ORCCID

User Documentation

Uploading Source Documents

Table of Contents

For each clinical trial, source documents are required to verify critical data and safety. Required source documents are pre-specified within the ORCCID system and are based on data entry. This document illustrates how to use the File Upload functionality in the ORCCID system to enable the User to upload source documents.

Within ORCCID, the uploaded source documents are linked to a specific Subject Visit (e.g. Baseline) or Event type (i.e. Outcome Event (OE) / Adverse Event (AE)). Once data has been entered and submitted for a module within a Visit, the system will alert the User that source documents are required. Please ensure that you are uploading the source documents to the correct Subject Visit or Event.

Anonymizing

Note, before uploading documents please ensure all Personal Health Information (PHI) contained within a document has been anonymized. The system does have the capability for OCOG to redact the source documents once uploaded, if necessary. Also ensure that each page of the source document has been labeled with the subject ID and subject initials (if applicable).

Supported File Types

- JPG
- PDF (cannot be password protected and/or encrypted)

Max File Size

- 10 Mb

Time Out

Similarly, to all other ORCCID pages, the system times out after 60 minutes of inactivity. You may need to re-upload the file when you log back in to ORCCID.
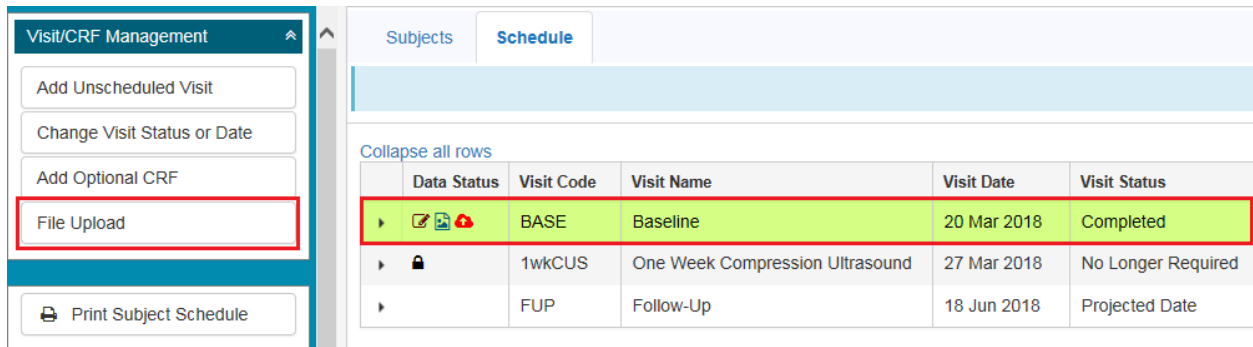
Source Document Icons

Icon(s)	Description
☁	There is source document(s) required for the visit but the source document(s) has not been uploaded.
☁	All the required source documents are submitted and are now pending verification by the OCOG Study Coordinator.
☁	All the required source documents have been verified by the OCOG Study Coordinator.
🖼	The visit/event(s) has file(s) uploaded.

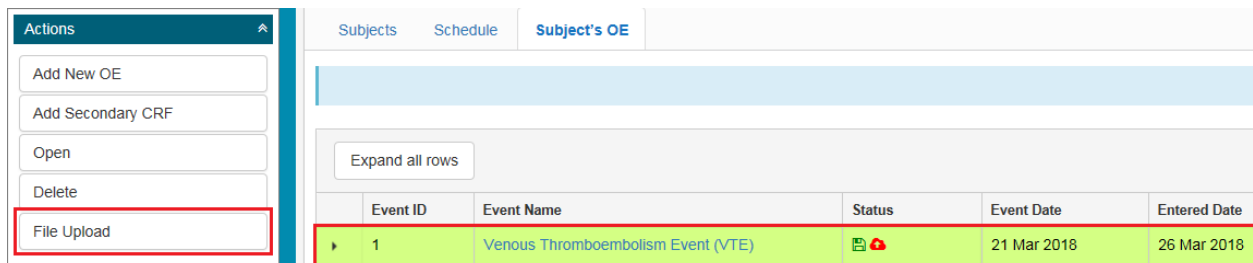*Table 1: Source Document(s) Icons*

When to Upload?

