CVM eSubmitter New File Attachment Quick Guide

I. Introduction

The CVM eSubmitter application has always provided the capability for sponsors to include external file attachments within responses to questions contained within a submission form. These external file attachments are included within the submission package generated by CVM eSubmitter and then transmitted by the sponsor to CVM.

Experience has demonstrated that the current approach for including external files within a submission is problematic to both industry sponsors and CVM reviewers. The goal of this quick guide is to point out the current limitations, provide an overview of the new features, describe in detail how to use each new feature, and provide practical use case examples.

Note: The improvements referenced within this document are currently only available within newly created Office of New Animal Drug Evaluation (ONADE) submissions. Existing ONADE submissions, including ONADE submission initiated before the release of the new features, as well as submission prepared for other CVM Offices will still use the older file attachment approach.

II. Limitations with the Current Approach

The primary limitations are as follows:

- Only one external file can be selected and attached to a response at a time, which is burdensome to sponsors when a submission requires the inclusion of many files (e.g., study information)

- External files are automatically renamed using non-descriptive identifiers upon receipt by CVM to avoid potentials issues with duplicate files names, which impacts the ability of CVM reviewers and statisticians to easily identify a file by name

- File names containing invalid special characters that cause a failure during receipt processing require the submission to be corrected by the sponsor and resubmitted

III. Overview of New Features

To correct these shortcomings, ONADE has implemented several improvements regarding how external files are attached to a response and how these files are managed within the submission.

An overview of the new and improved features are as follows:

- Ability to quickly select one or more files in response to a question

- Ability to import large numbers of files into a submission from a folder

- Ability to identify file names with invalid special characters so that they can be corrected prior to the packaging of a submission

- Inclusion of a new Submission File List Manager that provides many new capabilities to simplify common tasks

- Ability to maintain sponsor given file names after receipt by CVM and through the review process

To incorporate these improvements, some fundamental changes were necessary with respect to how attached files within a submission are managed. Previously, the determination of uniqueness of a file was the combination of file name and file location (i.e., including drive and folder path). In addition, a descriptive title was required. Now, uniqueness is determined solely by file name and the descriptive title is optional.

Requiring each file name to be unique within a submission is a new constraint. However, to mitigate additional burden, the new Submission File List Manager includes the ability for the sponsor to provide a revised file name to correct duplicate and invalid character issues without having to physically rename files on the local file system. When provided, the revised file name is used to name the file within the submission package.

IV.   How to Use the New File Attachment Features

There are two primary eSubmitter activities involving external files included within a submission:

1. Attaching of files in response to questions

2. Review and management of the overall submission file list prior to packaging

Note: For additional information on the types and formats of files supported within CVM eSubmitter, see the "CVM eSubmitter File Specification Quick Guide", accessible via a link within each submission form that supports file attachments.

A.   Attaching a File to a Response

There are two types of file attachment questions within eSubmitter, single file attachment and multi-file attachment. See below for an example of each question type.

Single and Multi-File Attachment Question Samples
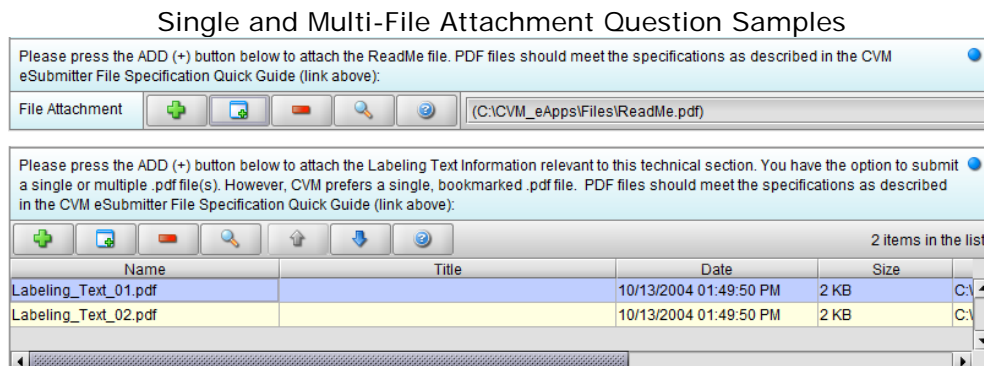
The capabilities involved when attaching files is similar across file attachment question types. There are several actions that can be performed from a file attachment question, these actions are described in the following sub-sections. Any differences between question types will be reflected in the sub-section.

