setting the savepoint properties, save options, and dependency customizations, press the right **Arrow** button to continue to the Confirmation page (see “Confirming changes”).

Confirming changes



1. Check the **Lock Savepoint** and/or **Blind Savepoint** box(es) to lock/blind the savepoint immediately after it has been saved.
2. When ready to save, click **Finish** in the *Confirmation* dialog.
3. In the Electronic Signature popup, enter a statement regarding the new savepoint being added to Integral or select one from the **Reason** menu and click **Next**.
4. Enter your Integral credentials to complete the electronic signature.

The saving process begins, and a progress dialog is displayed. Once the Phoenix project has been saved to Integral, the progress dialog closes.

Note: *When a Phoenix project is loaded into Integral for the first time, a revision is logged. However, a savepoint (i.e., a snapshot of the project) will not be registered. Only after it is loaded into Phoenix from Integral and saved back will savepoints be registered.*

Saving updated projects to Integral

The Integral **Save** and **Save As** options are enabled when an item or savepoint is loaded from Integral into the Object Browser. These options are in the **Integral** menu or on the right-click menu for a project in the Object Browser as **Save to Integral** and **Save As to Integral**.

Using the **Save** option for a project creates a savepoint folder containing the Phoenix project in Integral. A savepoint is a snapshot of the project as it currently exists. At any point in the future, you can take the project back to a prior state by loading the corresponding savepoint.

Note: *If the Phoenix project was generated using the* **Add Savepoint** *option in Integral (available on the savepoint container menu), no savepoint will be generated upon the initial save operation. The* **Add Savepoint** *option does not register the new Phoenix project in Integral, it simply creates the project in Phoenix. Therefore, the project file is not yet associated with any savepoint container or Integral project. You must save the new project to Integral, then any subsequent saving operations will result in savepoints to which the project file is saved.*

Once you load a project from Integral into Phoenix, create a savepoint before making any changes. You can then easily return to the starting point as needed. If you try to create a savepoint after making changes to the project, you are warned about the changes and asked to choose to either save the changes as a new savepoint (**Save As**) or discard the changes and load the latest saved version from Integral (**Get Latest**).

Selecting either **Save** or **Save As** takes you to the *Settings* dialog, where you can make the necessary modifications before saving to Integral. See “Defining the settings for a savepoint project”.

Saving Phoenix Project as a Savepoint

A Phoenix project file that was created outside of Integral and, therefore is not associated with a savepoint, can be saved to Integral as a savepoint. This allows savepoint features to be applied to the Phoenix project and changes can be saved as if it were a savepoint created through Integral.

1. In Phoenix, right-click the Phoenix project in the Object Browser.

   It must have the icon before the name. If it has the icon, it is already associated with Integral.
2. Select **Save Project as Savepoint** from the menu.

   Once your Integral credentials have been verified, the *Save Project as Savepoint* dialog is displayed.
3. All of the repositories to which you have been permitted access are listed in the **Repository** pull-down. Select the one to which the Phoenix project is to be saved.
4. Identify the Integral savepoint container in which to save the Phoenix project as a savepoint by choosing the **Root Folder** first and then selecting the **Savepoint Container**.

   Use to restrict the list of root folders to only the ones marked as favorites. To refresh the list, click .

   Only savepoint containers to which you have appropriate permissions for saving are listed.
5. Click the arrow button at the bottom to proceed to the Settings page.

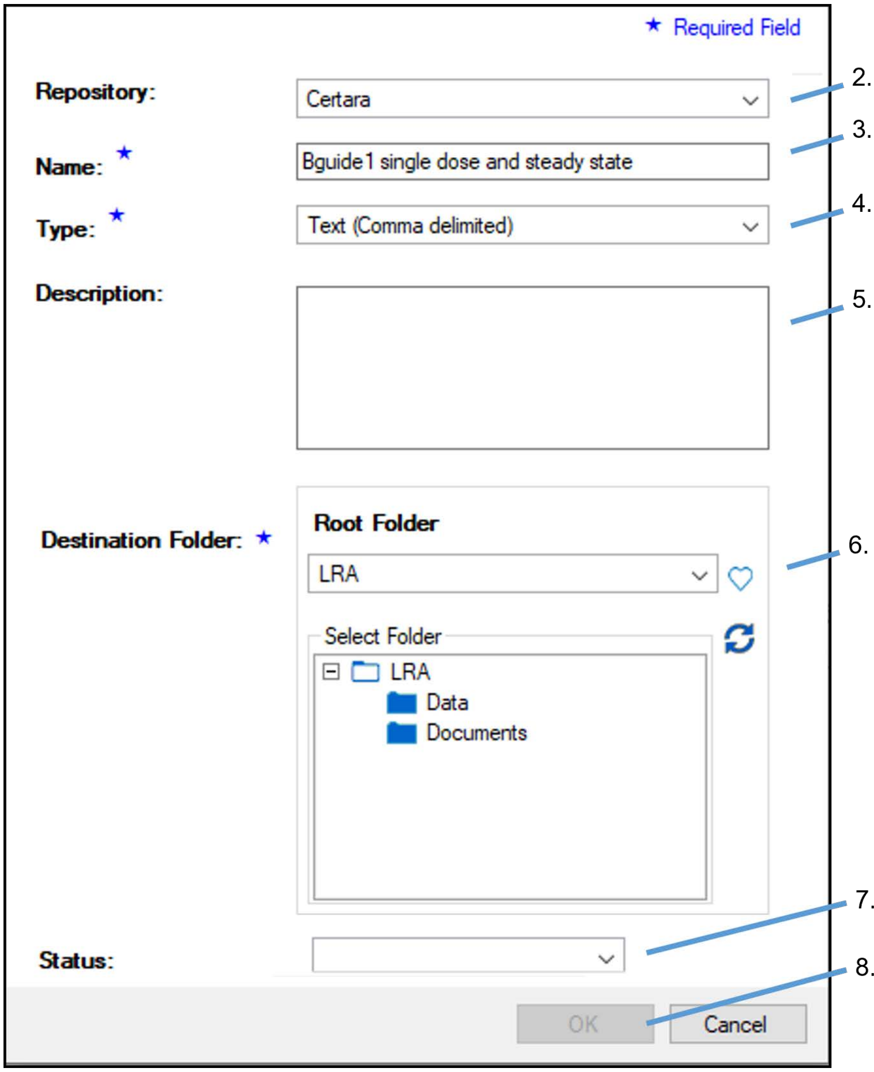
   Refer to the “Defining the settings for a savepoint project” and subsequent sections for further details.