After entering the study data into the CRF module(s), if there are source documents required for any of the entered modules within a Visit; the **Source Document(s) Required** (⬆) icon will appear in the Data Status column of the **Schedule** page. For example, in Figure 1, the source document(s) are required for the Baseline visit.

Figure 1: When to upload the source document(s) – Schedule page

On the Outcome Events (OEs) and Adverse Events (AE) screens the uploaded files are related to the event. Once data is entered in an Event CRF that requires source document(s) to be uploaded, the **Source Document(s) Required** (⬆) icon will appear in the event relating to that CRF. For example, in Figure 2, the source document(s) are required for the outcome event, Event #1.

Figure 2: When to upload the source document(s) – Subject's OE page

You may upload additional source documents to the File Upload Page as long as they pertain to the Required source document list. You can access the File Upload page even if the **Source Document(s) Required** (⬆) icon is not shown.

Where to Upload?

All source document(s) should be uploaded to the **File Upload** page. The **File Upload** page can be opened from the **Schedule** page, the **Subject's OE** page or the **Subject's AE** page:

Open from the Schedule Page

1. Select the relevant visit (e.g. Baseline).
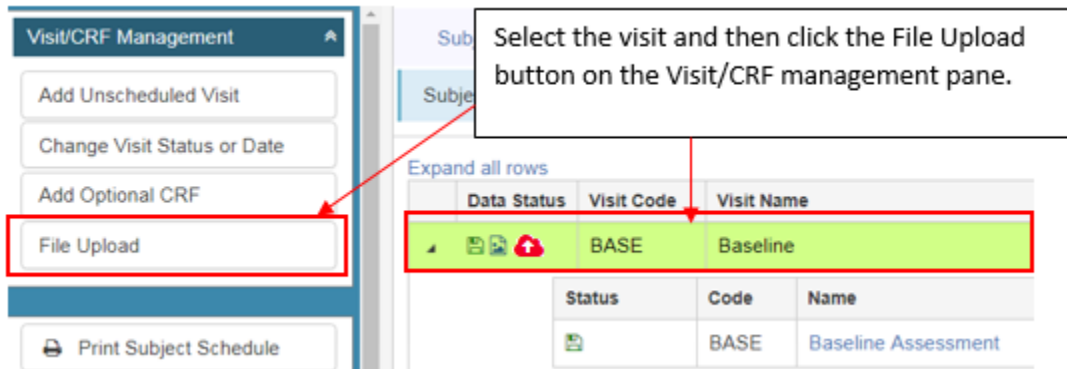2. Click the **File Upload** button on the Visit/CRF Management pane.

Figure 3: Access the File Upload page from the Schedule page

Open from the Subject's OE Page or the Subject's AE Page

1. Select the event
2. Click the **File Upload** button on the Actions pane.
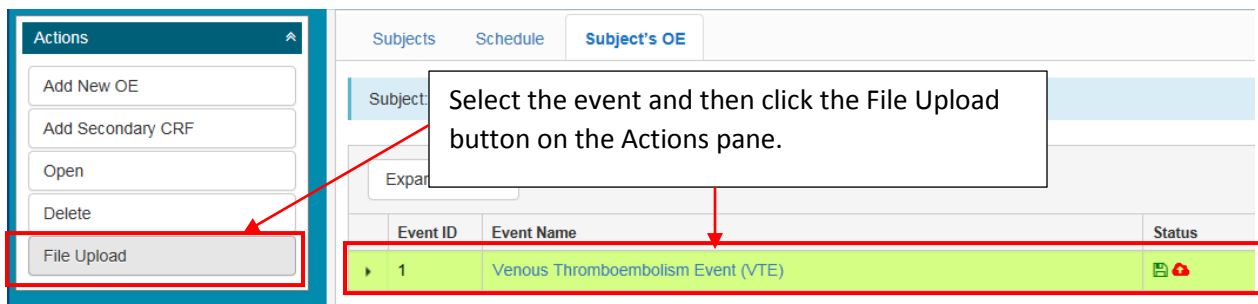
Figure 4: Access the File Upload page from the Subject's OE page