1. Add File from File System Action

Activating the "Add File from File System" action displays a file system browser dialog that allows for navigating the local file system to select one or more files to be attached. The selection behavior is dependent on the question type. Single file attachment questions only allow for single file selection, while multi-file attachment questions support multi-file selection using standard multi-select capabilities (i.e., Shift-Click to select a beginning and ending range, Ctrl-Click to select multiple files individually). The types of files that can be

selected is dependent on the individual question. See below for examples of the system browser dialog in single select and multi-select modes.

File System Browser Dialog with Single and Multi-File Selection Examples
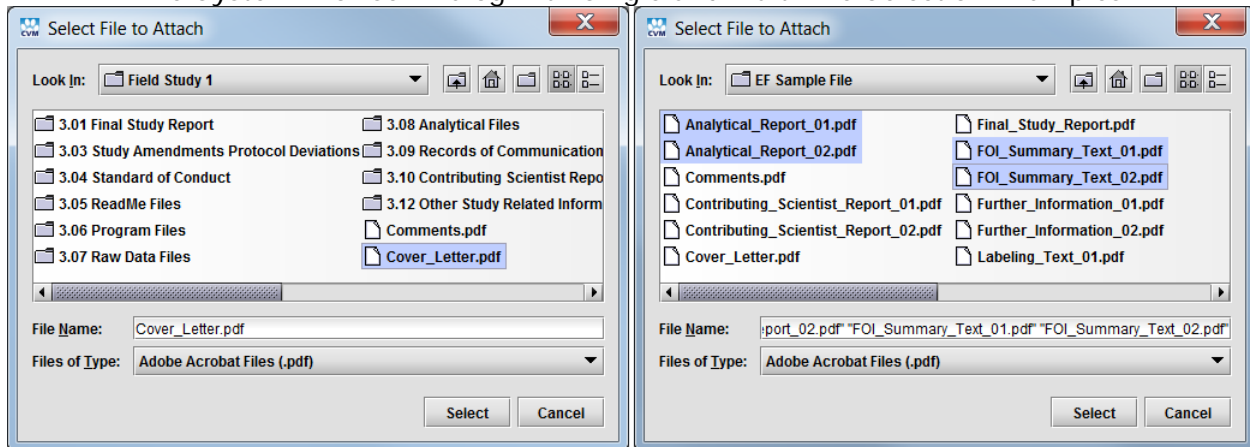
2. Add File(s) from Submission List Action

Activating the "Add File(s) from Submission List" action displays the Submission File List Manager dialog that allows for navigating the existing list of files that are already part of the submission to select one or more files to be attached. The selection behavior is dependent on the question type. Single file attachment questions only allow for single file selection, while multi-file attachment questions support multi-file selection using standard multi-select capabilities (i.e., Shift-Click to select a beginning and ending range, Ctrl-Click to select multiple files individually). The types of files that can be selected is dependent on the individual question.

See section IV.B Managing the Submission File List for details on using the Submission File List Manager to select one or more files in response to a question.

3. Remove File Action

Activating the "Remove File" action removes the selected file from the question response. For single file attachment questions, it clears the file attachment response, while for multi-file attachment questions it removes only the selected file.

When a file is removed from a question response, it is not physically deleted from the local file system, but only no longer associated to the question. However, it still resides within the submission file list for use within another response, if needed.

4. View File Action

Activating the "View File" action opens the file for previewing the contents. The assumption is that sponsors will have Adobe Reader, or another application that supports viewing PDF files installed.