Once the process is completed, the electronic signature submitted (if required), and the Phoenix project saved to Integral, the icon in the Object Browser changes to .

Note: *Users with an “Limited” license can only create eSignature disabled folders.*

Adding items to Integral

1. With the item to save selected in the Object Browser, select **Integral > Add Selected Item** (or right-click the item in the Object Browser and select **Add Selected Item to Integral**).



2. All of the repositories to which you have been permitted access are listed in the **Repository** pull-down. Select the one to which the item is to be saved.
3. Enter a name (**Name**) for the item or use the default name.
4. Select the type of the item being added from the **Type** pull-down.
   a. For **SAS Transport Files**, select the CDISC Model for the file from the menu.
   b. For **Text** (Space, Tab, or Comma delimited), check the box(es) if the file has a header row and/or has a units row.

   Options available when a Phoenix object is selected are:

   - Excel Workbook: Saves the object results worksheets to Integral.

   - Phoenix Template: Saves the object as a .PHXTMPLT file.

- Phoenix Object Settings: Saves the object settings to a .PHXSETTING file.

5. Enter a description (**Description**) of the item.
6. Identify the Integral folder in which to save the item by choosing the **Root Folder** first and then selecting the sub-folder.

   Use to restrict the list of root folders to only the ones marked as favorites. To refresh the list, click .

   Items that do not appear in the **Select Folder** list include: savepoints, locked folders, blinded folders (unless you have View Blind, Create, and Read permissions for that folder), folders where upload=false, and folders where you do not have both Create and Read permissions
7. Optionally choose a **Status** for the item from the menu.

   The values predefined in Integral include **Final**, **Draft**, **Reviewed**, and **Approved**. Other values may be defined by the Administrator.
8. Press **OK** to add the item to Integral.

After entering the information for an electronic signature, if the item already exists in Integral, a pop-up dialog displays asking if the existing file should be overwritten.

Press **Yes** to add the selected item as a new revision of the existing item.

Press **No** to return to the *Add Selected Item* dialog without adding the item to Integral.

When **SAS Transport Files** is selected as the Type, there is an additional step of reviewing the column names to complete the process.

1. In the dialog, enter information that is appropriate for the data being exported:
   – **SAS Variable**: The name of the SAS variable (limited to eight characters).
   – **SAS Label**: The SAS column label header (limited to 40 characters).
   – **Include**: Set to **True** to include or **False** to exclude the column.
   – **Precision Type**: Set the precision type to either **Significant Digits** or **Decimal Places**.
   – **Precision**: The number of significant digits or decimal places.
   – **Data Type**: Select the data type as **Numeric** or **Text**, or leave it set to **Auto** to export the column as it is in Phoenix.
   – **Format**: The .NET format to use for numeric data. G displays values in fixed-point or scientific notation (e.g., G, G4, G8). E displays values in scientific notation, followed by a precision specifier (e.g., E, E4, E8). F displays values in real numbers (e.g., F, F4, F8).
2. Optionally enter a **Data Set Name**.

   This name is internal to SAS and independent of the actual file name.
3. From the **Data Set Standard** menu, choose the standard version (**Version 5,6**, **Version 8**, or **Version 9**).
4. To save the SAS export settings in the Documents folder, press **Save Settings**.

   The settings are saved as a text file and named after the dataset name.

5. To load the SAS export settings from the Documents folder, press **Load Settings**, select the SAS export settings file in the Documents folder, and press **Select**.
6. Press **OK** to save the worksheet as an SAS Transport File.

Loading Integral items in Phoenix

Open an Integral savepoint project in Phoenix

1. In Phoenix, open the Integral Browser (**Integral > Browser**).
2. In the Integral Browser, click the ellipsis button for a Phoenix project file, or a savepoint folder with its “Analysis Type” property set to “Phoenix Project” that contains a project file, and select **Load Savepoint**.

   (If the selected Phoenix project file is not in a “Phoenix Project” savepoint folder, use the **Load Project** option in the ellipsis menu.)

When a project is loaded from Integral, the right-click menu in Phoenix contains additional options. These include:

Check State: Checks to see if the version of the project loaded in Phoenix is identical to the one stored in Integral and displays a message stating the findings.

Refresh from Source: Reloads the project with the version stored in Integral.

Open other items

From the Integral Browser (**Integral > Browser**), click ellipsis button for an item that Phoenix can read and select **Load Selected Item**.