You can also navigate to the **File Upload** page to upload the source document(s) if the **Automatically Generated Visit Source Document(s)** confirmation message appears after saving the CRF. Click on the link within the message box as shown in Figure 5.

Automatically Generated Visit Source Document(s)

The Field(s) on this CRF requires you to upload source document(s) to this Visit (UNSCHED).

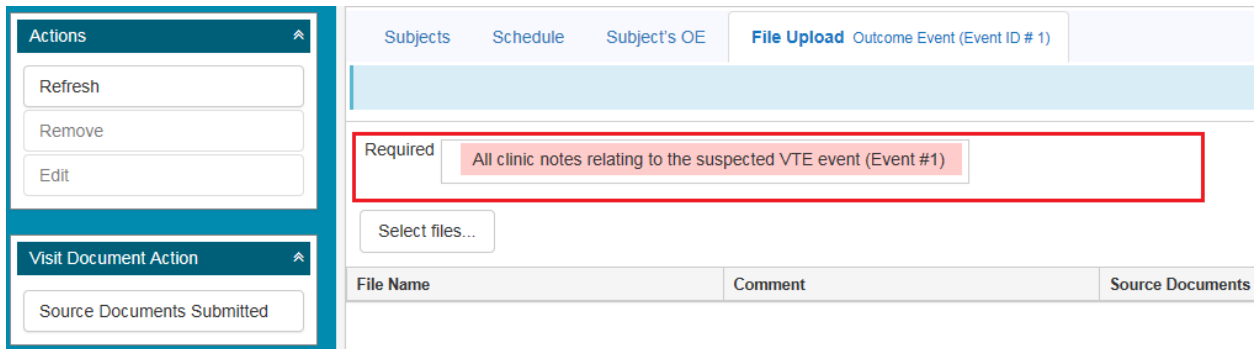Please navigate to the Schedule page and click the File Upload button on the left (or click this link).

This message will stop displaying once your OCOG Coordinator has verified the Source Document.

OK

Figure 5: Automatically Generated Visit Source document(s) confirmation message

What to Upload?

On the **File Upload** page, the details of the required source document(s), per Visit and/or Event are listed at the top of the page.

Figure 6: What to Upload?

Source Document Highlighting Colours
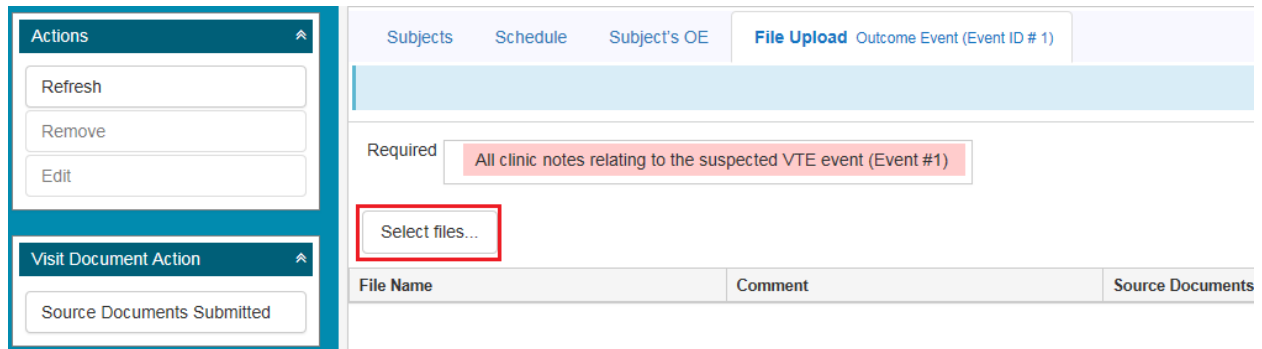
The following table shows the color and description for the source documents.