However, for other types of files (e.g., XML, SAS), there is no guarantee within eSubmitter that there is applicable software installed on the workstation. The best eSubmitter can do is pass the file reference to the workstation operating system (e.g., Windows) and allow it to determine the default application to open based on the file type presented. Since the

operating system does not inform eSubmitter regarding the success of opening the file, eSubmitter displays the following warning message to the user prior to the attempt to open the file.

eSubmitter Warning Message when Attempting to View Non-PDF files
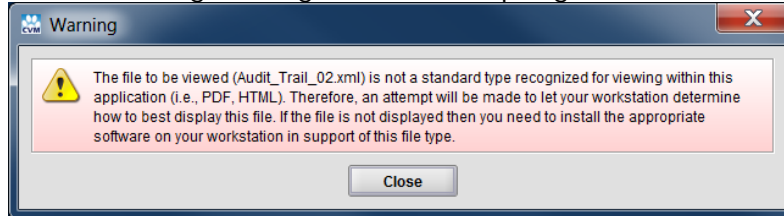
5. Move File Up and Down Actions

Activating the "Move File Up" and "Move File Down" actions allows the user to reorganize the order of files displayed within a multi-file question response.

6. Display Help Action

Activating the "Display Help" action opens this quick guide.

7. Invalid File Status Indicator

In addition to the standard missing data check, file attachment questions also reflect a validation check of the individual file for a single file attachment question, or multiple files for a multi-file attachment question included within the response. A file validation check is based on two criteria, invalid characters in the file name and the inclusion of duplicate file names within the submission file list. If either of the two validation criteria are cited, the question displays an invalid file indicator, see the red/white "X" icon along the right side of the question text below.

Sample File Attachment Question with Invalid File Indicator
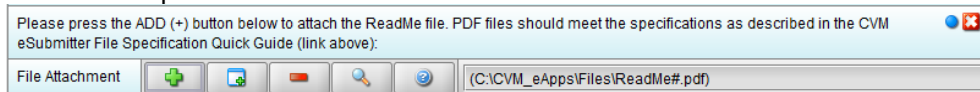
Like the missing data check, file name validation issues are also reflected as a question mark within the node/section of the form outline control, as well as the missing data/validation report. A submission cannot be packaged when validation issues exist within the submission file list.

To correct file name validation issues, either click the invalid file indicator or select the "Submission File List" option from the "Tools" menu to open the Submission File List Manager. For details on how to correct invalid file name issues, see section IV.B Managing the Submission File List.

B. Managing the Submission File List

The Submission File List Manager supports the following primary uses:

- Prefilling the submission file list prior to associating files to question responses, allowing files to be selected from the submission list in place of navigating the file system
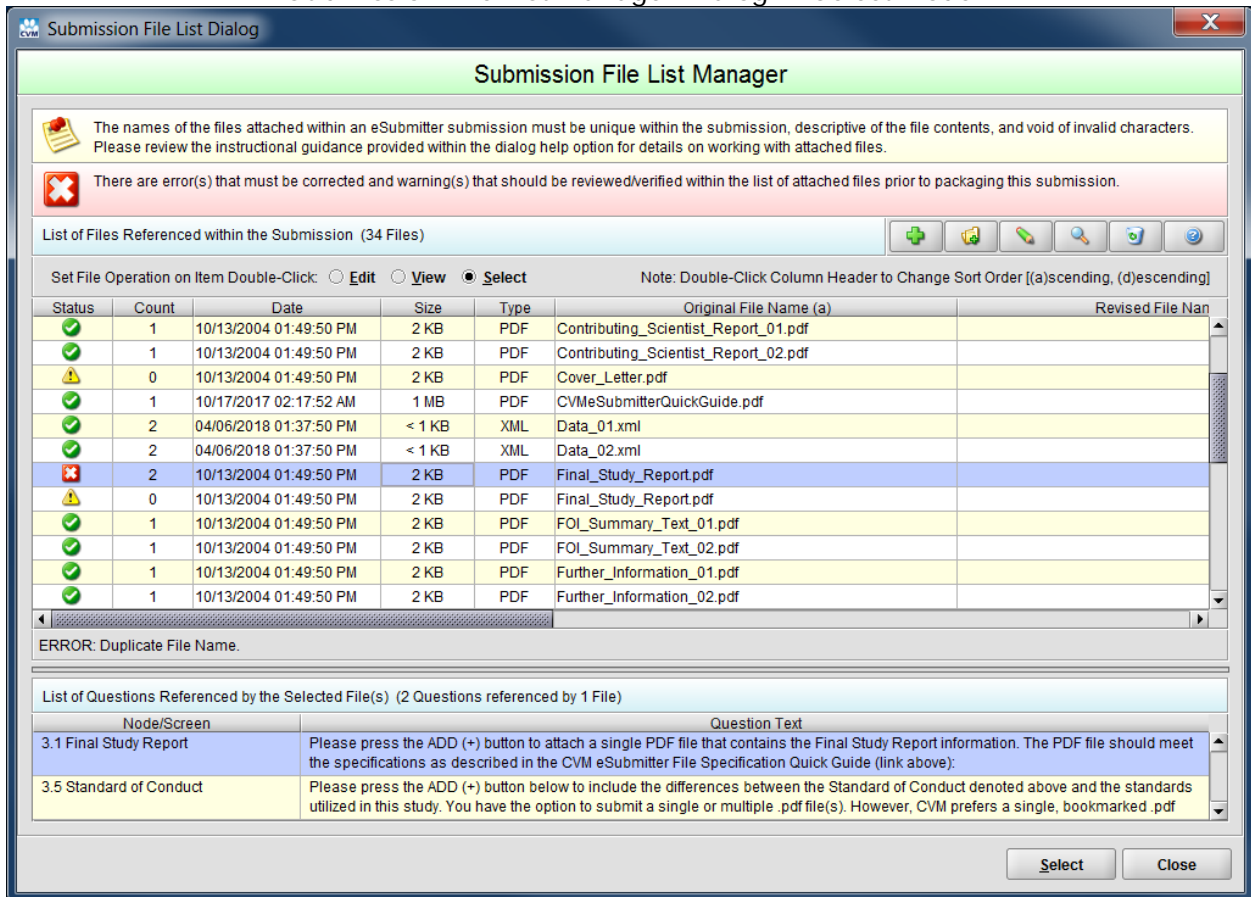- Correcting file name validation issues

- Reviewing/Verifying files associated within a submission prior to packaging the submission for transmission to CVM

The Submission File List Manager supports the following two operational modes.

- Standard Mode: Opened from the Tools menu, standard mode is primarily focused on managing the file list and correcting issues

- Select Mode: Opened from a file attachment question, select mode contains an additional "Select" option and is primarily focused on selecting one or more files to be included within a question response

A visual representation of the dialog is presented below.

Submission File List Manager Dialog in Select Mode

Submission File List Dialog

Submission File List Manager

The names of the files attached within an eSubmitter submission must be unique within the submission, descriptive of the file contents, and void of invalid characters. Please review the instructional guidance provided within the dialog help option for details on working with attached files.

There are error(s) that must be corrected and warning(s) that should be reviewed/verified within the list of attached files prior to packaging this submission.

List of Files Referenced within the Submission (34 Files)

Set File Operation on Item Double-Click: ○ Edit ○ View ● Select   Note: Double-Click Column Header to Change Sort Order [(a)scending, (d)escending]

Status	Count	Date	Size	Type	Original File Name (a)	Revised File Nan
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_01.pdf	
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_02.pdf	
⚠	0	10/13/2004 01:49:50 PM	2 KB	PDF	Cover_Letter.pdf	
✓	1	10/17/2017 02:17:52 AM	1 MB	PDF	CVMeSubmitterQuickGuide.pdf	
✓	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_01.xml	
✓	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_02.xml	
✗	2	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
⚠	0	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_01.pdf	
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_02.pdf	
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_01.pdf	
✓	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_02.pdf	

ERROR: Duplicate File Name.