If there are multiple projects open in Phoenix, a dialog will prompt for selecting the desired project.

Items loaded into Phoenix using the Phoenix Integral Browser are read-only, unless they are detached. (See “Detaching an item in Phoenix from Integral”.) Also, if there are dependencies that are out-of-date, a request is displayed asking if those dependencies should be updated.

Note: *You can also load a previous savepoint version from Integral to Phoenix through the Savepoint section of Integral’s History tab.*

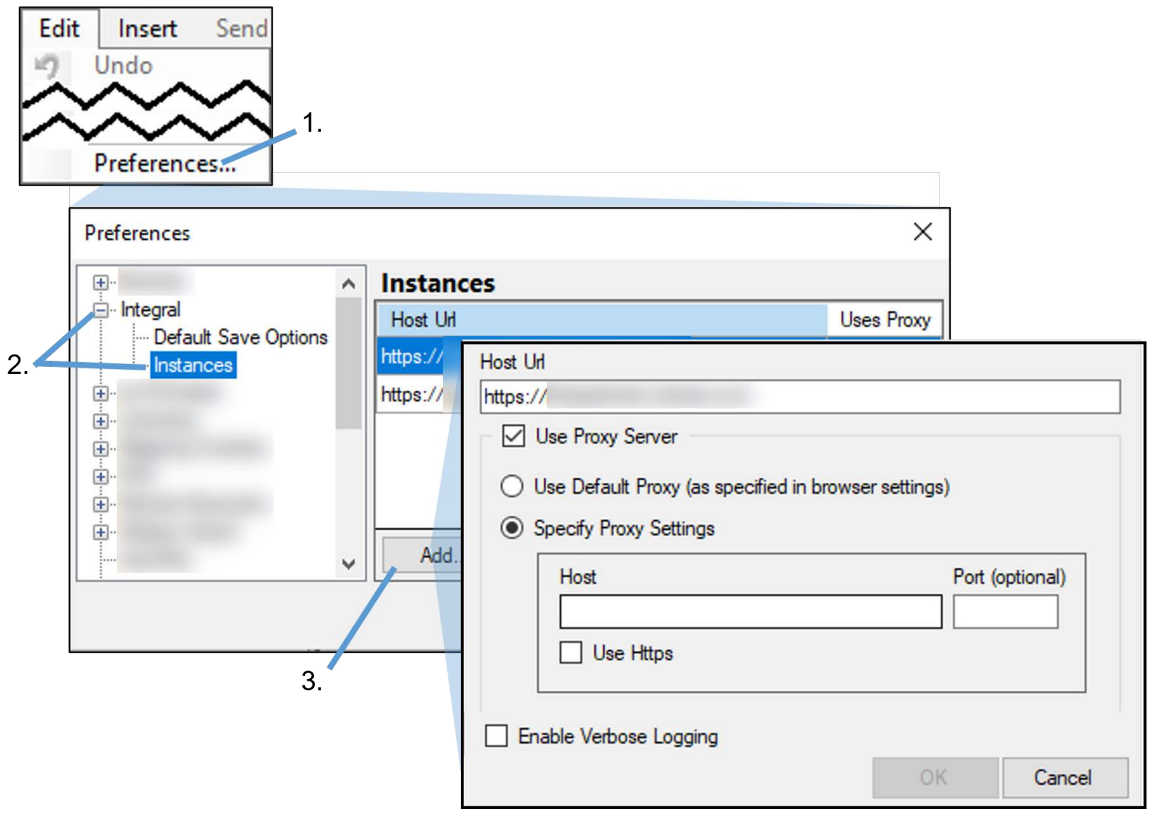
Detaching an item in Phoenix from Integral

When an item from Integral is loaded into Phoenix, it is read only. You can break the connection with Integral using the **Detach** option. When an item is detached from Integral, the source data information is cleared, and modifications can then be made without affecting the item stored in Integral. It also allows sharing the project with a user who does not have Integral installed.

From Phoenix, right-click the loaded Integral item and select **Detach Integral Item**.

Setting up a connection

The Integral connection information must be provided before Phoenix can connect to Integral.



1. Select **Edit > Preferences.**
2. In the *Preferences* dialog, click the (**+**) sign beside Integral and select **Instances**.
3. Click **Add** to display the *Integral Configuration* dialog and enter the configuration properties.

   To connect directly, enter the address to the web site in the **Host Url** field.

   To connect via proxy, check the **Use Proxy Server** box and then choose whether to **Use Default Proxy** or **Specify Proxy Settings** by entering the **Host** and **Port** information to access a different proxy. (Check the **Use Https** box if this is an HTTPS proxy server.)
4. Click **OK** to save the new Integral instance.