	Examples	Description
Pink highlighting source document	Clinic Notes	The source document is either not uploaded or uploaded but not yet verified by the OCOG Study Coordinator
Green highlighting source document	Clinic Notes	The source document has been uploaded and verified by the OCOG Study Coordinator

Table 2: What to Upload

How to Upload and Submit Source Documents?

1. Once in the File Upload page, click the **Select files…** button to browse and navigate to the file containing the source document on your computer.
2. It is suggested that the file name be relevant to the source document (e.g. Ultrasound Report)

Figure 7: How to Upload I?

3. Choose the file(s) you want to upload and click the **Open** button.
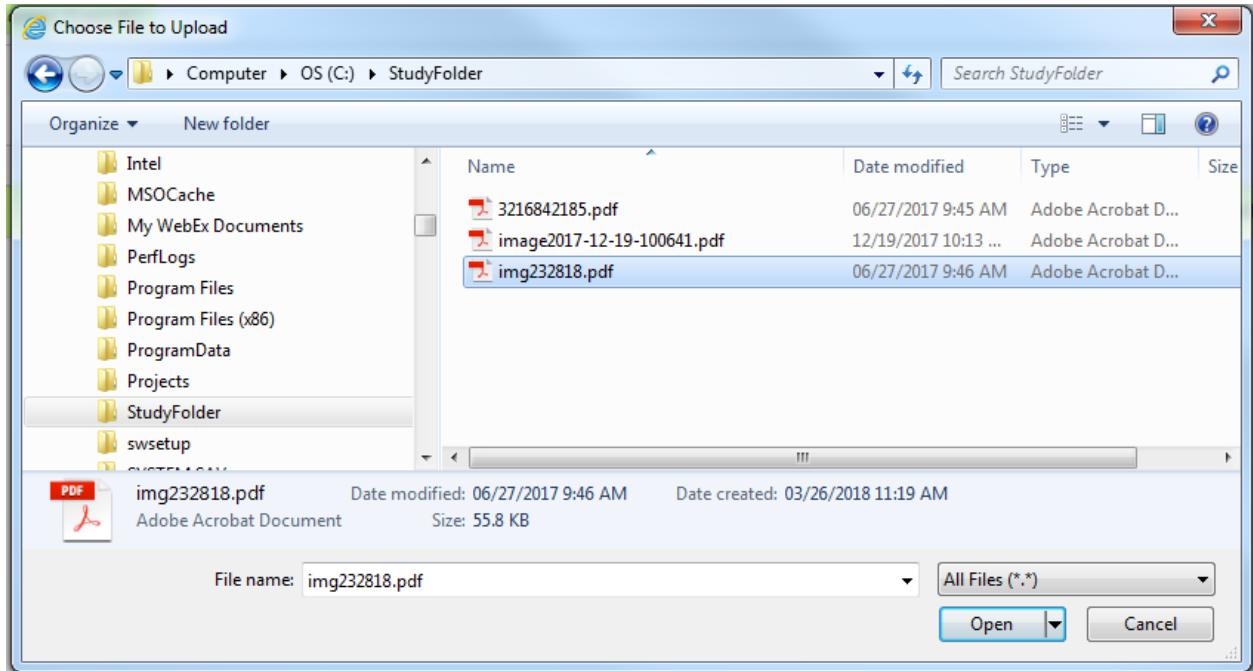4. Reminder, ensure file is either JPG or PDF format and not more than 10 Mb.

Figure 8: How to Upload II?

Tip: To select multiple files, press and hold the **Ctrl** key and mouse click on all the files that you want to upload. Then click Open.