List of Questions Referenced by the Selected File(s) (2 Questions referenced by 1 File)

Node/Screen	Question Text
3.1 Final Study Report	Please press the ADD (+) button to attach a single PDF file that contains the Final Study Report information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):
3.5 Standard of Conduct	Please press the ADD (+) button below to include the differences between the Standard of Conduct denoted above and the standards utilized in this study. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf

Select   Close

The following sub-sections describe the messages and tasks that can be performed using the Submission File List Manager.

1. Informational Message

The informational message at the top of the screen describes CVM's expectations with respect to file names provided within a submission (i.e., file names are unique, descriptive of the contents, and void of invalid characters).
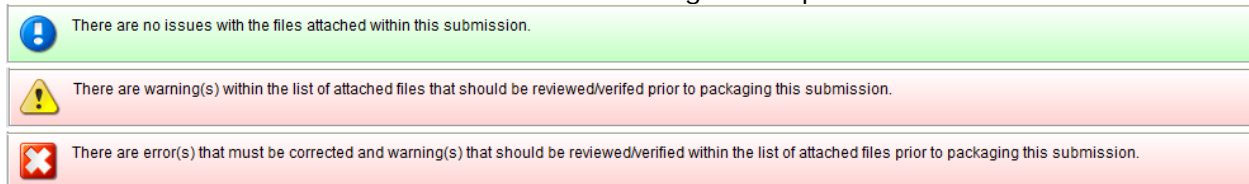
2. Overall Status Message

The overall status message provides an "at a glance" indication of the status of the overall file list (i.e., a summarization of the individual file status indicators, for more information on individual file status indicators, see sub-section IV.B.5.b). There are three overall status types:

- Informational: Denotes no validation issues within the list

- Warning: Denotes potential issues (i.e., warnings) that should be reviewed/verified prior to packaging

- Error: Denotes validation issues that must be corrected before the submission can be packaged

The overall status message is updated automatically as actions are performed on the file list (e.g., correcting file name validation issues, attaching files as responses to questions).

Examples of overall status messages are provided below.

Overall Status Message Examples

ℹ️	There are no issues with the files attached within this submission.
⚠️	There are warning(s) within the list of attached files that should be reviewed/verified prior to packaging this submission.
❌	There are error(s) that must be corrected and warning(s) that should be reviewed/verified within the list of attached files prior to packaging this submission.

3. File List Header

The file list header resides above the table and includes a count of the files within the submission list. It also includes a row of buttons that perform actions on the file list. See below for a visual representation of the file list header.

File List Header

List of Files Referenced within the Submission (34 Files)	➕ 📋 🔑 🔍 🗑️ ❓
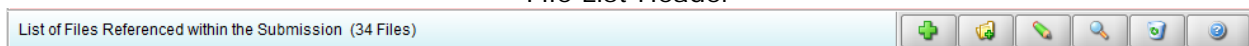
The following sub-sections describe the individual actions available within the file list.