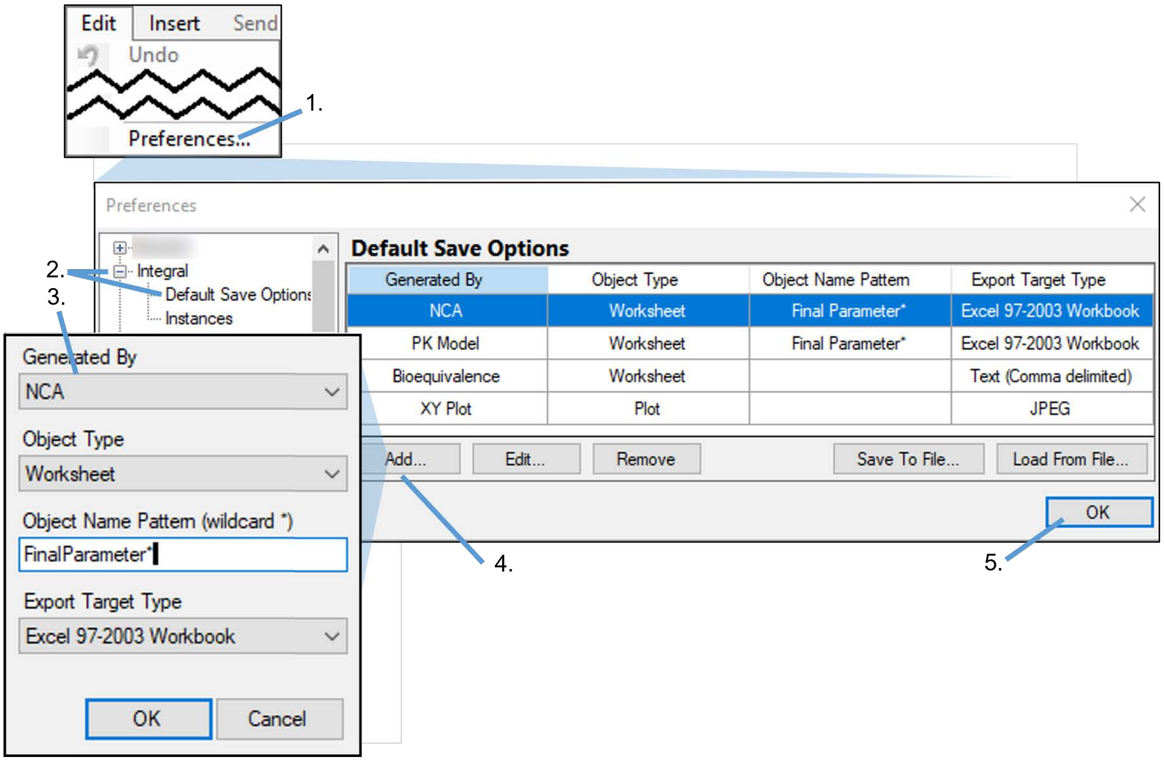
To edit an existing Integral instance definition, select it in the *Preferences* dialog and click **Edit**. Then make the modifications in the displayed dialog.

To delete the instance definition, select it in the *Preferences* dialog and click **Remove**.

Note: *Users cannot edit or remove instances to which they are currently connected.*

Configuring default save options

The default save options can be configured in the Integral section in the *Preferences* dialog. The default save options determine how operational object output is displayed in Integral. An operational object's output should be displayed when it is useful for data mining or reports, or if the output is loaded individually into another project to be re-used or shared.



1. Select **Edit > Preferences**.
2. In the *Preferences* dialog, select **Integral > Default Save Options**.
3. To add a default save option, click **Add**.

   To edit an option, select it and click **Edit**.
4. In the *Default Save Option* dialog, select the Phoenix operational object from the **Generated By** pull-down menu.
5. From the **Object Type** pull-down menu, choose the type of object to be saved.
6. In the **Object Name Pattern** field, enter a pattern to look for in the name of the object to be saved.
7. From the **Export Target Type** pull-down menu, select the format for the exported file.
8. Click **OK** to complete the save option definition.

   For example, the previous image shows a new default save option being defined involving NCA. When the program encounters an NCA or a PK Model generated worksheet with a name that starts with "Final Parameter", it is to be exported to Integral as an Excel workbook. Similarly, any Bioequivalence worksheet is to be saved as a text file (CSV), and any plot generated by the XY Plot object is to be saved to Integral as a JPEG file.
9. To remove a save option, select the option and click **Remove**.

10. To save the defined options to an XML file, click **Save to File**, then select a location and enter a filename in the dialog. To load options from a file, click **Load from File**.

Saving the default save options to a file is a useful way of synchronizing settings across an organization.

Note that these are the “default” options and, as such, can be overridden in certain circumstances. For example, the use of a Phoenix template, in which save options have been specified, will override the default save options defined in the Phoenix *Preferences* dialog. The same is true for previously saved Analyses – the save options settings in the analysis take precedence over the default settings.

You can clear the save settings from the template and apply Integral’s default save settings by using **Clear Save Options** button in the Save Options tab, followed by the **Apply Default Save Options** button. After doing this, the template can be saved to integral as a new revision and subsequent usages of the template will have updated save options.

Using PKS scenarios and Integral

If you have the legacy PKS plugin, you can continue to use it to update data and scenarios. Any changes made through the PKS plugin will be synchronized with the information in Integral. However, the reverse situation is not true. Change made through Integral will not be synchronized to PKS.

PKS scenarios can be opened in Phoenix through the Integral plugin by going to the corresponding project and loading the desired scenario. Phoenix will open the scenario as a project. Note that a new version of the scenario cannot be saved.