Once the files have been successfully uploaded, they will be listed in the grid as seen in Figure 9, and the Files names will be shown in the Comment column.
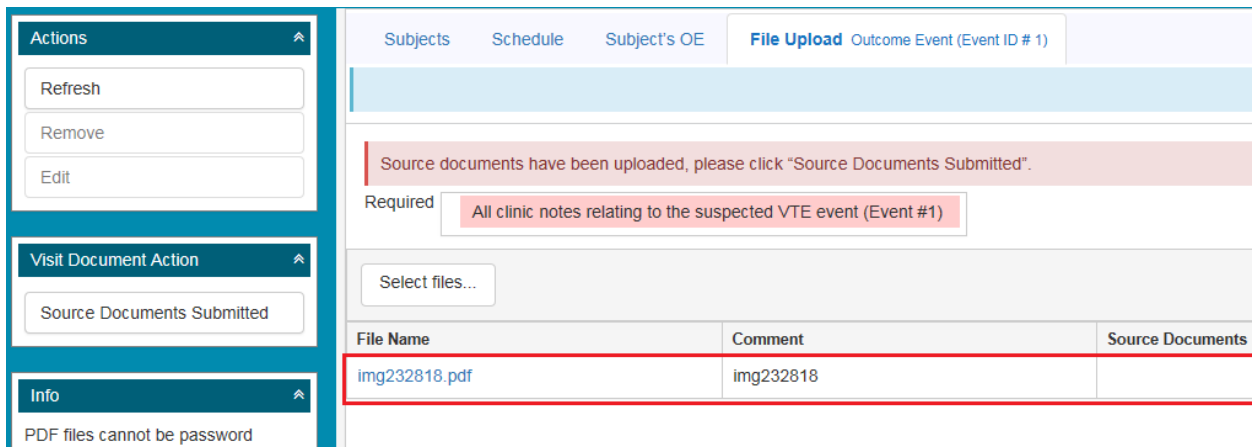

Figure 9: How to Upload?

If the file name that is uploaded does not contain the type of document, then please utilize the **Comment** section to specify the type of required document that was uploaded (e.g. Clinic Note).

To Modify the Comment

a. Select the file record.
b. Click the **Edit** button on the **Actions** pane.