a. Add File(s) Action

Activating the "Add File(s)" action displays a file system browser dialog that allows for navigating the local file system to select one or more files to be included within the submission list. Multi-file selection is supported by using standard multi-select capabilities (i.e., Shift-Click to select a beginning and ending range, Ctrl-Click to select multiple files individually). The types of files that can be selected is dependent on the master list of file types supported by ONADE.
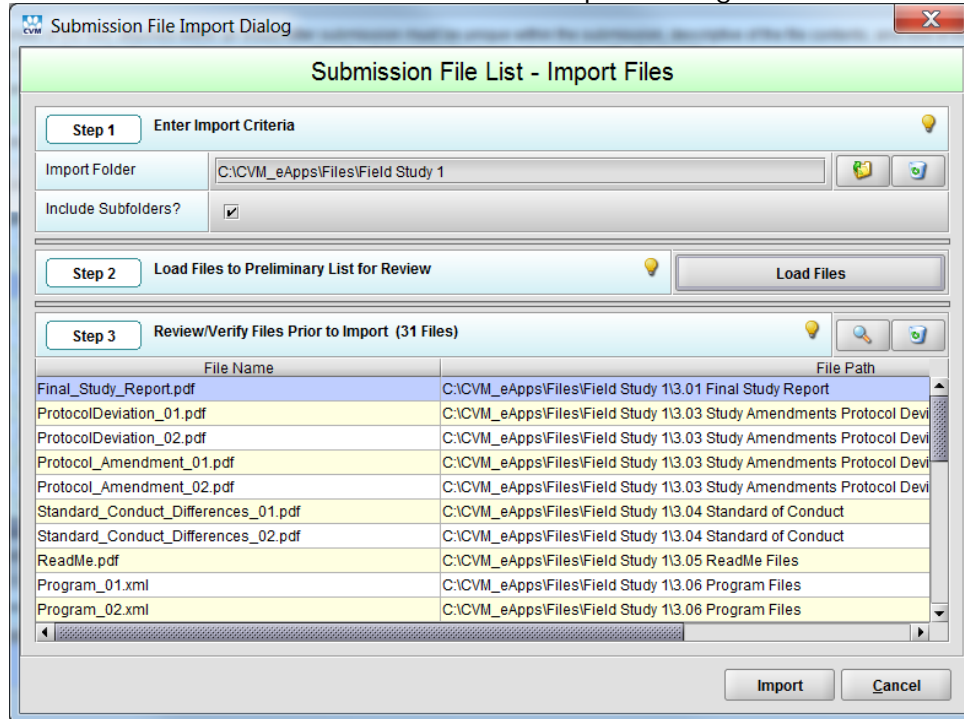
b. Import Folder of Files Action

Activating the "Import Folder of Files" action displays the Submission File List – Import dialog. The value of the import capability is to support submissions that include many attached files already contained within a defined folder structure. Using the import capability, all the files within a specified folder can be imported with a single action, and made available for selection within file attachment questions contained within the

submission form. The types of files that can be imported is dependent on the master list of file types supported by ONADE.

See below for a visual representation of the Submission File List - Import dialog.

Submission File List - Import Dialog

The importing of files is a three-step process.

(1) Step 1: Enter Import Criteria

The first step to importing files is the selection of a folder. Activating the "Select Folder" option opens the file system browser dialog for selecting a folder. An optional, include subfolders option is available when the files to be imported are stored in a multi-folders structure.

(2) Step 2: Load Files to Preliminary List for Review

The second step is to load the files into a preliminary list after scanning the file system and identifying files that are applicable to import.

(3) Step 3: Review/Verify Files Prior to Import

The final step is to review the preliminary list. During this time, files can be previewed and/or removed, as needed. Lastly, the import option is activated to move the files from the preliminary list and into the submission file list. During the import, any files already existing within the list are ignored to prevent duplication.

c. Edit Selected File Reference Action

Activating the "Edit Selected File Reference" action displays the Submission File List – Edit File Information dialog. See below for a visual representation of the Submission File List – Edit File Information dialog.

Submission File List – Edit File Information Dialog

There are three independent tasks that can be performed on a file item.

(1) Option 1: Enter a Revised File Name

The revised file name replaces the original file name when a file is included within the submission package. The inclusion of a revised file name has no impact on the original file residing on the local file system. There are three common reasons for providing a revised file name:

- Correction of an invalid file name due to a duplication with another file name included within the submission (required)

- Correction of an invalid file name due to invalid characters within the name (required)

- Adding clarity to the file name (optional)

The revised file name capability includes a "Copy" option. The copy option copies the original name to the revised name, removing any invalid characters in the process. It is useful when only minor adjustments are needed to the name (e.g., "Final Study Report" becomes "Final Study Report for Study 123").

(2) Option 2: Enter a Descriptive Title (optional)

The descriptive title provides another method for adding clarity to a file name. While the revised name is preferred for adding clarity over the descriptive title, the descriptive title does not impose the same character constraints as the revised name.