Integral Client Application

The Integral Client Application is a synchronization tool between your local data and data uploaded to Certara Integral. Information on the following topics is available:

Connect Integral with Local Directory

User interface description

Set the local directory

Sync Integral root folder and contents to local directory

Sync new local folders and files to Integral

Sync Savepoints to Integral

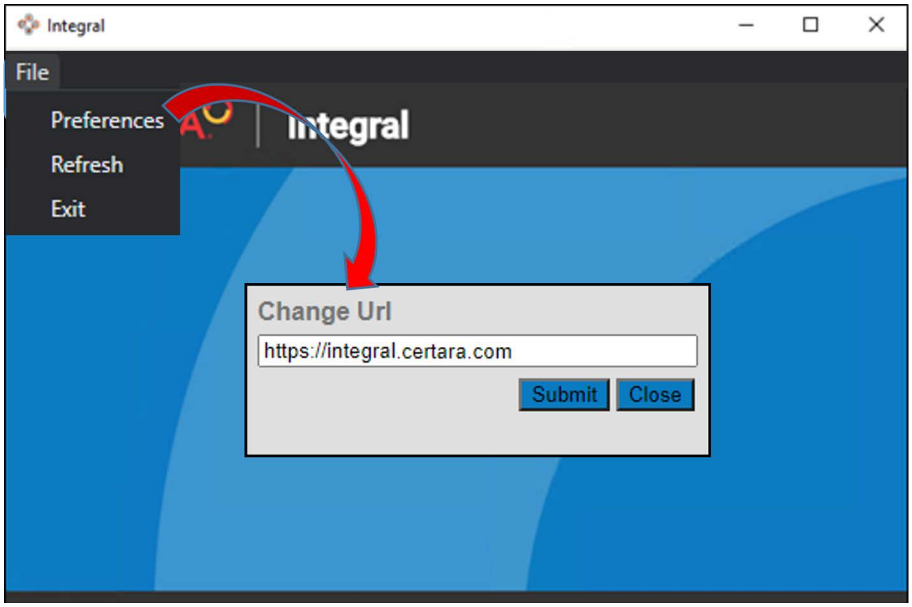
Show dependencies

For more information on Integral itself, see “Learn About Integral”.

Connect Integral with Local Directory

If the URL for Certara Integral was not specified during installation of the Client Application, you will need to do the following steps to access the application.

1. Double-click the Select **File > Preferences** from the menu.

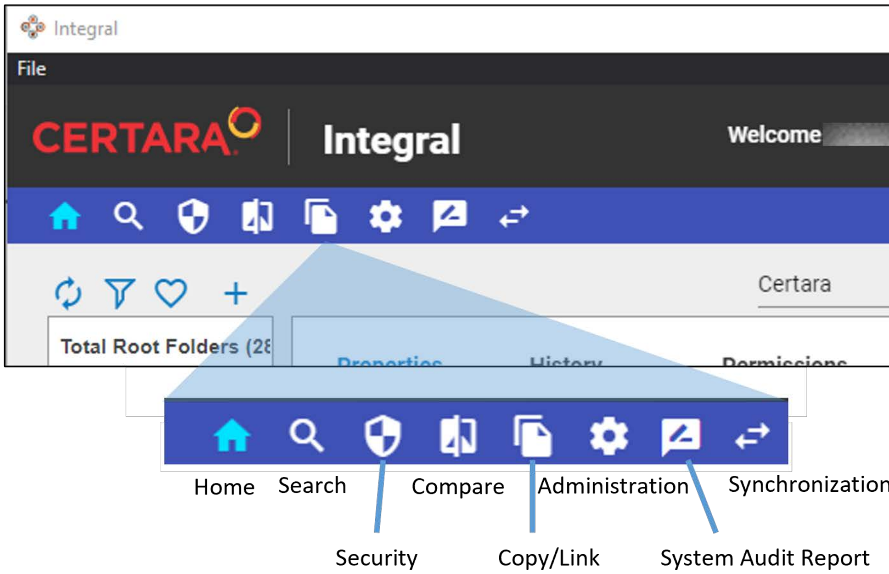


2. In the *Change Url* pop-up, enter the URL for Certara Integral:

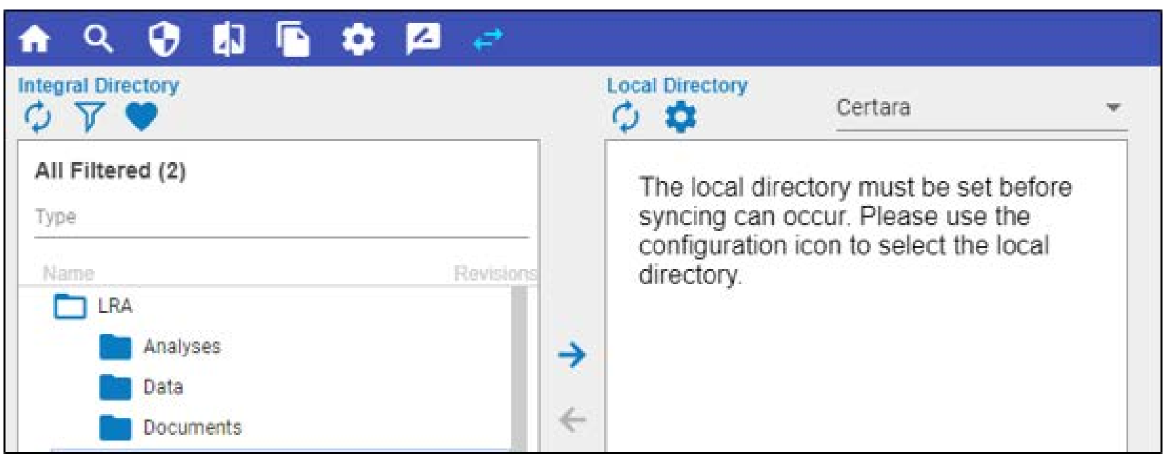
   `https://integral.certara.com/`

   and press **Submit**.
3. In the *Sign In* pop-up, enter your Integral username and password and click **Sign In**.