Figure 10: Modify the Comment I

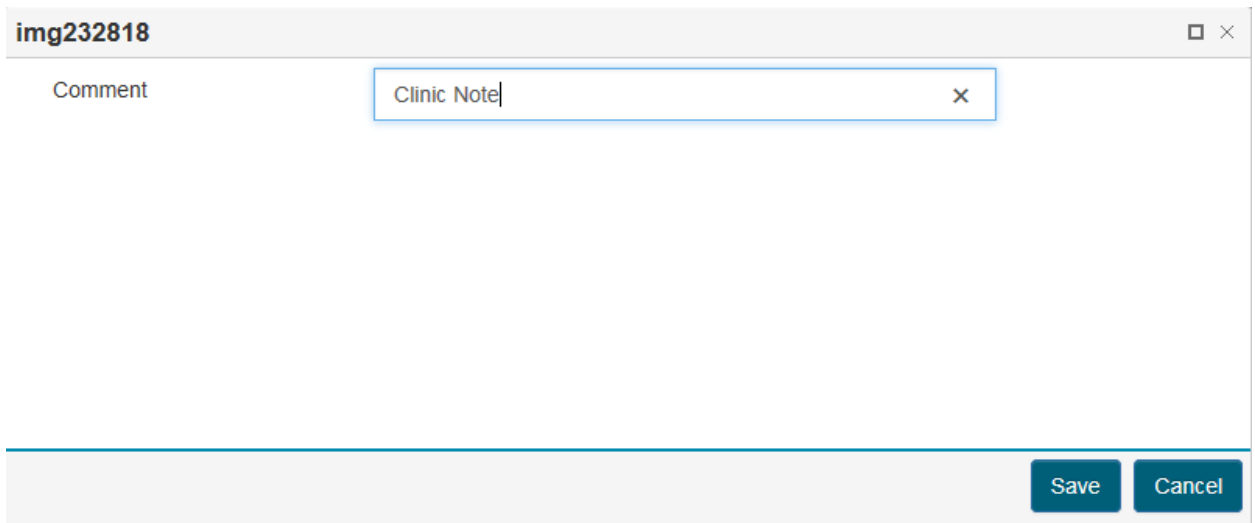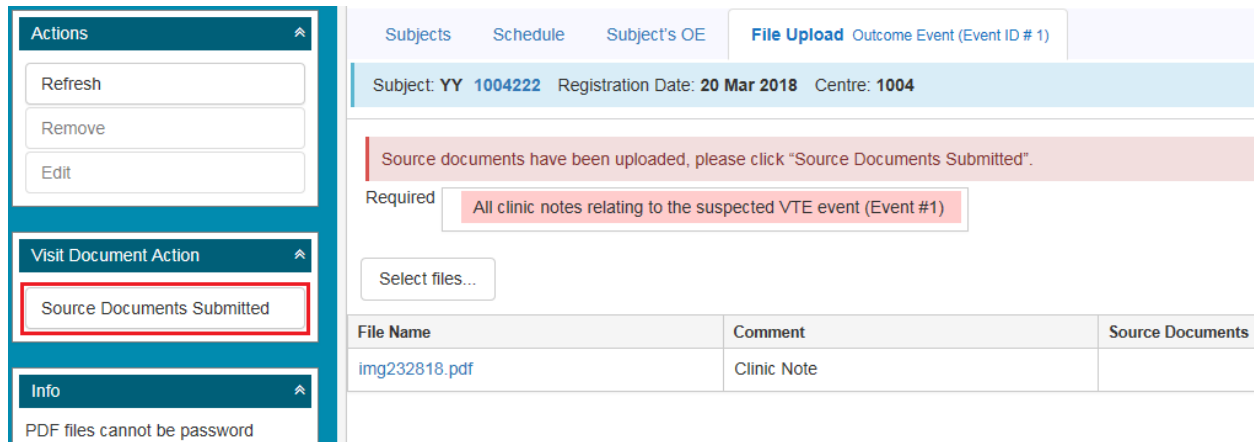c. Modify the text in the Comment Text Box in the following pop-up window.

Figure 11: Modify the Comment II

5. Once all the required Files have been uploaded for the Visit or Event, click the **Source Documents Submitted** button (this alerts the OCOG Study Coordinator that they can verify the documents that have been uploaded).
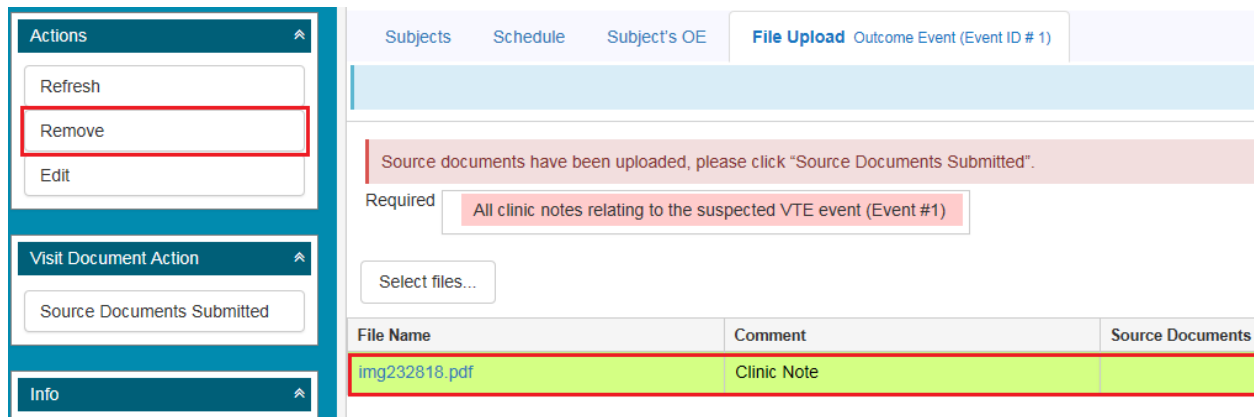
Figure 12: How to Submit the Source Document(s)

Click the Schedule tab on the top of the page to return to the **Schedule** page. The Subject Visit/Event **Has Attached Files** icon 🖼 and the **Source Document(s) Submitted** icon ☁ will be shown in the Data Status column of the visit.