(3) Option 3: Exchange/Swap the File Reference

The exchange/swap file option provides a simple approach to switching out a file without having to navigate to the question within the form. The primary use is when a newer version of a file becomes available during the preparation of the submission.

d. View Selected File Action

Activating the "View Selected File" action opens the selected file from the submission list for previewing the contents. It follows the same approach to viewing an attached file as is implemented within the file attachment questions. For additional details, see section IV.4 View File Action.

e. Remove Selected File(s) Action

Activating the "Remove Selected File(s)" action removes the selected file(s) from the submission file list. When a file is removed from the submission list, it is not physically deleted from the local file system, but only no longer associated to the submission. Multi-file selection is supported by using standard multi-select capabilities (i.e., Shift-Click to select a beginning and ending range, Ctrl-Click to select multiple files individually).

f. Display Help

Activating the "Display Help" action opens this quick guide.

4. File List Sub-Header

The file list sub-header resides above the file list table and includes options for determining what operation is performed when double-clicking on a row within the file list table. The double-click is the quickest method for activating a row within a table. However, there are three common tasks that could be performed depending on the need. Allowing the operation to be adjusted by the user lets the user match the operation to the need.

Examples of when the user may want to control the double-click operation.

- Submission File List Manager is open in Select mode: The operation defaults to "select" so that a user can quickly select the files within the table to be added to a question response without needing to activate the select button

- Fixing file naming issues: Setting the operation to "edit" allows the user to simply activate the "Edit File Information" dialog by double-clicking on a file item within the table, without having to additionally activate the edit button

- Reviewing file contents: Setting the operation to "view" allows the user to simply open the file by double-clicking on a file item within the table, without having to additionally activate the view button

The file list sub-header also provides instructions on how to sort the file list columns. See below for a visual representation of the File List Sub-Header.

File List Sub-Header

Set File Operation on Item Double-Click: ○ **Edit** ○ **View** ⦿ **Select**   Note: Double-Click Column Header to Change Sort Order [(a)scending, (d)escending]

5. File List

The file list is a scrollable region at the center of the dialog that resizes as the dialog is resized. The list can be scrolled vertically to reveal all the files within the list, as well as horizontally to show the columns of information about each file.

The following columns are available (left to right from within the table view).

- Status: Identifies if there are any issues with the file

- Count: Number of questions the file is referenced by

- Date: Date/Time stamp of the file as recorded by the local file system

- Size: General size of the file

- Type: Type of file based on the file extension (e.g., PDF, XML)

- Original File Name: File name as it exists within the local file system

- Revised File Name: File name to be used when including the file in the submission package

- Descriptive Title: Optional descriptive title for the file

- File Location: location of the file within the local file system

See below for a visual representation of the file list with a single file selected.

Submission File List with a Single File Selected

Status	Count	Date	Size	Type	Original File Name (a)	Revised File Nan
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_02.pdf	
⚠️	0	10/13/2004 01:49:50 PM	2 KB	PDF	Cover_Letter.pdf	
✅	1	10/17/2017 02:17:52 AM	1 MB	PDF	CVMeSubmitterQuickGuide.pdf	
✅	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_01.xml	
✅	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_02.xml	
❌	2	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
⚠️	0	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_02.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_02.pdf	

ERROR: Duplicate File Name.

a. Multi-Select Action

The file list also supports the selection of multiple files. Multi-file selection is supported by using standard multi-select capabilities (i.e., Shift-Click to select a beginning and ending range, Ctrl-Click to select multiple files individually).

Multi-File selection can be useful in the following scenarios.

- Selecting multiple files to be included with a question response

- Selecting multiple files to be removed

- Seeing the combined status of multiple files within the file item status message, see sub-section IV.B.5.d, for additional information related to the file item status message

- Seeing the combined set of question references within the question list.

See below for a visual representation of the file list with multiple files selected.

Submission File List Display with Multi-File Selection

Status	Count	Date	Size	Type	Original File Name (a)	Revised File Nan
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Contributing_Scientist_Report_02.pdf	
⚠️	0	10/13/2004 01:49:50 PM	2 KB	PDF	Cover_Letter.pdf	
✅	1	10/17/2017 02:17:52 AM	1 MB	PDF	CVMeSubmitterQuickGuide.pdf	
✅	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_01.xml	
✅	2	04/06/2018 01:37:50 PM	< 1 KB	XML	Data_02.xml	
❌	2	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
⚠️	0	10/13/2004 01:49:50 PM	2 KB	PDF	Final_Study_Report.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	FOI_Summary_Text_02.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_01.pdf	
✅	1	10/13/2004 01:49:50 PM	2 KB	PDF	Further_Information_02.pdf	

ERROR: 6 Files selected; 1 with No Reference to a Question; 2 with Duplicate File Name.

b. File Item Status Indicators

Each file within the file list has an individual file status. There are three file statuses available.