User interface description



Click to view the Sync panels.

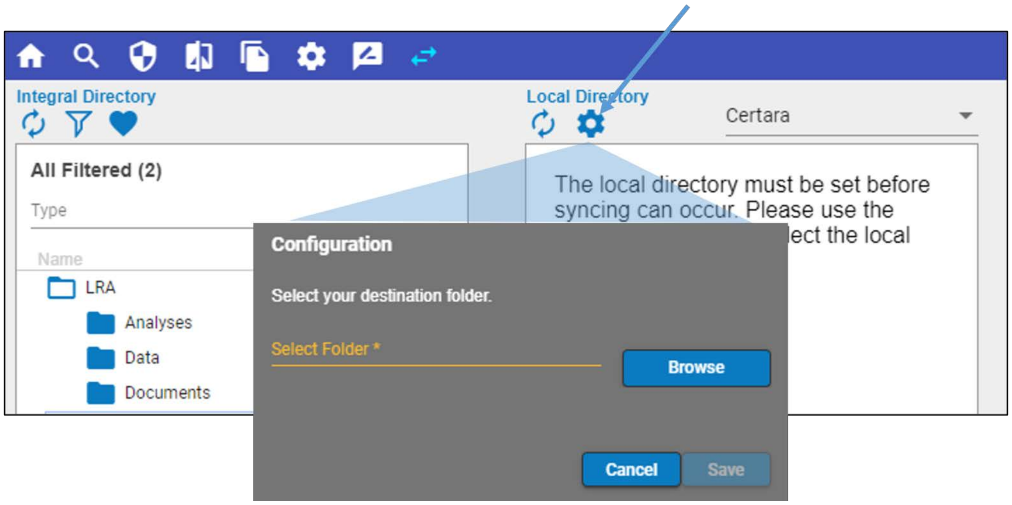


There are two panels, the left displays the Integral directory contents and the right shows the local directory content (once a local directory is specified (see “Set the local directory”).

Set the local directory

A local directory must be identified before any synchronization can occur. Do the following steps to set the local directory:

1. Click  to view the Sync panels.
2. Click  to display the Configuration popup.



3. Specify the local folder to use as the Integral local directory by either typing directly in the **Select Folder** field or click **Browse** to use the file browser.
4. Click **Save**.

Sync Integral root folder and contents to local directory

Only root folders are able to be synchronized from Integral to the local directory. If files and folders were modified within the root folder structure, the entire root folder will need to be synchronized from Integral to the local directory for the updates to show in the local directory.

1. Click .
2. In the Integral Directory list on the left, locate and select the root folder and click .

   Or

   Click and select **Sync To Client**.
3. In the *Synchronize to Local* popup, click **Sync** to confirm the action.

Note: *If there is new content (file or subfolder) in both Integral and the local directory, and you want to keep the local new content, be sure to synchronize the local directory with Integral first. Otherwise the local new content will be replaced by the content from Integral.*

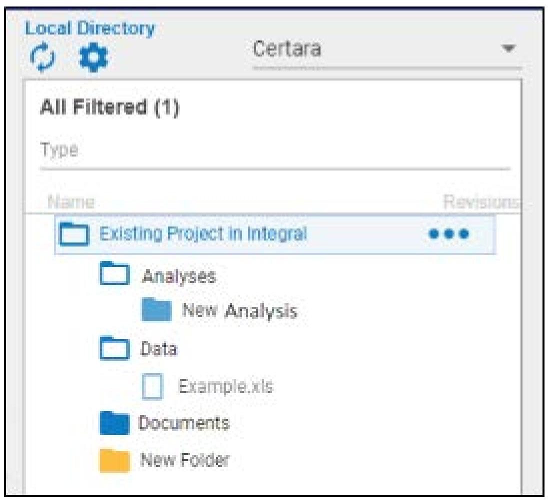
4. Click **OK** once the synchronization is complete.

Sync new local folders and files to Integral

Synchronization from the local directory to Integral can happen at any level, root, folder, subfolder, file, etc. For savepoint enabled folders, the synchronization will happen at the savepoint folder level. It is best practice, when synchronizing a savepoint enabled folder, to synchronize at the savepoint folder level and not at a higher level (e.g., a parent or root folder). This allows access to options such as setting the type, choosing dependencies, etc.

Note: *For root folders to synchronize, both the folder and structure must be created in Integral first. This is because Integral needs the folder type to be set before it synchronizes and this can only be done within Integral itself. Similarly, if the name of a root folder is changed locally, it must also be changed in Integral before synchronization will be successful.*

When files are added to the local directory, they are listed in the Local Directory panel using a lighter blue color and gray title. When folders are added to the local directory, they are listed as either a solid yellow icon (indicates that the folder does not have an associated folder type) or a light blue icon (has an associated folder type but is not yet synchronized with Integral). The folder type must be assigned to a folder with a yellow icon before it can be synchronized with Integral.



Folders and files that have been synchronized with Integral display a darker blue color icon and the title is black.

To assign a folder type

1. Click ••• and select **Set folder type**.
2. Select the **Folder Type** from the pull-down.
3. Enter a **Description** in the field.
4. Click **Apply**.

Once the type is set, the folder icon changes to the lighter blue color, indicating that it is now able to be synchronized with Integral.