How to Delete a Source Document?

1. On the File Upload page, select the file which you want to delete.
2. Click the **Remove** button on the Actions pane.

Figure 13: Delete a Source Document

3. Confirm deletion.

Delete File

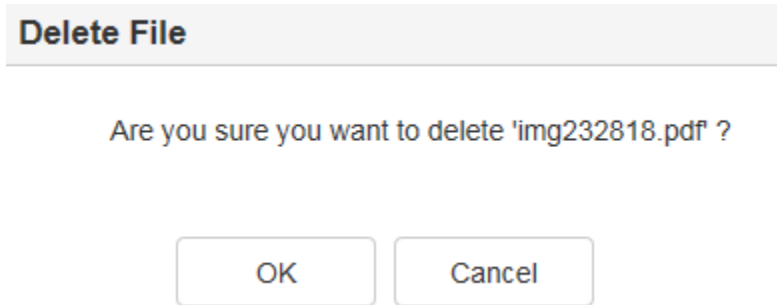Are you sure you want to delete 'img232818.pdf' ?

OK   Cancel

Figure 14: Confirm deletion

The file will be removed if it was not verified by the OCOG Study Coordinator. Otherwise, the following message appears on the screen.
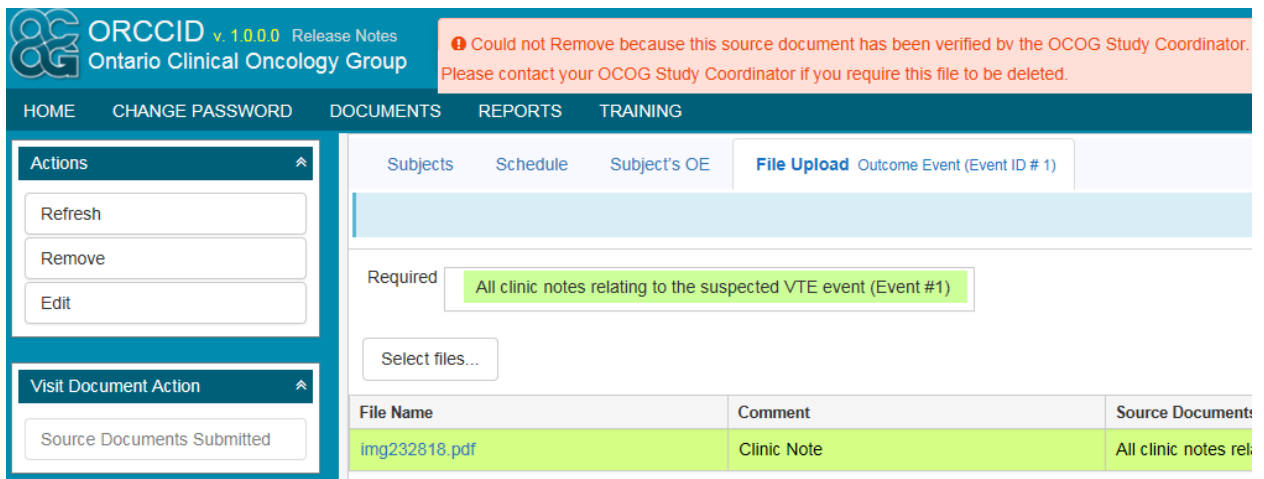

Figure 15: Delete a mapped source document

In this case, please contact your OCOG Study Coordinator if you still require the file to be deleted.