- Error status: The file name is invalid and must be corrected before packaging.

- Warning status: The file is not referenced within a question and will not be included with the submission package. While there may also be a file naming issue, the warning takes precedence since the file is not going to be included in the submission package.

- No Issue status: There are no issues with the file.

c. Column Ordering and Sort Action

Each column within the file list can be reordered and sorted. To reorder a column, click and drag the column left or right to the new location. To sort a column, double-click on the column header. The column with the active sort will have an (a) for ascending or (d) for descending in the header name. When a column is first sorted, it appears in ascending order. Each additional attempt to sort the same column alternates between ascending and descending.

d. File Item Status Message

The file item status message displays below the table and represents additional details related to the status of the selected file(s). For example, the file item status indicator may represent an error, while the status message details the type of error (e.g., duplicate file name vs. invalid characters or both).

6. Question List

The question list is a scrollable region at the bottom of the dialog. While it only shows two question references at a time, the question list can be scrolled vertically to reveal all questions referenced to the selected file(s).

The following columns are available (left to right from within the table view).

- Node/Screen: Identifies the outline node/screen that contains the referenced question

- Question Text: The text of the referenced question.

See below for a visual representation of the question list.

Question List Display

List of Questions Referenced by the Selected File(s) (2 Questions referenced by 1 File)	💡

Node/Screen	Question Text
3.1 Final Study Report	Please press the ADD (+) button to attach a single PDF file that contains the Final Study Report information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):
3.5 Standard of Conduct	Please press the ADD (+) button below to include the differences between the Standard of Conduct denoted above and the standards utilized in this study. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf

V. Practical Use Case Examples

Three practical use case examples of how the new file attachment capabilities can improve the process of preparing a submission have been included.

A. Create a Submission with Few Attached Files

- Create the new submission

- For each file attachment question, use the "Add File from File System Action" to quickly navigate to and select the files to be attached (using multi-select when applicable)

- As part of a review, before packaging the submission, open the Submission File List Manager to correct any file naming issues and verify that the appropriate files are included (i.e., following the steps in use case V.C "Reviewing the Attached Files Prior to Packaging"

B. Create a Submission with Many Attached Files

- If not already done, organize the files to be included within the submission in a structured manner within the local file system (most applicable to study related submissions that include 100's of files)

- Create the new submission

- Open the Submission File List Manager and use the import capability to quickly add all the files to the submission

- Correct any file name issues after the import, or plan to do so during the final review before packaging

- For each file attachment question, use the "Add File from Submission File List Action" to quickly navigate the submission file list and select the files to be attached (using multi-select when applicable)

- As part of a review, before packaging the submission, open the Submission File List Manager to correct any remaining file naming issues and verify the appropriate files are included (i.e., following the steps in use case V.C "Reviewing the Attached Files Prior to Packaging"

C. Review the Attached Files Prior to Packaging

- Open the Submission File List Manager dialog

- Sort on the Status column in descending order, so all file items with issues are displayed at the top

- If any files names are invalid (i.e., error status), set the file operation on double click to Edit mode

- Double click on each row with an error status to display the Edit File Information dialog and correct any file naming issues

- If any files contain a count of zero (i.e., warning status, not associated to a question), set the file operation on double click to View mode

- Double click on each row with a warning status to view the file content and verify that the file is not to be included within the submission package

- Select an appropriate sort order for reviewing all files and set the file operation on double click to View mode

- Step through the files in the list from top to bottom, verifying the file name against the section(s)/question(s) listed within the referenced question list to ensure each file is attached to the appropriate question, double click to view the selected file to verify the contents, as needed