To synchronize to Integral

1. Select the new folder or file and click ←.

Or

Click next to the new folder or file and select **Sync to Integral** from the menu.

2. Enter the electronic signature credentials required to perform the synchronization.

Note: *If the folder is in a savepoint container folder (e.g., an Analyses folder), there are additional steps required for uploading. See* "Sync Savepoints to Integral"

If any files are currently being used by another program (e.g., Excel), a warning message states that there are locked files preventing successful synchronization. (However, if a file, such as a .DAT or .TXT file, is simply open in a program like Notepad, the warning is not presented.)

Once the Integral update is complete, click above the Local Directory panel to refresh the list. Notice that the icons change to the darker blue color and the titles are now black after synchronization.

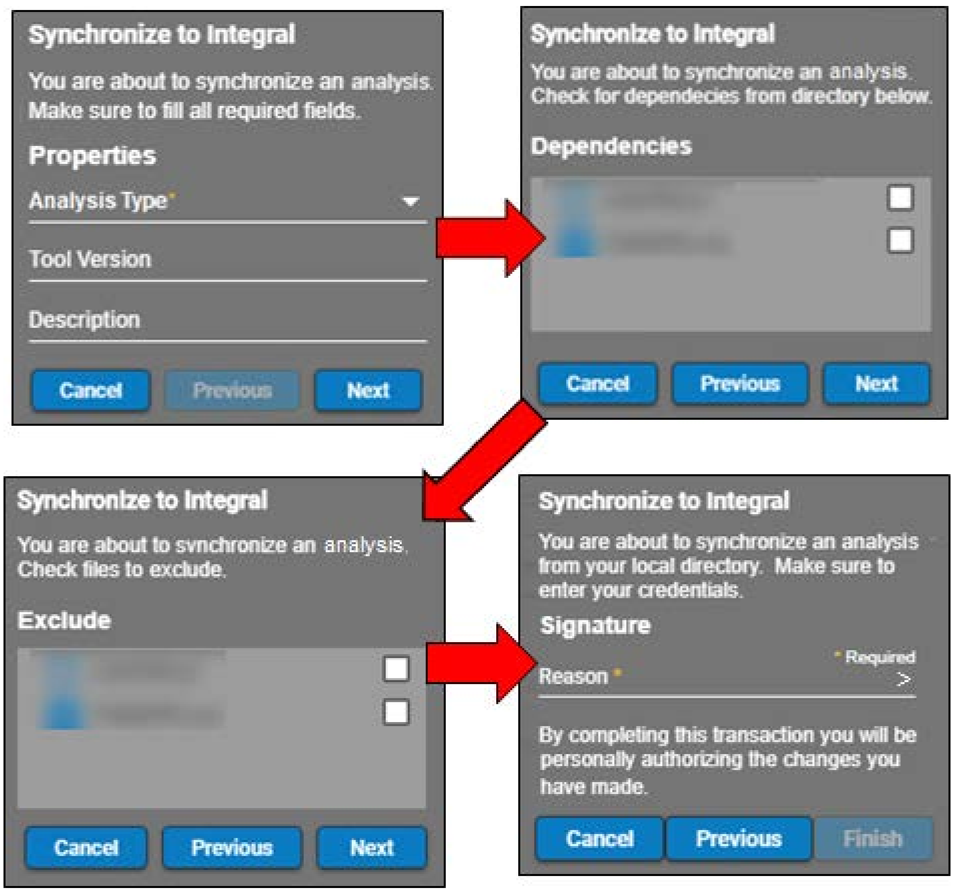
Sync Savepoints to Integral

Synchronization of a savepoint happens at the folder level. If a savepoint contains multiple files/project folders, after each synchronization, the version number will advance for the files/project folders with updated contents. Version numbers will remain unchanged for files/projects folders with no updates.

1. Select the savepoint folder and click ←.

   Or

   Click ••• next to the modified folder and select **Sync to Integral** from the menu.



   The *Synchronize to Integral* wizard walks through the necessary steps required to set up the synchronization.

2. Enter the appropriate properties for the savepoint and click **Next**.
3. Check the boxes for any other savepoint enabled folders upon which the savepoint being uploaded depends and click **Next**.
4. Check the boxes for any local subfolders that should be excluded from the synchroniza-tion with Integral and click **Next**.

   Selecting a folder will exclude all files/subfolders within it.

5. Enter the reason for the synchronization or select one from the menu and click **Finish**.

6. Enter your electronic signature credentials and click **Next** to perform the synchronization.

The synchronization begins and a new savepoint will be created (if the synchronization is successful). A popup will inform you when the synchronization has completed.

7. Click **Close**.

If the synchronization does not complete successfully, a popup message is displayed and the synchronization does not occur.

Show dependencies

Click  next to the savepoint folder and select **View Dependencies** from the menu.

A *Dependencies* popup lists the name and revision number of the items on which the savepoint depends. It also lists the latest revision number available for that item, so you can quickly identify the items that need to be updated with the latest revisions.

Glossary

Actual time

Time that a dose or observation actually happened (in UTC), as opposed to ***nominal time***. See also Relative time and Clock time.

Analysis

Any type of procedure that results in information that describes a set of data.

Analytical method

The type of assay that was performed to assess the concentration of drug (or other compounds) in a sample, which is usually collected from blood, plasma, or urine.

Arm

Generally refers to a treatment or combination of treatments administered to a group of subjects or patients. For crossover studies, arm is sometimes used to denote a sequence group (a group of patients that received a particular sequence of treatments).

Assay

Analysis of a substance or mixture to determine the quantity of its constituents or to detect the presence of a substance.

Audit trail

A report that contains all additions, changes, and deletions made to the study data, units, observation data, and dosing data from Integral.

Baseline covariate

An independent variable in a Drug model, sampled before active treatment begins in a study.

Blinding type

Indicates which individuals involved in a study are allowed to see the treatments associated with data that is collected.

Clock time

Time expressed as a date and/or time (in UTC), rather than relative to first dose or start of study. See also Relative time.

Column

A display of the attributes of each subject and for each subject data collection point in a study. Columns can also contain observation data, reasons for changing data (for the audit trial), etc.

Compound

The drug molecule under study. A compound may include one or more Formulation of that drug. The term is used in Integral to group ***studies*** that are investigating the same molecule.

Conversion factor

Part of an equation that enables conversion of data from one unit to another. For example, to convert from grams to milligrams, multiply the number of grams by a conversion factor of 1,000 to get the number of milligrams.

Covariate

An independent variable in a Drug model. Generally, some subject characteristic of interest, such as age or blood pressure. See also Baseline covariate.

Database

A file or set of structurally-related files that contains data. May contain one or more data sets. For example, in Integral, users log on to one ***database***, in which they may access any number of data sets.

Dropout

Event at which a subject’s participation in a study ends.

Drug model

Any combination of population PK/PD model(s), parameter and baseline covariate distributions, disease progress models, placebo models, adherence models, etc. A drug model may include one or more Structural model.

Duration

Length of an infusion dose.

End time

Time that a dose ends (for example, ***relative actual end time***, ***relative nominal end time***, etc.).

Event

Thing that happened at a specific time: a single dose, observation, or unscheduled event. See also Unscheduled event.

Form

Description of the physical attributes (i.e., an indication) associated with a product (i.e., a molecule).

Formulation

The point of dose input into a ***structural*** (PK/PD) ***model***.

Formulation context

The dilution of the formulation.

Grid

A grid control, displaying data in a worksheet.

Group

Short for Treatment group.

Indication

An effect that is of interest produced by the application of a molecule. The FDA approves an indication, not a molecule. For example, the FDA approves Drug X for treating disease Y. The FDA does not approve Drug X in general.

Model

A set of mathematical equations that describe the underlying process of interest.

Model data

The information used to describe the process presented by the study data.

Nominal time

Time specified in the protocol for a dose or observation, as opposed to Actual time that a dose or observation was taken. Expressed relative to the first dose, or the start of the study, phase, or period.

Observation

A single piece of data for a subject collected at a particular data collection point. Observations can be explained, filtered, and analyzed by several defined dimensions. Each observation has associated audit information.

Observation data

Time-dependent events that contain some form of measured values. The data collected during the study.

Parameter

Variable defining the shape of a ***structural model***.

Phase

A specific component of a clinical trial, such as lead-in or treatment.

Plot

A graph or chart of data.

Portfolio

A collection of molecules.

Product

Chemical entities (i.e., a molecule) under investigation in a study having an associated form.

Profile

A collection of data points described by a collection of unique identifiers, which uniquely identify subject responses for a particular situation.

Property

Column properties are settings for a data column, i.e. column name, type and default units.

Protocol

Planned activities in the trial, including: enrollment, lead-in phase windowing, study design structure, subject assignments, and scheduled treatments and observations for the lead-in, active and follow-up phases of the study.

Relative time

Elapsed time since the first dose or the start of the study, period, or phase. As opposed to Clock time. Uses: ***relative nominal time*** or ***nominal_time_relative***, ***relative actual time*** or ***actual_time_relative***, ***relative actual end time*** or ***actual_end_time_relative***. See also Nominal time and Actual time.

Savepoint

An analysis saved to Integral that requires an e-signature and represents a snapshot of the analysis and its results at that point in time. Savepoints are generated through the Integral Plugin for Phoenix or the Integral Client Application and are uniquely versioned by Integral automatically.

Sequence

Short for ***treatment sequence.***

Simulation

Generally, a Monte-Carlo simulation.

Sort keys

A collection of unique database fields that distinguishes one set of data points from another (such as a plasma level profile). The difference between the sets of data points usually ascribes certain different attributes to the underlying processes being studied. For parallel trials, treatment and subject are generally the sort keys used to capture individual subject data, while treatment, period (or phase), and subject are generally used for crossover trials.

Structural model

The set of functions defining the shape of a model (such as a structural PK, PD, or PK/PD model). Does not include parameter distributions.

Subject Identification

The ability to uniquely identify subjects is crucial to the functionality of the system. Since this application will be receiving data from many sources in many formats, no one unique identifier exists between the systems. Integral requires users to define a set of fields (data elements) that, taken together, can uniquely identify a subject for a study.

Subject identifier

That which uniquely identifies a subject from any other subject in a study.

Treatment

Combination of one or more drugs given at specific doses and times/schedule.

Treatment group

Generic term for a ***treatment arm*** (in a parallel study design) or ***treatment sequence*** (in a crossover or Latin square study design).

Unit

The unit of measurement associated with sample data that are collected.

Unit category

A group of units that measure the same thing (length, time, concentration, etc.).

Unscheduled event

A PD ***event*** with some probability of occurrence, such as an adverse drug reaction or subject dropout.

Workbook

A file that contains one or more ***worksheets***.

Worksheet

A page in a ***workbook*** that contains a data grid.

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